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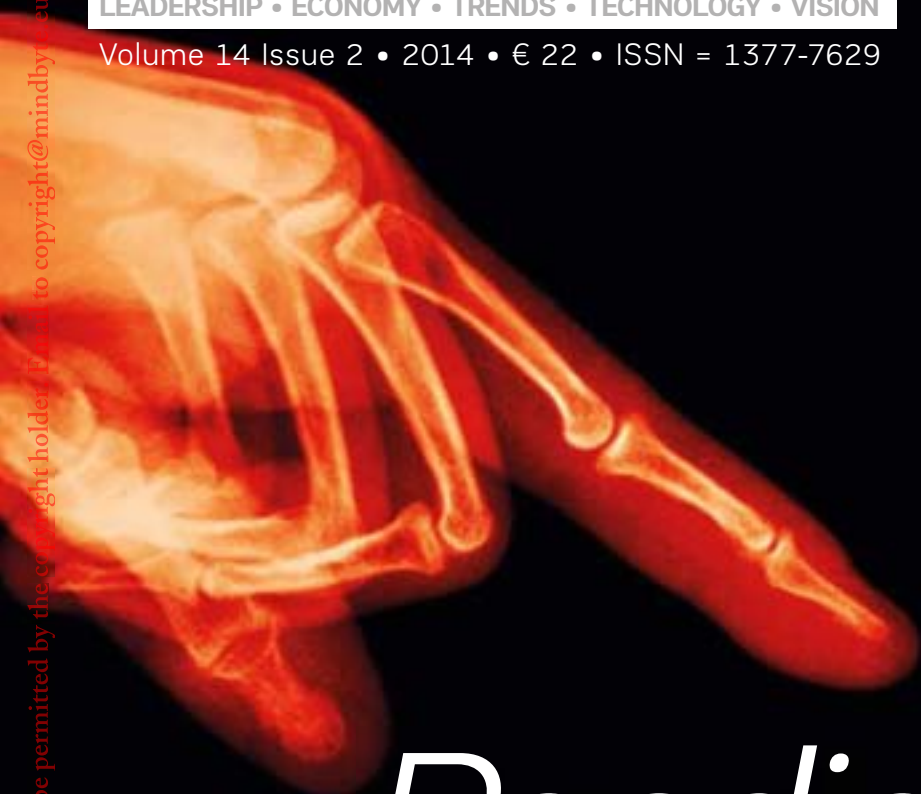
MANAGEMENT

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Volume 14 Issue 2 • 2014 • € 22 • ISSN = 1377-7629



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Paediatrics



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BIG NEWS FOR LITTLE PATIENTS.

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PAEDIATRICS

Our cover story is dedicated to the rapidly moving field of paediatrics. This specialty is receiving increased attention as the focus shifts from a 'one size fits all' procedure to a more tailor-made approach. Medical diagnostic equipment is being adapted to better accommodate children's smaller body size and optimise exam results, and imaging radiation dosing is reduced to ensure minimal exposure to harmful radiation.

Alan Dilani explains the challenges associated with design for paediatric health on page 12, Mary Tyson and Johann Blickman discuss the considerations for implementing or expanding child life services in the paediatric healthcare setting on page 20, and the Image Gently campaign in Italy on radiation dose reduction is presented on page 23.

Our Imaging Insights section highlights include the latest KLAS report on PACS technology (page 26), and we bring you part 2 of the ECRI's top 10 health hazards list introduced in our previous issue. Bo Li shares quality tools every radiologist should know in The Magnificent 7 (page 27), and we get a fascinating insight into the new field of Virtopsy thanks to Wolf Schweitzer and colleagues on page 34. Elisabeth Schouman-Claeys

analyses the use of contrast media in imaging and the risk management providing simple rules of conduct (page 37). Her article is followed by an interview with contrast expert product Olivier Clément.

In IT Intelligence on page 58 Tim Williams describes the new Healthcare Information Security and Privacy Practitioner qualification.

Franco Orsi's article on high intensity focused ultrasound is in Interventions (page 50) and in our Cardio Spotlight (page 52) Randy Yeh and colleagues explain the appeal of the triple rule-out CT angiography test for patients with chest pain, while cautioning that there are refinements to be made before it can be widely adopted.

The balanced scorecard is the subject of this issue's Management Matters on page 54.

Our interview with Nicolas Grenier, President of the European Society of Molecular and Functional Imaging Research, is in Perspectives on

page 61 and Compass focuses on the UK with a summary of the impact that the Francis Inquiry Report has had on the NHS one year on.

The Datebook on page 9 features a preview of the upcoming Arab Paediatric Medical Congress taking place in Dubai May 30-31. EUROSON will be held May 25-28 in Tel Aviv. Christoph Dietrich, President of the European Federation of Societies for Ultrasound in Medicine and Biology is interviewed on page 10. ■

As always, the team welcomes your comments and suggestions: letters@healthmanagement.org
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HealthManagement

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Subscription Rates (4 Issues/Year)

One year:	Europe	85 euros
	Overseas	105 euros
Two years:	Europe	150 euros
	Overseas	180 euros

Production & Printing

Total classic and digital circulation: 62,500
ISSN = 1377-7629a
Printed in Hungary by Gyomai Kner Nyomda Zrt

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According to the standards of International Business Press Audits.

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Danish Project Wins First TMC Radiology Quality Award



A group from the Diagnostic Centre, University Clinic of Innovative Patient Pathways at the Regional Hospital Silkeborg in Denmark has won the inaugural TMC Radiology Quality Award with their project on Plastic Organic Groups. This is a work method for fast quality improvements in daily clinical work, which they used to focus on the possibilities of improving quality in patient pathways. The winners received a Diploma and €10,000, which they will donate for further research in the Radiology Department.

In their winning submission, the Danish team noted that radiology departments are uniquely placed for taking leadership in developing innovative solutions bridging medical specialities. Their project set out to improve clinical challenges, including diagnosis of minor stroke. At the outset they met national standards for diagnosis of minor stroke in only 70% of cases. Two weeks after the first meeting national standards were met for 90% of patients, and after four weeks waiting time was reduced fourfold. After six weeks diagnos-



Image.

Back row (L-R), Lluís Donoso Bach (Spain), Jarl Jakobsen (Norway), Peter Mildenberger (Germany) and Iain McCall (UK) from the international jury. The jury also included Peter Aspelin (Sweden), Elisabeth Schouman-Claeys (France) and Emanuele Neri (Italy).

Front row (L-R) Annette Meyer Balle, Rikke Aarhus, Agnete Hedemann Nielsen, Susanne Skovlund Petersen from the winning group with Hans Billing, Medical Director, Telemedicine Clinic.

The TMC Radiology Quality Award was set up by Telemedicine Clinic for professionals, individuals or groups from European radiology departments that have implemented systems, methods or processes with a demonstrated positive quality impact. The projects were judged by a distinguished international jury.

"Having the opportunity to work with close to 100 radiology departments in several European countries, we frequently come across a number of good examples of initiatives to improve quality. We believe solid solutions for quality assurance and improvement within radiology is very important and by introducing this unique award we hope to encourage more such initiatives," said Dr Hans Billing, Medical Director at Telemedicine Clinic.

tic methods had completely changed, and all patients below 60 years of age were diagnosed using MRI. Other changes included using carotid CTA instead of ultrasound and reorganisation, which enabled diagnosis to take place in one day.

The winning group was presented with their prize at the European Congress of Radiology in Vienna in March.

Further Reading: Nielsen AH, Balle AM, Petersen SS, Aarhus R (2013) The radiology department as partner in bridging the knowing-doing gap: how can leadership encourage radiologists, secretaries, radiographers, clinicians, and nurses to develop innovative patient pathways? *HealthManagement* 13(3): 50-1. Available at: <https://healthmanagement.org/c/healthmanagement/issuearticle/the-radiology-department-as-partner-in-bridging-the-knowing-doing-gap>

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Genome Sequencing and the Potential to Personalise the Treatment of Individual MRSA Infections

The spread of the antibiotic-resistant pathogen MRSA (methicillin-resistant *Staphylococcus aureus*) remains a concerning public health problem, especially among doctors trying to determine appropriate treatment options for infected patients. Bacterial pathogens, such as MRSA, cause disease in part due to toxicity, or the bacterium's ability to damage a host's tissue. In a recent study published in *Genome Research*, researchers used the genome sequence of MRSA to predict which isolates were highly toxic, thus potentially personalising the treatment of individual MRSA infections.

To study MRSA's toxicity, "the standard approach has always been to focus on a single or small number of genes and proteins," said lead author Ruth Massey, from the University of Bath. However, this has not always been successful because toxicity is a complex trait encoded by many genetic loci.

In this study, the authors used whole genome sequences from 90 MRSA isolates to identify over 100 genetic loci associated with toxicity. Despite belonging to the same ST239 clone, the isolates varied greatly in toxicity.

Importantly, the highly toxic isolates shared a common genetic signature. By looking for this signature in the MRSA

genome, the researchers were able to predict which isolates were the most toxic and thus more likely to cause severe disease when used to infect mice.

"As the cost and speed of genome sequencing decreases, it is becoming increasingly feasible to sequence the genome of an infecting organism," said Massey. In a clinical setting, sequencing may be useful for deciding the course of MRSA treatment. For example, a clinician may treat a highly toxic infection more aggressively, including prescribing certain antibiotics known to reduce toxin expression. The patient also may be monitored more closely for complications and isolated from others to help control the spread of infection.

Although many novel genetic loci involved in MRSA toxicity were identified in this study, it remains to be determined how each influences disease. In addition to examining genomes of other MRSA strains, such as the particularly antibiotic-resistant USA300 strain, the authors are working to apply their methodology to other bacterial pathogens, such as *Streptococcus pneumoniae*, a leading cause of deaths in infants and children under the age of five.

To read the study in full, please visit:
<http://genome.cshlp.org/content/early/2014/04/02/gr.165415.113>

Laboratory Medicine: Both a Profession and a Clinical Science

Writing for the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), Bogdan Solnica, Milena Dabrowska and Grazyna Sypniewska have assessed the state of laboratory medicine as both a profession and also a clinical science. In their paper they offer ideas on performance (Laboratory Medicine As A Profession And Clinical Science – How To Perform Both Of Them Well).

The authors stress that laboratory medicine or laboratory diagnostics is a medical science and clinical discipline. The two are separate and yet intrinsically linked. We are all aware of the importance of labs in the hospital and healthcare sector. Lab results dictate medical decisions and play a vital role in terms of screening. Indeed the authors have found that laboratory diagnostics account for 10% of all healthcare costs.

The demand for laboratory diagnostics is increasing and the very nature of laboratory medicine is also changing thanks to automation, consolidation, integration and centralisation of procedures. In turn there are new professional competencies for laboratory staff (handling new equipment, information systems, turnaround time, analytical quality and methodology).

The paper states that there are two key factors in the competence of laboratory staff: professional training and human resources management. There is a wide range of tasks and roles within the laboratory, some tasks requiring more professional qualifications than others. The authors divide laboratory staff into two main categories: technicians and diagnosticians.

Pre- and postgraduate training and continuous professional development should ensure laboratory staff have the proper skills to fulfil their varied roles. Management ability is also important.

The authors conclude their study emphasising the fact that laboratory medicine is also a clinical science which works across all other clinical disciplines. Laboratory tests are essential diagnostic tools and laboratory medicine involves analysis and interpretation of results. Proof of its role as a clinical science can be seen in evidence-based laboratory medicine (EBLM).

To read the article in full please visit:
<http://www.ifcc.org/ifcc-communications-publications-division-%28cpd%29/ifcc-publications/ejifcc-%28journal%29/e-journal-volumes/ejifcc-2010-vol-21/vol-21-n%2C2%80-3/laboratory-medicine-as-a-profession-and-clinical-science-how-to-perform-both-of-them-well>



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IFCC WORLDBLAB ISTANBUL 2014

CONGRESS HIGHLIGHTS

Hosted by the Turkish Biochemical Society, the International Federation of Clinical Chemistry and Laboratory Medicine will be welcoming delegates from around the world to the new Istanbul Congress Center (ICC) from 22-26 June, 2014.

The congress will provide a cutting-edge educational and scientific experience, focusing on the latest developments in Biochemistry.

Scientific Programme

Containing high quality science, this programme is coupled with a strong focus on how important laboratory medicine services are to clinical medicine and the well-being of patients and the public.

Plenary Lectures

Held every day in the Harbiye Auditorium from 11:45 - 12:30

Monday, 23 June

Imaging brain function and connectivity with ultrahigh field magnetic resonance.

K. Ugurbil (USA)

Tuesday, 24 June

Inflammation, immunity and atherosclerosis

G.K. Hansson (Sweden)

Wednesday, 25 June

Ion Channels: from laboratory to clinic (and back)!

M.B.A. Djamgoz (United Kingdom)

Thursday, 26 June

Deciphering the plasma genome: applications to prenatal diagnosis and oncology

D. Lo (Hong Kong)

State of the Art Symposia

Parallel symposia are scheduled daily during the congress from 9:00 - 11:00

Monday, 23 June

- New Technological Developments In Laboratory Medicine
- Emerging Vascular Markers
- New Horizons Of Laboratory Medicine For Autoimmunity
- Laboratory Medicine Practice Guidelines:

A Multidisciplinary Approach

- Epigenetics And Laboratory Medicine
- The Impact Of Laboratory Medicine On Clinical Outcomes
- Selected Topics In Laboratory Medicine: Quid Novi, Quo Vadis
- Biomarkers And Personalized Pharmacotherapy
- Patient Focused Laboratory Medicine

Tuesday, 24 June

- Clinical Laboratory's Role In Decision Making: Risk Assessment And Interpretation Of Laboratory Test Results
- Pandemia Of Obesity, Metabolic Syndrome And Diabetes: Role Of Laboratory Medicine
- Data Generation And Ethical Issue In Laboratory Medicine
- Biologic Variation And Its Effect On The Reference Values
- Preanalytical, Analytical And Postanalytical Aspects In Molecular Diagnostic
- Expanding Role Of Clinical Laboratory In Infectious Diseases. Automation?
- Peer Review And Ethics In Publications In The Electronic Age
- Environmental Issues
- Bleeding And Thrombotic Disorders: Evaluation By Haemostasis Laboratories
- Evidence Based Laboratory Medicine In Decision Making: A Value-Based Business Perspective

Wednesday, 25 June

- How ISO 15189 Has Influenced Laboratory Testing?
- Established And Emerging Markers Of Renal Function - Chronic Kidney Disease - Best Laboratory Practice
- Biomarkers For Neurodegenerative Diseases
- Cancer And Laboratory Medicine
- New Developments In Hemostasiology
- Immunodeficiencies - A Cutting Edge Workshop Representing Top Research And Novel Diagnostic Options.
- Standardization Of Common Endocrine Tests
- Inborn Errors Of Metabolism In The

AFCB Region

- Tumor Markers In Clinical Practice: An Update
- PhD Training In Clinical Chemistry, Clinical Biochemistry, And Laboratory Medicine: Where Are We Heading?
- Challenges And Issues Of External Quality Assurance In Laboratory Medicine
- Continuous Quality Improvement - A Practical Approach To Achieve Operation Excellence

Thursday, 26 June

- POCT: Its Impacts On Patients And Laboratories
- Bone Metabolism And Osteoporosis
- New Advances In Prenatal And Postnatal Testing
- New Strategies In The Diagnosis Of Hematologic Diseases
- New Insights In Quality Management Of The Total Testing Process
- Clinical Utility And Standardization Of Emerging And Less Common Tests
- Qualitative And Quantitative PCR: HIV Viral Load And Eid
- Balkan Clinical Laboratory Federation (Bclf) Symposium

Industry Sponsored Workshops

Parallel ISW are scheduled daily during the congress from 14.30 - 15.30 and from 16:00 to 17:00, and include presentations on a variety of research issues from companies such as Randox Laboratories, Mindray, Siemens, Abbott, Sysmex, Diasys, Sekisui, Ids, Ab Sciex, Becton Dickinson, Diasorin, Snibe and Ghent University.

Satellite Meetings

June 20-22

XIIIth International Congress of Pediatric Laboratory Medicine

June 22

POCT Satellite Meeting

June 22

LC-MS/MS in Clinical Laboratory



Further information

Full programme details and further information: <http://www.istanbul2014.org/>

EXPERTS GATHER AT THE ARAB PAEDIATRIC MEDICAL CONGRESS 2014



Children's health is one of the most important areas in the healthcare industry, and it receives an important focus from government to enhance quality care for children in the region. Government's concerted dedication is manifested through establishing leading health facilities, attracting the most qualified healthcare workers and promoting awareness about recent advances in paediatrics and neonatology.

As it is important to enhance knowledge sharing, the region's top paediatricians and the regional health authorities will be gathering at the Arab Paediatric Medical Congress,

taking place at Amwaj Rotana Hotel in Dubai on 29-31 May 2014.

The programme features outstanding contributions from key experts such as Prof. Tawfik A. Khoja, Director General, Executive Board, Health Ministers' Council for the Cooperation Council States, Dr. Muna Al Kuwairi, Director of Primary Health Care Department, Ministry of Health UAE, Dr. Farida Al Hossani, Manager, Communicable Diseases Department, Health Authority Abu Dhabi, Dr. Yasser Nakhlawi, Chairman of Paediatric Institute, Sheikh Khalifa Medical City and Dr. Julian Eason, Chief of

Neonatology, Corniche Hospital, along with other key regional and international speakers.

The Arab Paediatric Medical Congress will be a unique and extremely rewarding opportunity for gaining knowledge in evidence-based paediatric and neonatology topics, and overcoming key challenges related to diagnosis and management of paediatric and neonatology disorders. Different areas will be covered such as Nutrition, Gastroenterology, Transplantation, Cardiology, Infectious diseases, Vaccination, Adolescent Medicine and many more.

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Arab Paediatric Medical Congress
30-31 May 2014
Dubai, UAE



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CME ACCREDITED

Promoting and Enhancing Quality and Evidence-Based Care for Our Children

TOP 7 REASONS TO ATTEND

- Gain expert knowledge in evidence-based paediatric and neonatology topics
- Learn about vaccination update and evidence use of antibiotics
- Join interactive workshops in nutrition, cardiology, antibiotics, Ventilation and neurology
- Meet outstanding regional and international experts in Paediatrics and Neonatology
- Submit your research paper to participate in Arab Paediatric Medical Research Award
- Overcome the most important paediatric nutritional disorders
- Network with your peers in the field of paediatrics and neonatology to build relationships and exchange knowledge

The ONLY Congress to Gather Key Stakeholders Across the Entire Healthcare Community Led by:

	Dr. Mahmoud Saleh Elhalik Head of Paediatric Dept. Latifa Hospital
	Dr. Farida Al Hossani Manager, Communicable Diseases Department Health Authority Abu Dhabi
	Dr. Yasser Nakhlawi Chairman of Paediatric Institute Sheikh Khalifa Medical City
	Dr. Julian Eason Chief of Neonatology Corniche Hospital
	Dr. Anwar Sallam Chief of General Pediatrics Al Mafraq Hospital

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The event will feature the Arab Paediatric Medical Research Award to foster excellence in paediatric research. "We encourage researchers to submit their abstracts describing new research findings and advances in this field to be qualified for the awards, as paediatric research plays a lead role towards the progress of childcare in the region", said Dr. Doaa Said, Congress Director and Managing Director at Maarefah, the organiser of the paediatric congress.

The two days of the congress feature a variety of interactive workshops, which cover the most pressing concerns in children's health such as evidence-based use of antibiotics and nutrition strategies for high-risk neonates.

"According to the World Health Organization, infectious diseases kill over 17 million people a year. Therefore, antibiotics are essential to save lives and to improve the quality of life. On the other hand, antibiotics are among the most commonly prescribed drugs in the world. Inappropriate use of antibiotics increases the cost of healthcare, induces side effects and contributes to the emergence and spread of bacterial resistance. Therefore, we have included a practical workshop in the programme to enlighten the paediatricians on the rational use of antibiotics to overcome microbial resistance", added Dr. Doaa.

"Urgent action is required to control

and prevent the emergence of bacterial resistance, as this is a pressing health-care concern in the UAE", noted Dr. Nawal Al Kaabi, Head Infectious Diseases, Paediatric Residency Programme Director at Sheikh Khalifa Medical City.

Dr. Nawal Al Kaabi will be leading the workshop to help paediatricians understand the appropriate selection of antibiotics and promote the rational use of antibiotics. Other expert-led workshops will cover neonatal ventilation, nutrition and clinical scenarios in paediatric heart diseases, epilepsy and more. ■

For more information about the Arab Paediatric Medical Congress, please email info@arabpediatriccongress.com



EUROSON 2014: BUILDING A EUROPEAN ULTRASOUND COMMUNITY

The European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) holds its 26th Congress (EUROSON 2014) in Tel Aviv from 26-28 May. EFSUMB was formed more than 40 years ago, and has a key role in education, research and interdisciplinary collaboration.

The European Federation of Societies for Ultrasound in Medicine and Biology has the slogan "Building a European Ultrasound Community".

As EFSUMB's President how do you see that goal being realised?

What we have done is to create pillars to identify and promote our community. For example, for teaching we have created an EFSUMB course book and course book student edition. We produce scientific guidelines and recommendations. We have guidelines on ultrasound and contrast-enhanced ultrasound, which were created in cooperation with our member societies. We also have recommendations on reporting and on minimum training requirements. The other pillars of our Federation are the

EUROSON Schools, and the EUROSON Congress. We cooperate at every kind of level in various activities.

EFSUMB has produced several guidelines, including those on CEUS and elastography. What other guidelines are being developed?

We have published guidelines on contrast-enhanced ultrasound for liver (Claudon et al. 2013) and non-liver applications (Piscaglia et al. 2012). The former was a joint venture between the EFSUMB and the World Federation of Societies for Ultrasound in Medicine and Biology. I am currently editing a book about interventional US in German and English, covering technical and clinical aspects and also endoscopic guidance. This was behind the

idea and basis to initiate a new generation of evidence based EFSUMB-guidelines, which will be available early in 2015.

Ultrasound as a modality is used by many specialist doctors. Can you comment about standards and quality of training in Europe?

There's a lot of work going on in education and training at every level. We have defined standards for every level, from the student up to very specialised doctors. We can only offer our quality standards to be approved by the local authorities of the respective countries, as we are not a regulatory authority.

EFSUMB has proposed the term "Echoscopy" for bedside focused,



Interviewee

Prof. Dr. med. Christoph F. Dietrich

President, European Federation of Societies for Ultrasound in Medicine and Biology, 2013-2015

*Chief Physician
Medical Clinic 2
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Interviewed by

Claire Pillar

Managing Editor, HealthManagement

clinically simple applications with handheld scanners (EFSUMB Executive Bureau 2013). Can you explain more about this and how does it differ from point-of-care ultrasound?

You can do point-of-care ultrasound with a high-end ultrasound machine, with a mobile unit, which has sophisticated features, and you can do it with a hand-held device. However, the term point-of-care ultrasound does not imply which machine and what level of expertise the doctor performing the examination should have. This is our definition of "point-of-care", and the term "echoscopy" means it's not a ultrasound examination, it does not exclude pancreatic or liver tumours. It's a term that covers limited clinical questions that can be answered by a handheld device. It can be used after biopsy, for checking fluid, or if there is bleeding, to look for pleural and pericardial effusion and ascites, in the shock

patient, for contractility of the heart and also for the gall bladder and other abdominal organs and vessels.

You edited the comprehensive EFSUMB Course Book. Please tell us more.

The EFSUMB course book on ultrasound can be freely downloaded all over the world. The idea behind it was to build the ultrasound community in Europe. We bring together three authors from three different countries on each chapter, working together, and to me that is building an ultrasound community in practice. All countries are invited to review the book chapters. The book includes a learning system and is accompanied by videos on examination techniques, tips and tricks. It is particularly useful for those countries, which might not have so many resources. Therefore up to now we offer the book

as a free download or as a print publication at a reasonable price.

Can you tell me more about the Ultrasound Learning Centres project of the EFSUMB?

There are qualified learning centres all over the world, which not only promote courses but also offer US learning according to defined criteria. This project is in process in Europe.

What are you looking forward to the most at EUROSON 2014 in Tel Aviv?

I believe in building up a European ultrasound community. That's the real challenge, so it is good to hold the congress in the 'periphery' of Europe. The congress offers the opportunity to continue building up a European ultrasound community with high technology and collaboration with colleagues and industry. ■

Further information

EFSUMB
www.efsumb.org

EFSUMB Course Book
<http://www.efsumb.org/ecb/ecb-01.asp>

EFSUMB guidelines and recommendations
<http://www.efsumb.org/guidelines/guidelines01.asp>

EUROSON 2014
www.euroson2014.org

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DESIGNING A SALUTOGENIC CHILDREN'S HOSPITAL



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Image 1.
The Royal Children's Hospital, Melbourne,
Australia

Research on the salutogenic direction highlights the impact of architecture that inspires the designer and planner toward designing for a healthy society and an environment that stimulates health and wellbeing and prevents the onset of diseases at all levels of society. The approach of salutogenic design for hospitals promotes health and wellbeing by creating a built environment that includes wellness factors, contributing to the sense of wellbeing for staff and strengthening the healing process.

The salutogenic approach to the design of children's hospitals incorporates creativity and innovation through the interdisciplinary application of sciences such as architecture, medicine, public health, psychology, design and engineering with culture, art and music.

Salutogenic design stimulates and engages users in the environment, both mentally and socially, and supports an individual's sense of coherence. The salutogenic approach to

design begins with the quality of the space being able to capture people's attention, and in many cases positive psychological attributes start to emerge. Anxiety experienced by the patients in hospital surroundings is vastly reduced, leading to positive feelings that can support recovery and improve wellbeing for the patients. A salutogenic approach focuses on positive factors that promote wellbeing as opposed to those that make people unwell by virtue of poor designs that lack inspiration. The main characteristics of great designs carry elements that stimulate the mind and senses in order to create pleasure, creativity, satisfaction and enjoyment.

The international Academy for Design & Health has performed extensive empirical research on salutogenic design for healthcare buildings, and studied hundreds of articles and other literature connected to the physical environment, health and behaviour to explain the

benefits of promoting psychosocially supportive design and the power of properly designed spaces to influence wellbeing and health.

There are many inspirational ways in which design can contribute to better care and hospital planning, and this article looks at general principles as well as the example of the Royal Children's Hospital, Melbourne, Australia, which has architectural design that promotes the sense of wellbeing through experiences and emotion.

Salutogenic Hospitals

The overall goal of salutogenic hospital design is to deliver the most appropriate medical services for patients in a very stimulating environment that supports the healing process for patients and is experienced by staff as an enjoyable and efficient workplace.

A salutogenic hospital furthermore provides services that actively prevent people getting sick





by identifying risk factors in early stages through regular checkups. The salutogenic hospital serves its local community, its patient population and its own staff through the application of a holistic, knowledge-based approach to the delivery of medical treatment and clinical services, provided in combination with preventative measures and public health information that promotes health, wellbeing and quality of life.

The children's hospital should be designed with consideration of all ages and sizes and should reflect interior design that creates welcoming and engaging spaces for all, particularly in common spaces where patients and their families come together.

The Royal Children's Hospital, Melbourne

The Royal Children's Hospital in Melbourne is surrounded by nature and parkland. The buildings blend into their surrounding through external façades that camouflage and unify the buildings with the landscape.

All sides of the building exploit the play of direct sunlight. Sunshades and window treatments have multiple purposes, protecting the buildings from the strong Australian sun, bringing views inside and creating an impressive, organic structure.

The Royal Children's Hospital is an example of a large hospital experienced by visitors and children in manageable elements through a

colourful and stimulating form with daylight creating stress-free navigation across the entire building.

Navigation

Creating a small building unit landmark, the plaza has a different floor surface with a clear circulation system, which simplifies the horizontal and vertical navigation from the street. From the landmark entrance there is a zone to distinguish between the different parts of this level as well as different zones within the hospital. These design stimuli help visitors navigate easily within the hospital without wasting energy and reducing stress. The main entrance as a plaza or street

Image 2. Navigation through a central 'street' allows intuitive wayfinding and creates a landmark for the hospital

Challenges in Paediatric Imaging: Maximising Dose Efficiency

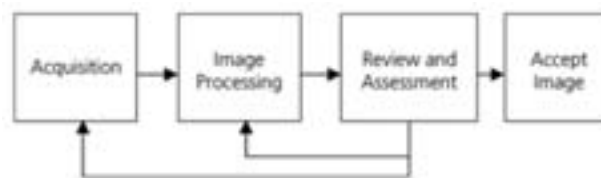


Figure 1. Flow diagram for the image-formation process, including review and assessment and feedback on quality

Optimising Image Acquisition in Digital Radiography

The first stage in getting the image is to capture the X-ray image with an efficient detector using the appropriate acquisition protocols (e.g. kVp, mAs and filtration) across the wide range of paediatric body types. In digital radiography, Carestream offers a range of innovative, freestanding, wireless DRX detector products.

Advantages

- **CsI(Tl) X-ray absorption layer** helps to ensure highest possible image quality;
- **Wireless design** eliminates hazards and risks from cables and reduces infection risk; virtually eliminates issues with patient positioning in a busy clinical environment, and does not disrupt the workflow of neonatal and paediatric ICUs;
- **Replaceable battery** guarantees that the detector is ready to use immediately;
- **Paediatric Capture Image Optimisation & Enhancement Software** offers default acquisition parameters and unique image-processing for seven age/weight categories for patient body size (from very low birth weight to adolescent) appropriate for different detector types, based on FDA recommendations.

Research into Acquisition Techniques

Carestream is continuing to research and develop improved acquisition techniques for paediatric patients. Use of a digital receptor means it is possible to target a specific signal-to-noise ratio in the image, versus maintaining a specific optical density in the final image. Separation of acquisition and display of a digital image offers the opportunity to develop task-specific tailoring for the amount and type of radiation used to create digital images.

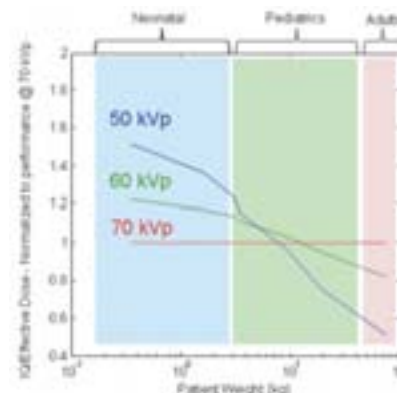


Figure 2. Shows a normalized image-quality metric (detectability index per unit of effective absorbed dose) for a 5-10mm sized lung nodule, as a function of patient weight. The results are normalized to those for the 70kVp technique, and show that for lighter patients, a lower kVp can provide improved image quality for a given patient dose, while higher kVps are more beneficial for larger patients.

The importance of minimising radiation dose to paediatric patients while maintaining image quality has come to the fore in recent years. Children and infants have a range of body types. Their organs and bones are still growing and are therefore more sensitive to ionizing radiation. Their long expected lifespan also requires close attention to radiation dose in order to minimise risk. The Image Gently® campaign of the Alliance for Radiation Safety in Pediatric Imaging, which is supported by Carestream Health, is channelling efforts to educate everyone involved, from radiologists, physicists and radiographers to parents and referring physicians, on the need to adjust radiation dose when imaging infants and children. The Image Gently® campaign's "Back to Basics" initiative encourages the use of child-specific imaging practices in digital radiography.

One size does not fit all, and the need to adjust dose and review quality in paediatric imaging is apparent throughout the imaging process. It is not appropriate to use the same acquisition techniques and image-processing parameters as for adults. Parents and their children deserve the best quality image at the lowest possible dose.

The unique demands of paediatric imaging require a system wide approach to guarantee high-quality imaging at the lowest possible patient exposure. Carestream Health's products can assist in all stages of the process of acquiring and displaying images for diagnosis, and offer a range of features and functionality to provide the best and safest possible X-ray imaging across the full clinical range of exams for all paediatric patients.

In some procedures, such as scoliosis exams, it may be possible to reduce the exposure levels used for follow-up images. Exposure reduction works if the imaging task can be achieved with an image that is noisier than the high-quality primary exam, but still provides sufficient delineation to allow accurate clinical evaluation. In the example of scoliosis, Carestream Health has also implemented a long-length imaging capability that minimises the amount of overlap between consecutive images, thus reducing patient exposure and ensuring maximal coverage of the anatomical field of view.

Image Preview and Radiation Amount

Rapid display of the preview image allows the radiographer to quickly decide whether the patient's anatomy was correctly captured or if the image needs to be retaken. This improves speed and efficiency in completing exams, which is particularly important for young patients. To help, Carestream has implemented the IEC Exposure Index (EI) standard for quick assessment of the amount of radiation used to create the image. The Deviation Index (DI) allows an immediate evaluation of the acquisition technique compared to the institutional target of exposure for the given exam. This immediate feedback, coupled with the other developments in technique selection described above, helps the radiographer provide more consistent image quality.

Optimising Image Processing and Display

The next step is to perform appropriate image processing that presents the diagnostic information clearly and most efficiently to the radiologist. Carestream's EVP Plus Software can be tailored to adjust the image-processing parameters to an individual site's preference. With information about the patient's size and age, the IP parameters can also be adapted to display the features of the clinical information in a more informative way compared to using adult image-processing configurations. The eight-band frequency decomposition, multi-frequency noise reduction and controlled edge-restoration capabilities mean that the available clinical content of the bony structures in the smallest NICU patients can be appreciated as well as the trabecular detail of older more developed patients, for example. The fine detail and lower contrast of the smallest NICU patient's anatomy requires accentuation of different frequency components than the features of the larger adolescents.

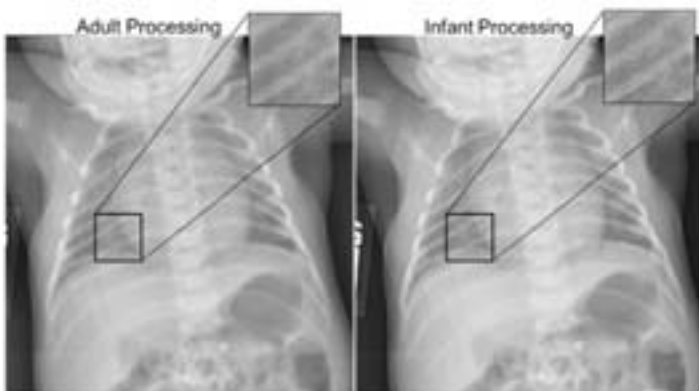


Figure 3. An infant chest image processed with both adult (left) and infant (right) image processing. Note that many infant chest details are not apparent when using adult processing.



Figure 4. A teenage chest image processed with both adult (left) and infant (right) image processing. Note that fine details of the teen chest are overemphasized when using infant processing.

Quality Control

A continuous quality control (QC) programme is essential to maintain delivery of high quality images. Carestream Health has implemented a number of imaging system capabilities that enable a site to easily track key quality criteria.

Software Tools

To test digital radiography (DR) and computed radiography (CR) quality, Carestream Health offers the Total Quality Tool (TQT) package. The package includes test phantom kits, and enables efficient evaluation of the digital X-ray detector's current performance level. The IEC Exposure Index allows quick evaluation of the exposure levels used to acquire the images. The Deviation Index immediately compares the exposure used to the institution's target. Dose Reporting sends data on total dose back to the RIS, including rejects. The Administrative Reporting and Analysis Software enables queries on all Carestream systems across the institutional network from a single, central location. This can quickly highlight anomalous exposure levels, high repeat rates or other image quality issues, and allows for more proactive steps to solve potential problems. Together, these system capabilities can help technologists maintain their high level of image quality and consistency.

PRODUCT INFORMATION

Small format DRX 2530C Detector (including Paediatric Image Optimisation & Enhancement Software) – fits easily into a neonatal incubator X-ray tray

DRX-Revolution Mobile X-ray System – includes child-friendly graphics

For more information visit carestream.com/pediatrics

About Carestream Health

Carestream is a worldwide provider of dental and medical imaging systems and IT solutions; X-ray imaging systems for non-destructive testing; and advanced materials for the precision films and electronics markets—all backed by a global service and support network. For more information about the company's broad portfolio of products, solutions and services, please contact your Carestream representative or visit www.carestream.com

To view Carestream's latest news announcements, please visit www.carestream.com/news

Carestream



Image 3. (above)

The central 'street' offers natural wayfinding and enjoyable distractions in the main entrance on arrival at the hospital

Image 4. (below)

Waiting area



acts as a prominent gateway to all departments identified by signage or unique floor number.

Each zone can be identified through a single letter to avoid confusion, similar to an airport terminal, using a colour system for direction and identification to support easy navigation through the hospital. To simplify orientation and easily remember different zones a combination of numbers and other information that relates to the function of each department can be used, e.g. "Family accommodation zone A level 2".

Arrival/ Plaza/ Atrium/ Street/ Main Entrance

The main entrance will be the first experience for most people, whether patient or relative/ friend, and it therefore needs to reflect the hospital's image as a centre of health and be a welcoming environment.

The atrium as a landmark provides clear direction to information points and circulation routes. This is the initial point of navigation and it is essential that the visitor can directly recognise the main information points and that services are clearly visible for all. The use of both colour and signage are key elements within this space, and help create meeting places and points of reference.

The hospital includes remarkable elements such as the double height aquarium, which supports orientation and works as a landmark within the building, and also attracts all users' views and engages patient and staff. It provides a joyful and stimulating experience.

The main outpatients reception and waiting area are focal points within the atrium space. Incorporating the double-height space aquarium as artwork provides patients and visitors with a comfortable and relaxing environment whilst waiting for their appointment.

Circulation

Directional signage incorporated into floor and ceiling design supports wayfinding at the main 'street' and decision points with information centres. Clear signage and natural use of colour and shape provide assurance to patients and visitors when arriving in the hospital. Main circulation crossroads are highlighted in all floors and ceilings with natural daylight and art to make users aware of a potential direction. Different art and positive distraction elements here and in the main 'street' highlight entrances to different departments and rooms, and provide for people of all sizes and abilities easy navigation of the building.

Along the natural main 'street' as the hospital landmark, other areas are easily identified as gateways to further zones. These zones can comprise one or several departments. Each zone has its own unique shape and identity by design. The different floors are simply identified by the finishes used or through colour, art or graphics associated with the different floor identities to create interest and engage with patients and staff.

The main 'street' functions as a waiting area with play areas, a family lounge with café, gift shop, restaurant and services. There are different types of waiting areas provided for children and their families, for short-term and longer waiting periods with a variety of furniture types and attractions.

Patients' Rooms

Children's rooms are designed as a safe and pleasant environment with direct views of the park, and sky views inside the room designed to be experienced from the bed.

It is possible for parents / carers wishing to stay the night to use the visitor bed located in the room. Viewing nature through a window

has more positive health outcomes for the patient.

Therapies

Art both attracts and acts as a positive distraction during examination and treatment. The Royal Children's Hospital has decorated rooms and walls with imagery that is both beautiful and educational, reflecting the nature of Australia. The intention is that the images will have a relevance to the themes developed in the hospital. In treatment rooms, using positive distraction is a way of giving the patient a sense of control and a stimulative environment. This makes them feel more relaxed and comfortable with the procedure.

Any patterns indicated in the therapies department flooring are for clarification and engagement purposes. The therapies department has specific exercises and activities designed for the treatment of patients, which are likely to involve particular flooring. The design ensures that the most suitable floor patterns are integrated into the overall flooring solution for the therapies department with different art supporting navigation.

Art

Artwork brings creativity and life to children, fostering their imagination and creating a sense of fun whether being a patient or visiting a loved one. For staff as intellectual capital artwork provides positive stimuli. There is a children's zoo in the hospital and a cinema with movies to support healing, as well as digital interactive elements encouraging a sense of welcome and comfort. All elements are about reducing stress and strengthening the ability to better manage the level of stress associated with disease and hospitalisation. ■



Design and Health is a global knowledge network for continuous dialogue between researcher and practitioner. From 9 to 13 of July 2014, the Design and Health World

Congress and Exhibition will be held at Toronto and the International Symposium on Design and Health will be held in Beijing on 30 October – 1 November 2014.

Image 5. (above)
Child's bedroom

Image 6. (below)
Radiology Department



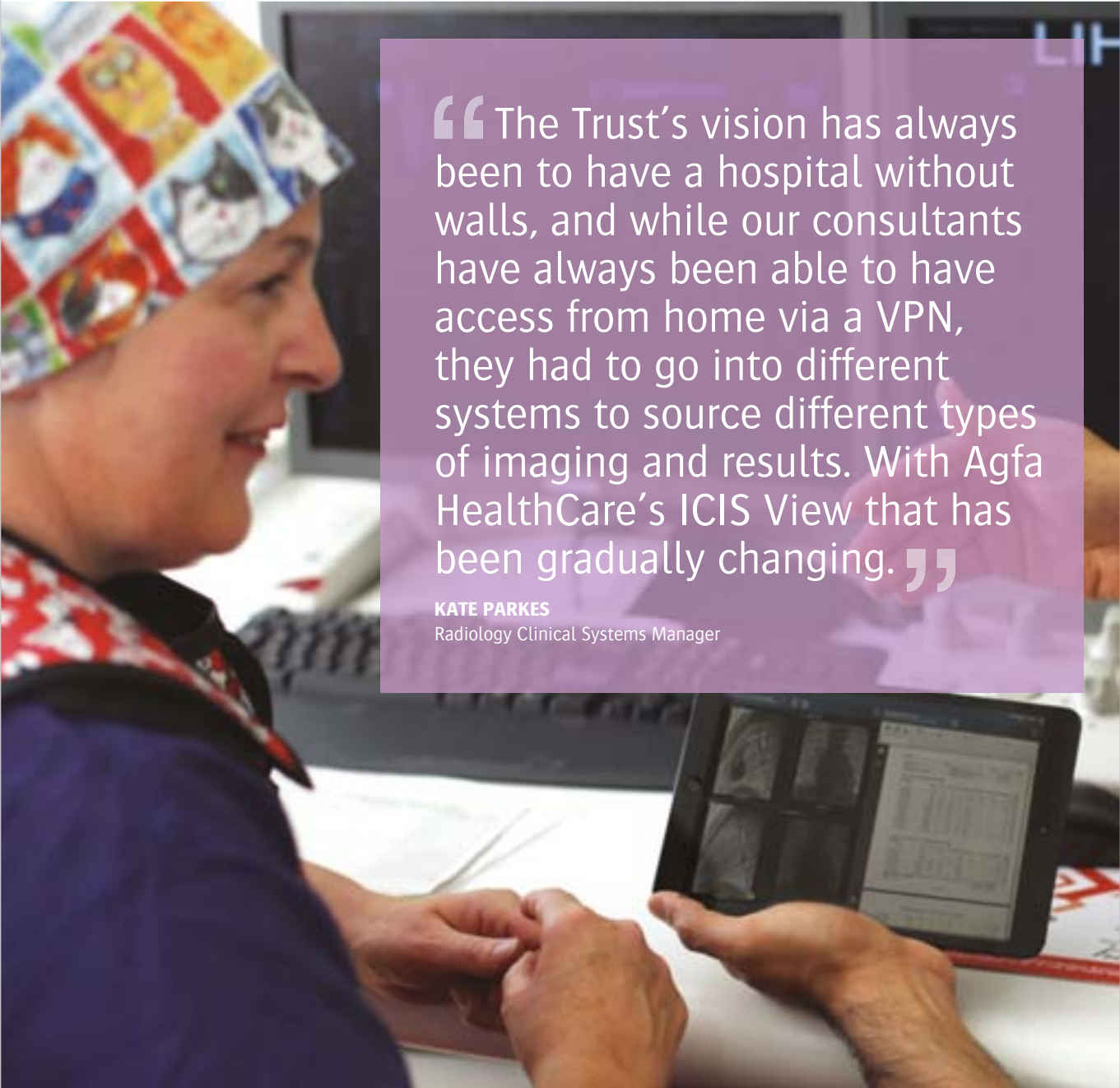
Birmingham's Children's Hospital, United Kingdom

One Vision

Kate Parkes, Radiology Clinical Systems Manager at Birmingham's Children's Hospital, explains how its installation of Agfa HealthCare's ICIS View is the latest step on its path to the ultimate goal of having every image and report on one service.

INTERVIEW WITH KATE PARKES, Radiology Clinical Systems Manager at Birmingham's Children's Hospital

"Birmingham Children's Hospital has a history as an early adopter of new IT technology," explains Kate Parkes. "As one of the first hospitals in the UK to adopt a full PACS system – as early as March 2003 we were completely digital – we are no strangers to using the latest technologies to enhance patient care and safety".



“The Trust’s vision has always been to have a hospital without walls, and while our consultants have always been able to have access from home via a VPN, they had to go into different systems to source different types of imaging and results. With Agfa HealthCare’s ICIS View that has been gradually changing.”

KATE PARKES
Radiology Clinical Systems Manager

Birmingham Children’s is one of the leading pediatric specialist hospitals in the UK, providing world-class health services for children and young people from Birmingham, the West Midlands and beyond. Specialist services include liver transplant surgery, cardiac surgery, epilepsy surgery, burns, major trauma, craniofacial surgery, blood and marrow transplantation, specialized respiratory and dermatology, neurology and cystic fibrosis and consultants frequently hold outreach clinics in the surrounding area.

Developing a hospital without walls

“The Trust’s vision has always been to have a hospital without walls, and while our consultants have always been able to have access from home via a VPN, they had to go into different systems to source different types of imaging and results. With Agfa HealthCare’s ICIS View that has been gradually changing.”

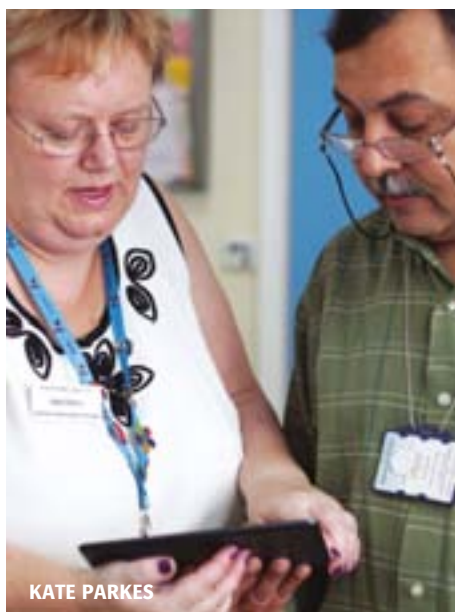
Images can be seen anywhere in the hospital

“ICIS View was being launched at around the time that we were looking to install a solution that would allow us to show our really large laparoscopic videos without impacting on the performance of the Trust’s intranet as well. In addition, for studies such as endoscopy and laparoscopy, historically a lot of the information was stored on DVDs and it was often difficult to find the disc to review as there was no central store. There was a similar issue with ECG and pacemakers information; the reports were filed in the patients’ records or in a folder in the cardiac unit. Now they can be seen anywhere around the hospital.”

Access to ICIS View has also had a fundamental impact on planning patient care says Kate Parkes. “It makes sure that when a child is seen by a multidisciplinary team (MDT), often with many specialties present, or when they are being discussed at the MDT meetings – which can often be as important as seeing the child – it is so much easier to flow all of the information through one service rather than having to keep switching between different systems.”

ICIS View also makes interaction with the patients and their parents easier

ICIS View also makes interaction with the patients and their parents easier through its use of tablets. “We are rolling out ICIS View on Apple iPad mobile digital devices at the moment, and although this is still quite new it is



KATE PARKES

definitely proving popular with the kids,” says Kate Parkes. “Children are very visual and they like looking at images on an iPad as it is familiar to them. If they can see something, then they can understand it, and children like to look at their images and see exactly what is what. They don’t have the fear that adults do and they are very inquisitive generally.

Real time images save time

“Also, it is a little bit more private than having it on a computer in the middle of the ward. The iPad can be taken to the bedside and while some parents obviously don’t want to see, anything that can help the child understand and be comfortable helps the parents. They can physically see changes and see improvements – or occasionally not – and it is all in real time. So, for instance, in the renal clinic or the liver clinic, they

have their ultrasound and then they go back to clinic and get their results there and then. It means children don’t have to come back for reports and follow up appointments and so saves time.”

As with any implementation of new technology, “there is a learning curve and often when you are the first to do something, there are teething problems,” admits Kate Parkes. “But, you also reap the benefits, especially if, as in our case, you have been involved in the Beta testing. We have had a say in how it looks, how it feels and how it works. And, as far as I know, we are the only site in the world that is running ClinApps*, a 3D software, on ICIS View and that has gone down really well with the clinicians here.

Our goal is all images and results from one source

“Our aim for our five-year plan is to pull all of our images into one source and then, following that, the results. We are still working with departments that haven’t worked with PACS before because they have never been required to – departments such as ophthalmology and the respiratory department. It has been a huge learning curve as the departments have to follow very strict workflow and in some cases, like the heart investigation unit, they have had to change their entire workflow and how they interact. But our staff is very supportive of the changes and PUG, our PACS user group, enables them to make requests for developing additional functionality. We have pretty much developed PACS as far as we can without a vendor neutral archive but, hopefully, that is on the horizon as we have a bid into Government for funding to help make that happen. I am confident that when we are ready, the solution will be there.” ■



DEFINING THE VALUE OF CHILD LIFE SPECIALISTS IN PAEDIATRIC HEALTHCARE SETTINGS

CONSIDERATIONS FOR IMPLEMENTING OR EXPANDING SERVICES



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A child coming into a healthcare setting brings with them a unique set of coping strategies, fears, family dynamics, and perceptions of what their experience will be like. Personalising care to fit the needs of that child and family is a crucial element of providing high quality, family-centred and cost-effective care.

Child life specialists enter the child's world when medical stresses do,

health care delivery for children" (Child Life Council et al. 2006).

From a mission perspective the addition of child life specialists to improve the experience of the child and family is crystal clear. The business aspect of the decision must entail more nuanced questions and a cost-benefit analysis that documents the advantages of having a robust child life programme.

.....

“Child life services have been widely recognised to impact impressions of quality and service and may be a factor upon which families decide where to bring their children for care”

.....

and their aim is to serve as a bridge between the realities of the healthcare setting and the needs of the child and family. There are several anecdotal reports that not only do child life specialists improve the experience of the child and family, but they also positively impact efficiency and coordination of care. Child life specialists have been shown prospectively to positively impact family satisfaction scores, family and staff reports of child cooperation and staff satisfaction (Tyson et al. 2014). The American Academy of Pediatrics, in a 2006 statement, recommended that “child life services should be considered an essential component of quality pediatric health care and are integral to family-centred care and best-practice models of

The Role of a Certified Child Life Specialist

Understanding the function of a Certified Child Life Specialist (CCLS) is the first crucial step to assessing impact and effectiveness. The role of a CCLS is diverse and constantly evolving to meet the needs of patients, families, and medical institutions. The Child Life Council's definition (2014) is that “child life specialists focus on the psychosocial needs of children, collaborating with parents and other members of the team to:

- Ease a child's fear and anxiety with therapeutic and recreational play activities;
- Foster an environment that incorporates emotional support;

- Encourage understanding and cooperation by providing non-medical preparation and support for children undergoing tests, surgeries, and other medical procedures;
- Advocate for family-centred care;
- Engage and energise children and families by coordinating special events, entertainment, and activities;
- Consider the needs of siblings or other children who may also be affected by a child's illness or trauma;
- Direct pre-admission hospital tours and resources, and consultations with outpatient families;
- Support families confronting grief and bereavement issues;
- Provide information and resources for parents and members of the interdisciplinary team.”

Child life specialists embody a variety of additional roles, depending on their specific position. These can include (but are not limited to):

- Making pre-procedure phone calls to provide anticipatory guidance to children and families and to advocate for individual needs;
- Serving as members/leaders of interdisciplinary committees and teams;
- Coordinating donations and seeking sources for programme funding;
- Administering paediatric volunteer programmes and providing training and supervision;
- Educating hospital staff on the developmental needs of children;
- Promoting a child-focused atmosphere.

The many and diverse roles of the

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child life specialist make the scope of the profession especially difficult to define and quantify. Each aspect of the profession must be viewed in the context of the cost of providing each service and the benefit to the patient, family, medical institution and broader community.

Considerations for the Implementation or Expansion of Child Life Services

Healthcare leaders considering the initiation or expansion of a child life programme must consider a variety of factors, including:

• Who is your competition?

Healthcare institutions are competing in an environment where patients have choices and are influenced by impressions of quality and service. Patients are consumers of healthcare, who are increasingly more informed. The competitive nature of healthcare systems makes service an important strategic and competitive tool. Child life services have been widely recognised to impact impressions of quality and service and may be a factor upon which families decide where to bring their children for care.

• What is the structure and flow of your institution?

The specific role and corresponding impact of a CCLS depends on the services provided at your institution and the process by which the patient is served. In an inpatient setting the types of interventions provided by a CCLS may decrease length of stay and improve the coordination of care provided. In an outpatient setting a CCLS will likely improve flow and increase the number of procedures that can be done per day. CCLS are a relatively low cost resource that can be tremendously effective in



roles that other staff may otherwise take on. For instance, in a paediatric radiology department without a child life specialist an imaging technologist may help to prepare the child in the MRI room for a few minutes before the scan begins. With the addition of a child life specialist, the preparation of the child can begin over the phone or in the waiting room, such that the higher cost resources of the imaging technologist and MRI room are not used for that portion of the process.

• How are the services that you provide paid for?

The financial impact of a CCLS is largely dependent on the payment and reimbursement system of an institution. For example, CCLS are often able to impact rates of sedation by offering additional pain management techniques, but in a fee-for-service environment that may not be financially beneficial to the healthcare organisation. If payments are bundled or diagnosis-related group (DRG) based however, a reduction in those kinds of higher cost procedures could be quite financially advantageous. A thorough analysis is recommended in both deciding if to implement a child life programme, and also in deciding where existing or new CCLSs should focus their time within the programme.

• Where does your institution rank with regards to patient satisfaction scores?

Do not underestimate the importance of patient satisfaction scores and the potential impact that the provision of child life services could have on those scores. The widespread use of patient satisfaction survey tools has changed how hospitals assess quality care, and the ease with which customers can access and compare this data has significant ramifications for the business strategy of healthcare organisations. In addition to the importance of image among consumers, satisfaction data is increasingly linked to quality and even reimbursements.

Communication and an awareness of the patient's perspective, both key aspects of the child life role, have been shown to be determining factors of satisfaction. The Press Ganey Hospital Pulse Report (2010) found that, based on survey results from more than 1,700 hospitals in the United States, the top three issues identified by inpatients relate to communication and empathy, including response to concerns, being included in treatment decisions, and having one's emotional needs addressed while hospitalised. The highest priorities in the outpatient environment centred around meeting the



emotional needs of the patient and included response to concerns, sensitivity to needs, and concern for worries. These top priorities reported by patients directly relate to staff interactions and interactions that exist in the essence of the child life specialist's role.

• **Would marketing the availability of child life services strengthen your brand identity?**

The availability of child life services can be interpreted as a sign of commitment to family-centred, high quality care and attention to the patient experience. Philanthropic efforts may also be positively impacted by a strengthened brand identity that includes the provision of child life services.

• **Do you currently provide true family-centred care?**

In addition to being seen as a driver of patient satisfaction, family-centred care has become a focus in many healthcare institutions as a way to improve quality, safety, efficiency, and financial outcomes.

Charmel & Frampton (2008) analysed the business case for patient-centred care, noting that hospitals that provide patient-centred care reap a number of financial benefits, including:

- Reduced length of stay;
- Lower cost per case;
- Decreased adverse events;
- Higher employee retention rates;
- Reduced operating costs;
- Decreased malpractice claims;
- Increased market share.

Patient-centred care is often cited as a way to achieve product differentiation in healthcare. A study by Stone (2007) examined data for two comparable hospital inpatient units over five years. One unit implemented an extensive programme of patient-centred practices during this time and the other did not. The study showed that in each of the five years studied the patient-centred unit had:

- A shorter average length of stay than the control unit;
- A statistically significantly lower

- cost per case than the control unit;
- A shift in the emphasis from higher cost staff to lower cost staff;
- Higher than average overall patient satisfaction scores.

The philosophy of child life is synonymous with patient and family-centred care, and a Certified Child Life Specialist has the unique role of focusing on the empowerment and support of patients and families as well as advocating for patient-centred practices.

Conclusion

Child life specialists provide valuable services that support paediatric patients, their families, and the healthcare institutions where they work. Decisions regarding the implementation or expansion of child life services should consider the competitive landscape, financial impact, possibilities for marketing, influence on patient satisfaction scores, and institutional commitment to patient- and family-centred care. Engaging patients and families in decisions regarding child life programmes is encouraged where possible.

Although the case for child life is compelling and robust, future studies should seek to quantify the impact a CCLS has on efficiency and coordination of care within paediatric health settings. This detailed data would allow healthcare leaders to make more informed and detailed decisions regarding having child life specialists as members of the healthcare team. ■

Acknowledgements

Special thanks to a Simon Business School project team including Chelsea Pino, Stephanie Lempke, Lisa Snow, and Michael Weidner whose contributions supported these findings, to Jackie Wameling as the skilled Certified Child Life Specialist in the department where the project took place, and to Daniel Bohl, Laura Lazarus, Wendy Lane, Connie White, Liz Lattimore, Sue Bezek, and Kathy Perinello whose contributions and support have been invaluable on this topic.

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Key Points

- *Child life specialists aim to bridge the gap between the realities of the healthcare setting and the psychosocial needs of the child and family.*
- *Child life specialist roles are diverse and evolving, with a focus on efficient, high quality family-centered care.*
- *Considerations for implementing or expanding child life services include competition, workflow, reimbursement, patient satisfaction and marketing.*
- *Cost-benefit analysis is needed to show the advantages of a child life programme.*

IMAGING CHILDREN, GENTLY



The number of radiological examinations performed yearly all over the world has significantly increased in the last two decades (Brenner 2010; Furlow 2010). As a consequence, the radiation exposure to the population from medical sources alone accounts for more than 50% of all radiation exposure the population receives (Amis et al. 2007; Brenner and Hall 2007; Mettler et al. 2009). There is general agreement in the scientific community that this increment of radiation exposure may result in a small but significant increase of developing cancer later in life, and this is particularly true in young children. Children are considered to be more at risk for radiation-induced cancer than adults due to their higher biological sensitivity to ionising radiation and to the longer period of time it takes them to generate a cancer related to radiation exposure (Brenner 2002). To date, most of the risk estimations have been calculated from studies of survivors of the Hiroshima and Nagasaki atomic bombs (Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation 2006), but many researchers argue that this extrapolation could be affected by substantial bias, because during a nuclear blast not only radiation, but also a large amount of toxins are produced. In addition, radiological modalities tend to irradiate only specific body regions, in contrast to atomic explosions, which result in total body exposure. However, recent and strong epidemiological studies performed in populations exposed to ionising radiation with CT examinations during their childhood have demonstrated that the risk is real, and must be carefully considered if we think that many millions of CT scans are daily performed on children all over the world (Mathews et al. 2013; Pearce et al. 2012).

To date, radiological examinations of children (and in particular CT scans) have been performed by adapting adult protocols and not using specific and native paediatric protocols. This malpractice finds explanation in the dramatic lack of awareness about radiation risks among medical professionals. Many papers have clearly demonstrated that most healthcare professionals did not know the radiation dose delivered to patients for common radiological exams, and, if they do not believe it is a problem, they do not care (Brown and Jones 2013; Divrik Gökçe et al. 2012; Lee et al. 2004). This lack of awareness does not respect the two fundamental principles of radiation protection: justification and optimisation. Justification means to balance the risks and benefits of each procedure, choosing the right diagnostic tool and the right timing in order to maximise benefits

.....
“although it may be obvious, the best way to reduce radiation is to not image the patient at all, or, as an alternative, to image patients with MRI or US, which are ionising radiation free”

and minimise risks. Although it may be obvious, the best way to reduce radiation is to not image the patient at all, or, as an alternative, to image patients with MRI or US, which are ionising radiation-free. When it is necessary to use ionising radiation modalities, as in trauma or unstable patients, the optimisation principle acquires the greatest role; its goal is to perform images with sufficient diagnostic

image quality and the lowest possible radiation dose, according to the ALARA concept (as low as reasonably achievable). Optimisation requires clear understanding of all technical aspects of radiological equipment, which is increasingly complex in high dose procedures such as CT scans.

Image Gently® Campaign

In 2001 an article in USA Today (Sternberg 2001), based on papers published in the American Journal of Roentgenology, brought the public's attention to the potential risks related to CT examinations performed in children. The Society for Pediatric Radiology organised an international conference to promptly respond to public concerns. This led to the creation in 2008 of the Image Gently® (IG) Campaign, founded in collaboration with the American Society of Radiologic Technologists,

the American College of Radiology and the American Association of Physicists in Medicine. The purpose of this fundamental alliance, the Alliance for Radiation Safety in Pediatric Imaging, is to increase awareness by means of educational actions addressed to both parents and professionals. The website of the campaign (<http://imagegently.org>) gives the opportunity to get any kind of information, from easy brochures



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by which parents can learn about radiological examinations their children have to undergo, to detailed educational materials for referring physicians, physicists, radiologists and radiographers. To date, the alliance has sponsored campaigns in different radiological areas, such as diagnostic fluoroscopy, interventional radiology and nuclear medicine. The last campaign, called “Back to Basics” focused on digital radiography. The action of the alliance is completely changing professional behaviour, increasing awareness and sensibility towards paediatric patients. In the

make their contribution too. In 2012 the Italian Radiographer Federation joined the Alliance, recently followed by the Italian Physicist Association and the Italian Radiological Association (Società Italiana di Radiologia Medica - SIRM) Study Section of Paediatric Radiology. The first action to demonstrate our great interest has been the organisation of a congress specifically dedicated to the Image Gently® Campaign, which was held in October 2013 in Pisa, Tuscany, entitled “Image Gently: children sized radiology” (see image 1). Epidemiological, biological and techni-

paediatric CT, without causing parents to refuse studies recommended by the referring physician (Donnelly 2005; Larson et al. 2007). The availability of the IG contents in Italian can also allow all professional staff (physicians, nurses, technicians, etc.) to improve their knowledge about all issues related to the paediatric field, in order to take specific care of their little patients.

The spread of this campaign is particularly important in radiological facilities lacking specific expertise in paediatrics, which can lead to the execution of radiological examinations with more radiation than necessary and the inobservance of guidelines. Paediatric facilities have been shown to be more aware of radiation reduction methods, and are more likely to have paediatric protocols in place to reduce radiation. The lack of radiological staff training concerning paediatric protocols, along with the lack of new technological instrumentations, explains the difference in radiation dosage observed in some studies (Nosek 2013; Paolicchi et al. 2014). In order to support this need, it should be fundamental to set up an alliance between the most important paediatric hospitals. The aim is to create a link between paediatric and non-paediatric facilities, allowing the spread of good radiological practice in different sites; and, to overcome the several difficulties encountered by experts who are not used to handling young patients, providing them with ‘tools’ to work in autonomy, using acquisition parameters which are adequate according to worldwide standards.

What Needs Doing

Notwithstanding the increasing awareness of researchers worldwide and mass media towards patient radiation risk, with special attention to paediatric patients, the current situation demands further improvement. Many recent papers outline that knowledge

“the spread of this campaign is particularly important in radiological facilities lacking specific expertise in paediatrics”

last five years the Alliance for Radiation Safety in Pediatric Imaging has quickly grown and now includes more than 60 national and international professional societies who are contributing to dissemination of the message.

What We Are Doing in Italy

Italian radiological professionals want to

cal topics related to paediatric imaging were tackled from both a theoretical and a practical standpoint with the involvement of both radiologists and radiographers. Specific attention was paid to the need for equipment, tools and protocols dedicated to paediatric patients in order to minimise the radiation dose.

The Italian Radiographer Federation is now working on translating into Italian the IG website contents in order to maximise the spread of the campaign. The goal is not to simply translate the texts, but to provide clear and easily understandable content, which does not require a high education level, by using tools able to measure the level of readability. In fact, parents who have received satisfactory information tend to acquire a greater autonomy, and they collaborate better with radiological staff during the diagnostic follow-up of their children (Paasche-Orlow et al. 2003). Some publications demonstrate that a brief informational handout can improve parental understanding of the potential increased risk of cancer related to



Image 1.

of diagnostic radiation and its associated cancer-causing risks is still inadequate across the medical profession, particularly among more experienced professionals (Brown and Jones 2013; Divrik Gökçe et al. 2012; Lee et al. 2004). Improved training about radiation doses and potential risks from ionising radiation imaging is mandatory across the medical profession to ensure optimal use of these important diagnostic tools and the preservation of best medical practices. It is important to assure an adequate education level starting from university courses in the medical area, providing students with accurate knowledge about ionising radiation risks and later performing regular refresher courses for referring physicians and radiological operators.

A good way to increase knowledge and awareness is to develop interest in the ability to monitor and track the radiation dose used in medical imaging. Although radiological equipment is now able to produce a radiation report and to communicate it to the picture and archiving communication system (PACS), radiological staff have not yet completely understood the potential of carefully tracking radiation dose. Dose tracking can strengthen the process of justification and optimisation with the intent to better achieve patient protection. Several benefits can be obtained both by patients and operators. Patients could receive minimal radiation exposure, and thus acknowledge that there is a specific responsibility in the delivery of

medical radiation and improve their confidence in healthcare providers' care. On the other hand, operators could easily improve in terms of justification and optimisation, acquiring extensive radiation safety data sets, which might contribute to ongoing epidemiological research on malignancy risk from low-dose radiation, identification of best practices and incorporating radiation data into appropriateness criteria. Recently, many vendors have presented promising new software, which can extract the radiation dose report automatically from the radiological equipment and send it to the PACS, allowing the collection of statistics on cumulative and individual patient dose. This great interest in dose tracking has been confirmed by the International Atomic Energy Agency (IAEA), which has initiated the Smart Card Project, something like an ATM card that allows knowledge of patient radiation history (International Atomic Energy Authority; Rehani 2013).

Another necessity we have to face quickly is to identify reference dose levels specifically designed for paediatric patients. The European Regulation EUR 16262, which dates back fifteen years and has been in force until now, reported reference dose levels for the various radiological procedures only for adult patients (European Commission 1999). The recent publication of the new council directive 2013/59/Euratom entitled "Laying down basic safety standards for protection against

the dangers arising from exposure" (Council Directive (EC) 2013/59/EURATOM) has driven the European Commission to approve a project on the establishment of European diagnostic reference levels (DRLs) for paediatric patients. The project, promoted by the European Society of Paediatric Radiology, European Federation of Radiographer Societies and the European Federation of Organizations for Medical Physics, aims to provide European DRLs for paediatric examinations and to promote their use in order to optimise children's radiation protection, with a specific focus on CT, interventional procedures using fluoroscopy, and digital radiographic imaging.

Conclusion

We can assert that paediatric radiology is undergoing a cultural change. We have much improved the communication between the different actors in the radiological field, including manufacturers and patients, but we must further grow our awareness about radiation risks in order to choose the most suitable diagnostic tool, and respect appropriateness and optimisation criteria, which acquire a greater value for paediatric patients. We must pay much more attention to our daily practice, especially in radiological sites lacking specific paediatric expertise. The cooperation of all actors in the radiologic area is an essential requisite in order to realise this change. ■

Key Points

- The number of radiology examinations performed each year is increasing all over the world;
- Consequently, radiation exposure from medical sources is increasing;
- Recent studies have shown that the risk to children who have had CT examinations of developing cancer is a real one;
- In Italy radiographers and radiologists are adapting the Image Gently® campaign to minimise radiation dose to paediatric patients; a congress devoted to the campaign was held in October 2013;
- The campaign will link paediatric and non-paediatric facilities to promote good radiological practice;
- Dose tracking, establishing dose reference levels and improved training will also play a part.

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PACS TECHNOLOGY

ARE NEW VERSIONS LIVING UP TO THEIR PROMISE?

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Notes.

- The overall score is calculated by using all data from each of the 25 performance categories gathered over the past 12 months for each of the vendor's products measured. The overall average for all questions answered with a numeric rating (1-9) is multiplied by 8.4444 to reach a total of 76 possible points. The remaining 24 percent is calculated from average ratings for the Yes/No questions. The average percentage of positive responses is calculated and multiplied by 24. These two scores are added together to get the total score (out of 100).
- KLAS Confidence indicates the number of surveys from unique organizations, which have evaluated a particular product. Where data does not meet the KLAS Confidence level, it means that this is early trending data on a new product, from fewer than 15 reporting organizations. Most products included have had more than 30 validated interviews.
- Regional Vendors indicates a product for which more than 75% of the data collected is from providers in a single region of the USA

The PACS market globally is at various stages. In some parts of the world healthcare providers are buying PACS for the first time, for example in the Middle East and parts of Asia. Elsewhere, healthcare providers are replacing or upgrading their PACS systems.

KLAS Research has released a performance report on new versions of PACS, *PACS Technology 2013: New Versions Stepping Up?*

The vendor products surveyed are Agfa HealthCare, Avreo, Carestream, Cerner, DR Systems, FUJIFILM, GE Healthcare, INFINITT, Intelrad, McKesson, Merge Healthcare, Novarad, Philips, Sectra and Siemens. The full data is based on interviews from more than 1,100 healthcare providers in the United States.

Providers reported consistently good experiences with INFINITT, but KLAS notes that INFINITT has fewer installations in larger hospitals (> 200 beds). DR Systems also received praise in all sizes of hospitals.

Recent versions from Agfa, INFINITT and Sectra showed improved scores

compared to their legacy versions, while newer versions from Cerner, McKesson and Siemens gave concern to their clients, who mentioned long waits for upgrades.

DR Systems and Avreo scored well as innovators, although Avreo has few customers in hospitals with more than 200 beds.

About KLAS Research

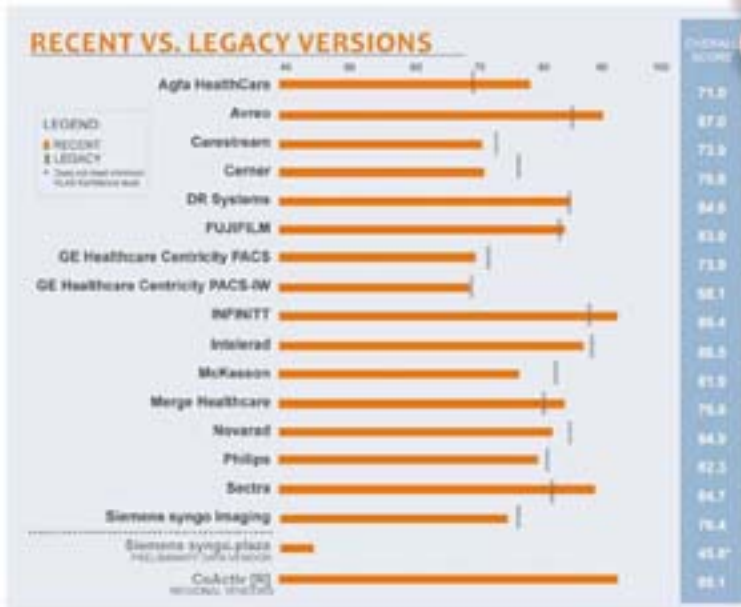
KLAS works with over 30,000 people in 5,000 hospitals and nearly 3,000 ambulatory organisations. KLAS sources its information predominantly from the United States. For the PACS data included above, data from outside the USA made up less than 10% of the surveys. KLAS conducts just under 30,000 interviews 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. ■

Notes.

Numbers are the average product quality rating, based on all data included in the report

The full report *PACS Technology 2013: New Versions Stepping Up?* is available from KLAS Research, www.klasresearch.com



THE MAGNIFICENT 7

QUALITY TOOLS EVERY RADIOLOGIST SHOULD KNOW



Introduction

A Japanese Samurai carried seven tools with him in preparation for battle. This historic tradition was modernised by Japanese businessman Kaoru Ishikawa, who utilised and promoted seven quality tools. While Ishikawa believed that management should allow employees to self regulate their own productivity, he also proposed that management should be able to illustrate to employees their own weaknesses (Watson 2004).

.....

“These seven quality tools can allow a radiologist to become fluent in the language of quality”

.....

These seven quality tools are the fundamental basics for statistics; however, they enable a user without a background in statistical analysis to make quality control comprehensible. These tools can be used as a systematic way to understand reasons for quality variation as well as establishing relationships between them (Ho 1999). Ishikawa also believed that these seven tools could solve 95% of a company's problems.

As most radiologists are aware, the world of radiology is rapidly evolving due to advancing technology and cost awareness. There has been a demand for increasing efficiency and minimising costs, similar to the demands of a thriving business or practice. These seven quality tools can allow a radiologist to become fluent in the language of quality. This will allow for more meaningful participation in hospital and accountable care

organisation (ACO) quality initiatives.

Histograms

Introduced by Karl Pearson in 1891, the histogram was used to demonstrate the reign of different prime ministers. It is thought that the word is derived from the Greek word 'histos', which means 'anything set upright,' such as the mast of a ship. While these tabulated frequencies can appear similar to a bar chart, bar charts show categorical data to visually compare cat-

egories, with height corresponding to the value of each category. In a histogram, the total area of the bar indicates the frequency of occurrence for each data interval.

The histogram is a visual representation of continuous data, which show the proportion of cases that fall within the organised categories. A normal distribution of data will appear as a bell curve. The data is first split into discrete, non-overlapping intervals, which are called bins. Each individual piece of data is sorted into a bin, and the number of occurrences in each bin is tabulated into a frequency.

In the radiology department, the histogram can be applied to assess numerical data. This can include the distribution of call volume, radiation doses, and turnaround time. For example, if the radiology department were to receive complaints about long wait times for generated reports, a

histogram could be constructed to show the underlying frequency distribution (Figure 1). Prior to this graph, it was assumed that all exams were read mostly within 45 minutes. In actuality, the turnaround times fell between 10 and 100 minutes; however, the majority of exams were read within 30-40 minutes. Twenty-five out of 255 exams were read between 70-100 minutes, causing the distribution to appear right-skewed. These larger values have caused the mean to be greater than the median and may warrant further investigation. However, it should be emphasised that histograms are most accurate when the process is stable (Tague 2005). Turnaround time can appear increased in the presence of computer malfunctions and faulty equipment.

Control Charts

Walter A. Shewhart, a physicist and mathematician who was working at Bell Telephone Research Laboratories, implemented the control chart to



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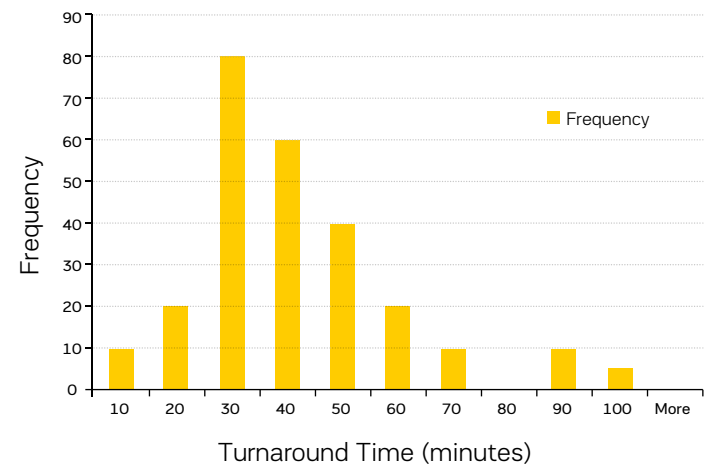


Figure 1.

Histogram of turnaround time in minutes. The shortest turnaround time was 10 minutes, and the longest was 100 minutes. This histogram does not demonstrate a normal, symmetric distribution, also known as a bell curve. Instead, the histogram appears to be right-skewed, indicating that the mean is greater than the median.

distinguish between the two categories of quality variation, assignable cause and chance cause (Best and Neuhauser 2006). Chance cause leads to variations of a process, which are uncontrollable. Assignable causes, on the other hand, can improve a

the radiology practice or department would include faulty machinery.

The control chart aims to distinguish chance cause from assignable causes of a process over a period of time. Based on historical data, the upper and lower control limits are set to three standard deviation units with the average set as the central line. These limits define whether the current event is 'in control', consistent, or 'out of control', unpredictable. If a process is assumed to be stable, then any process that falls out of control may warrant investigation.

For example, high case volume is important for an imaging centre. To monitor the case volume, a control chart could be constructed as shown in Figure 2. If there are too many studies on a certain day, then there will be a point that surpasses the upper control limit. If there are too few studies on a certain day, the lower control limit will be surpassed. In this example, the MRI case volume was monitored over a period of weeks. There were only two points, week 16 and 24, where the process was out of control. While week 24 had an exceptionally large case volume, week 16 may require investigation since the number of cases fell short compared to the historical average.

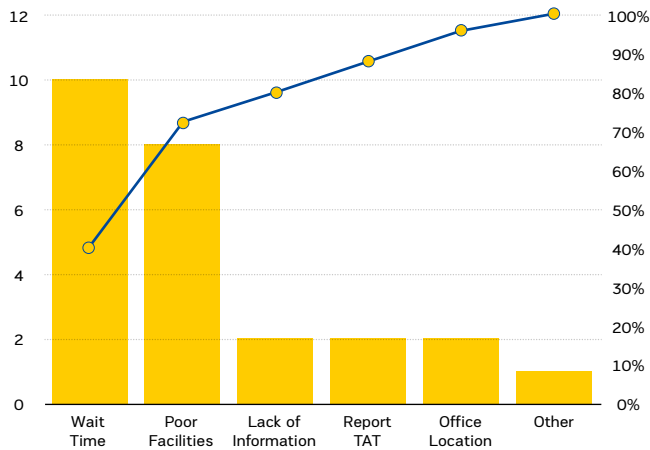
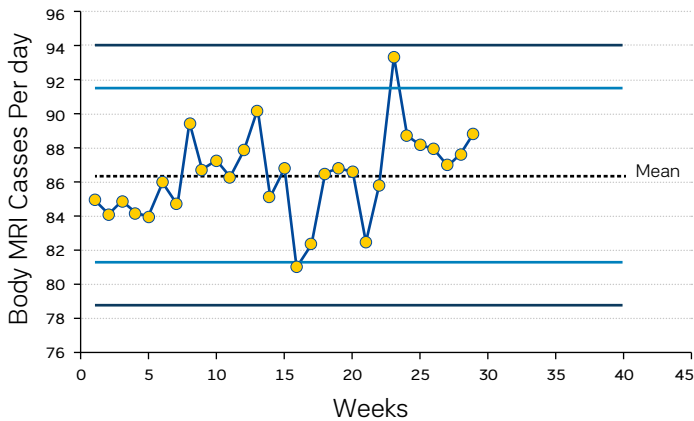
In order to create a Pareto chart, the data is sorted into categories and arranged by decreasing count. Causes are plotted on the x-axis and cumulative percentages on the y-axis; the points are joined to form a curve. A bar graph is also plotted with causes on the x-axis and frequency on the y-axis, with the bars on the far left being the tallest.

The goal of a Pareto chart is to focus on the most significant problem. For example, when evaluating the types of complaints received by the radiology department, it is important to determine what are the most common complaints and how often they occur compared to other less frequent complaints (Figure 3). Resolving the complaints that have the most impact will lead to the greatest benefit. In this example, the types of complaints concerning the radiology department were categorised and counted. The two largest categories were wait time and poor facilities. If both of these categories were improved through better communication and increased facility upkeep, 72% of the problems could be solved, by fixing 28% of the complaints. The effect would be different if attempts were made to resolve office location, which may require the patient to go to a different facility or location. If the office site were relocated, this would only solve 4% of the department's problems.

Cause and Effect Diagrams

Also known as the Fishbone diagram, Ishikawa himself has been credited for creating this concept (Watson 2004). The main problem is identified with a horizontal line, the 'spine,' running through it. Main causes and sub-causes to this problem are drawn as 'fish bones' arising from the 'spine'. The potential causes can then be potentially grouped together. Ideas that are lacking in

Figure 2. Control chart depicting MRI body case volume. Week 24 surpassed the upper control limit and week 16 fell short of the lower control limit.



Category	Frequency/Quantity	Cumulative %
Wait Time	10	40.00%
Poor Facilities	8	72.00%
Lack of Information	2	80.00%
Report Turnaround Time	2	88.00%
Office Location	2	96.00%
Other	1	100.00%

Figure 3. Pareto analysis displaying patient complaints when obtaining CT scans. The horizontal axis denotes each category being evaluated, and there are two vertical axes, the right side being numerical count and the left side pertaining to cumulative percentage.

process once identified (Best and Neuhauser 2006). The radiology practice or department often encounters chance causes in their day-to-day workflow, such as user variability in machinery and operation. Assignable but correctable causes in

Pareto Analysis

The Pareto chart was based on an observation made by Italian engineer and economist Vilfredo Pareto that 80% of the land in Italy was owned by 20% of the people. Also known as the 80-20 rule, the Pareto principle showed that, for any series of variables, a small number will be the cause for most of the effect (Harry et al. 2010). This rule can be applied to a radiology practice so that 80% of problems are attributed to 20% of the causes. In order to identify these potential causes, a cause and effect diagram, another tool described below, can be used.

a certain area will be illustrated as gaps within the diagram.

Cause and effect diagrams are best used for brainstorming. While the previous tools may help to identify a problem, this tool can be used to think of solutions or reasons for that problem. Issues such as decreased MRI case volume, increased turnaround time, long wait times, and poor facilities can be explored further using this technique. For example, to identify causes for delayed turnaround time, six major causes were identified (Figure 4). This included scheduling, patients, radiologists, nurses, technologists, and equipment. Multiple sub-causes have been identified for each of these categories. However, this tool cannot show which cause is more significant. To fully illustrate which of these causes would have the largest impact if fixed, a Pareto chart may be warranted.

Scatter Plots

The scatter plot is a classic method to depict a trend in data by showing how one variable (x-axis) is affected by another variable (y-axis). If there is a pattern, then the plotted data points will form a sloped line or curve. However, a pattern does not suggest that there is a relationship between the x and y variables, only that there is a correlation. A third variable may be present, affecting the two other variables. The correlation between these two variables can be deemed as positive, negative, or no correlation (Mikel 2010). A positive correlation exists when the increase of one variable corresponds with the increase of the other variable. A negative correlation exists when the increase of one variable corresponds to the decrease of the other variable. If the plotted points on the scatter plot appear randomly distributed, then no correlation is demonstrated.

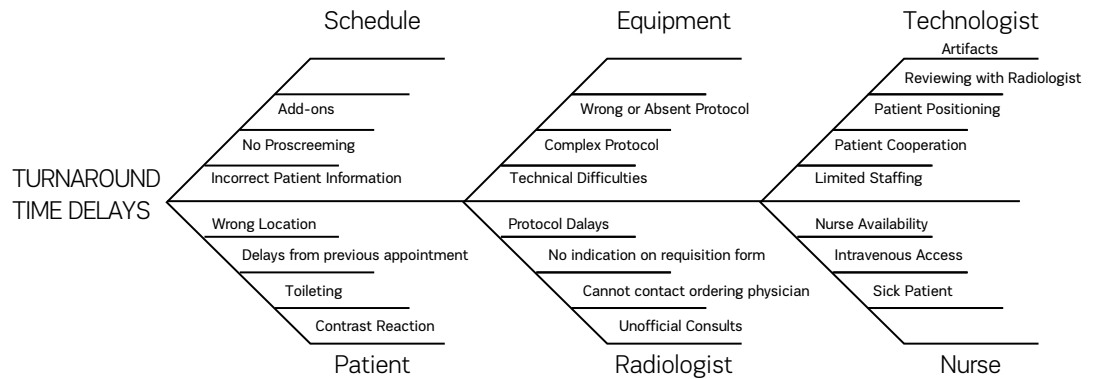


Figure 4. Cause and effect diagram to identify causes for delayed turnaround time.

The scatter plot is useful when causes have been generated (i.e. cause and effect diagram) and the most significant cause has been identified (i.e. histogram, Pareto chart). For example, if the radiology department noticed that certain images were difficult to read due to image noise, a scatter plot of patient weight and image noise could be examined. As shown in Figure 5, there is a positive correlation between the two variables. Based on this correlation, subsequent protocols could be customised for overweight patients to improve image quality.

Check Sheets

While check sheets are often confused for grocery checklists, this tool is used to ensure that tasks are completed in a reproducible and repeatable fashion. Quality control is often difficult to assess due to data collection errors, which include, but are not limited to, inaccurate data entry and poor handwriting. The check sheet decreases the chance of human error by standardising a form.

For example, when attempting to document disruptive phone calls to the CT reading room, a check sheet would be an optimal tool (Figure 6). The check sheet should be used over a period of time, such as a week, so that issues can be documented in a consistent manner. In this example,

the most frequent disturbance to the reading room was the wrong number being dialled, which was later shown to be an incorrectly listed phone number on the hospital directory website. Therefore, this tool is ideally used for gathering data to be subsequently analysed with the aforementioned tools.

Stratification

Stratification aims to categorise and separate raw data from a variety of sources. It is a technique used with other data analysis tools, such as a scatter plot or histogram, to elucidate a pattern. For example, when a scatter plot was constructed to show the relationship between the number of exams performed and time of day, there appeared to be no correlation between the two variables (Figure 7). It was then observed that, if the number of exams was separated by different

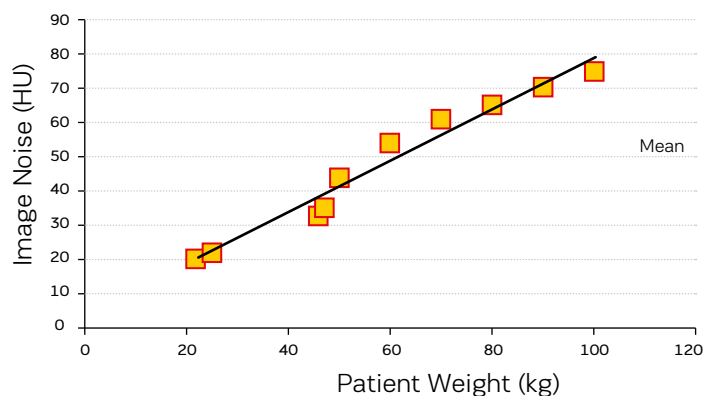
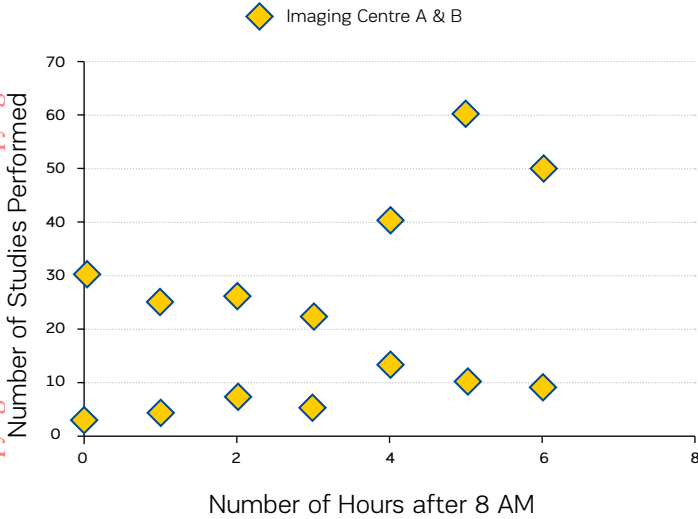


Figure 5. Scatter plot demonstrating positive correlation between patient weight vs. image noise (HU)

Figure 6. Check sheet used to demonstrate the amount of 'disruptive' telephone calls in a CT scan reading room.

Emergency Room Issues	Monday	Tuesday	Wednesday	Thursday	Friday	Total
Physician unable to take phone call	✓✓	✓	✓✓✓✓	✓	✓✓	11
Wrong patient history			✓	✓	✓✓✓	5
Wrong number	✓✓✓✓	✓✓✓✓	✓✓✓✓✓	✓✓✓✓	✓✓✓✓✓	26
Incorrect scan ordered	✓	✓	✓	✓	✓✓✓✓	9
Too many CT scans ordered on same patient	✓✓✓✓	✓✓✓✓	✓✓	✓✓	✓	15
Total Number of Issues	13	12	15	10	16	66

Without Stratification



With Stratification

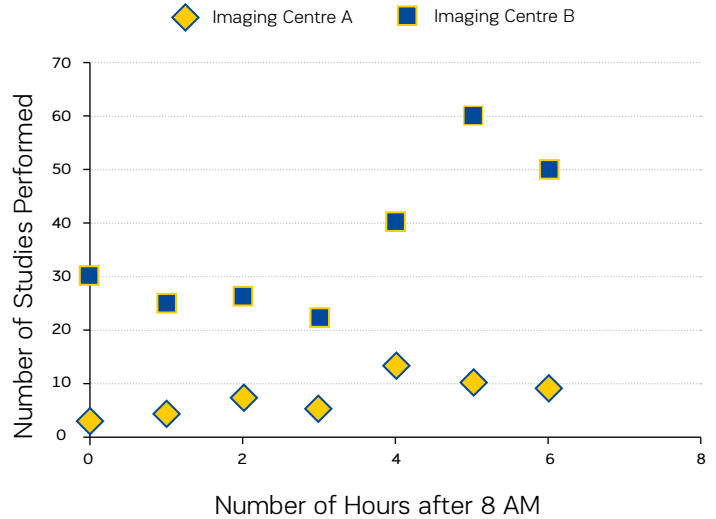


Figure 7. Stratification of data using a scatter plot. Without first separating between imaging centres, the relationship between the number of hours after 8 AM and studies performed is neutral with a random distribution. However, after separating the imaging centres, there is a positive correlation seen with each of the two sites. The number of studies performed at imaging centre B demonstrates a sharp increase after 12 PM.

imaging centres, a correlation could be demonstrated with both imaging sites. Both centres showed a positive correlation, meaning as the day progressed, more exams per hour were performed. However, after 12 PM, there was a sharp increase in the number of studies performed at imaging centre B.

It can then be assumed that imaging centre B may benefit from more coverage later on in the day.

quality, the Magnificent Seven can be used by radiologists to improve work efficiency and outcomes. These seven quality tools can empower radiologists to perform required quality activities, succeed as a member of interdisciplinary quality teams, and shape our future. ■

Conclusion

Originally used as tools that delivered companies better profits and higher

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Key Points

- Review of seven basic quality tools, the "Magnificent Seven." Originally used as tools to provide companies with better profits and higher quality, the Magnificent Seven can also be used by radiologists to improve work efficiency and outcomes, such as for a quality improvement project.
- Illustrated examples of the seven basic quality tools in the setting of a radiology department or practice.
- Discussion of the importance of using quality tools in the changing world of radiology, where there has been a demand for increasing efficiency and minimising costs. In addition, with these tools, the radiologist can become fluent in the language of quality. This will allow more meaningful participation in hospital and accountable care organisation (ACO) quality initiatives.

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QUALITY ASSURANCE IN RADIOLOGY: TWO APPROACHES



Quality is the new frontier in radiology and the necessary step to improve patients' outcomes and quality of care; more and more institutions, regions and nations have stated improved quality as their goal, and make it part of their mission statement. Quality control must be implemented at all steps of the imaging chain, from acquisition to reporting. In this article, we will look at two different approaches to Quality Assurance, starting with the evaluation of appropriateness of use of equipment and technical quality of the exams performed in Turkey, followed by radiologists' reviews in Canada.

The Turkish Approach to Quality: Equipment and Appropriateness

With improving imaging techniques, the number of radiological procedures has increased all over the world with time. However, accurate medical reporting depends on the true protocols and also quality of these examinations. In addition overuse of x-ray techniques can cause damage to the population. Before using any diagnostic modality, two important questions should be asked. Firstly, "Which modality should we select?" and secondly, "How do we use the image protocols according to the potential disease?" For these reasons, the Turkish Society of Radiology (TSR) and Health Ministry Department of Health Services have carried out a project with a working team* composed of members from the TSR and the Ministry of Health.

This project has included three main modality practices: CT, MRI and mammography. The surveillance project has been extended to state hospitals, university hospitals, private hospitals and outsourced health services of both state and university hospitals, which don't cover required examinations. With regard to the distribution age ratio of machines in Turkey, more than 60% of CT, MR and mammography machines were under five years old and 90% of them were under 10 years old.

The first step was to prepare the different electronic evaluation forms according to modalities. These forms have three parts. The first part was the evaluation of selected modality indication according to clinic diagnosis. Generally this part gave us the evaluation of the clinical physician aspect. The second part was the examination of radiological technique protocols and quality. The last part was centred on the

medical reports. The second and last parts related to the radiographers and radiologists respectively.

Once the forms were ready, one coordinator for each hospital was qualified by the Department of Health Services of the Health Ministry for selecting the radiological examination examples from their own centre. Meanwhile technical standards of radiological examinations, which were prepared by the Standards Committee of the Turkish Society of Radiology, were sent to the auditors, who were selected by the Turkish Society of Radiology. Auditor numbers were 153, 127 and 34 for CT, MRI and mammography, respectively. 4536 CDs of CT, 4432 CDs of MR and 1667 CDs of mammography were sent to inspectors by post. Only digital mammograms were evaluated in this project. CR Mammograms were excluded. The scores of results were evaluated by Pearson's chi-squared test.

CT Quality Results

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3183 of 4536 CT studies from 200 hospitals were scored by 155 radiologists. Distribution of examination areas was 55.5% for neuroradiology, 20.7 % for abdominal radiology, 18.5% for thoracic radiology and 5.3% for other systems. Indication criteria were adequate with the standards guidebook in 83.2% of all CT examinations.

In total 72.4 % of exams were adequate. University hospitals had the best results with an 84.3% score. Private hospitals and state hospitals results were 69.2% and 67.6% respectively.

The major cause of unqualified technique was found to be inadequate slice thickness (51.7%). The other reasons were using contrast material as 22.7%, scanning plan as 15.4%, incapability of patients as 11.9%, filtration of acquisition as 9%, technique problems of CD copywriting as 8.4%, field of view (FOV) as 7.4%, and inadequate scanning time and dynamic scanning, not using oral contrast material, artifact, spatial resolution, patient position etc.

Imaging Centre	Adequate (%)	Inadequate (%)
STATE HOSPITAL	67.6	32.4
UNIVERSITY HOSPITAL	84.3	15.7
PRIVATE HOSPITAL	69.2	30.8

Table 1.

Adequate findings of CT studies



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Slice thickness	51.7%
IV Contrast	22.7%
Scan Planning	15.4%
Incapability of Patients	11.9%
Filtration of Acquisition	9%
Technique Problems of CD Copywriting	8.4%
FOV	7.4%
Inadequate Scanning Time & Dynamic Scanning	7.3%
Oral Contrast	6.5%
Artifact	2.4%
Spatial Resolution	2%
Patient Position	1.4%
Other	4.2%

Table 2.

Causes of inadequate CT examination technique

Lack of Sequence	44.6%
Slice Thickness	39.1%
FOV	23.2%
Image Resolution	16.2%
Incapability of Patients	12.4%
Scanning Plan	10.6%
IV Contrast Agent	7.9%
Inadequate Coil	7.4%
Lack of Advanced MR Techniques	3.3%
Dynamic Study, Inadequate Scanning Time	2.6%
Artifact	2.1%
Technique Problems of CD Copywriting	1.2%

Table 4.
Causes of inadequate MR examination technique

Patient Position	75.2%
Contrast Density	33.8%
Artifact	28.3%
Patient Information on the Mammogram	16.6%
Compression	12.8%
Incapability of Patients	4.9%
Technique Problems of CD Copywriting	3.3%
Bucky Problems	2.4%

Table 6.
Causes of inadequate Mammography Technique

MR Quality Results

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3069 of 4432 MR studies from 193 hospitals were scored by 146 radiologists. The distribution of examination areas was 70.5% for neuroradiology, 21.1 % for musculoskeletal radiology, 4.5% for abdominal radiology and 2.9% for other systems. The indication criteria complied with the standards

Imaging Centre	Adequate (%)	Inadequate (%)
STATE HOSPITAL	68.2	31.8
UNIVERSITY HOSPITAL	84.7	15.3
PRIVATE HOSPITAL	69.9	30.1

Table 3.
Adequate findings of MR studies

Mammography Quality Results

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998 of 1667 mammogram from 165 hospitals were scored by 34 radiologists. The indication criteria complied with the standards guidebook in 87.9% of all mammograms. In total 43.9 % of exams were adequate. University hospitals had the best results with a 75.2% score (see Table 5). Private hospitals and state

Imaging Centre	Adequate (%)	Inadequate (%)
STATE HOSPITAL	42.4	57.6
UNIVERSITY HOSPITAL	75.2	24.8
PRIVATE HOSPITAL	20.9	79.1

Table 5.
Adequate Findings of Mammography Studies

Quality Improvements: Next Steps

According to the results of the radiological quality evaluation project in Turkey, the Ministry of Health and TSR have decided to take precautions in the next period.

1. Radiological quality evaluation will be repeated 1-2 times in a year;
2. According to the poor points of the results, certification programmes will be prepared for the radiographers.

These summarised reports were

provided from the first pilot study. More detailed results will be published in due course.

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guidebook in 83.9% of all MR examinations. In total 73 % of exams were adequate. University hospitals had the best results with an 84.7% score. Private hospitals and state hospitals results were 69.9% and 68.2% respectively.

The major cause of unqualified technique was found as lack of sequence at 44.6% range (see Table 4). The other reasons included slice thickness as 39.1%, FOV 23.2%, image resolution as 16.2%, incapability of patients as 12.4%, scanning plan as 10.6%, using IV contrast agent as 7.9%, using inadequate coil as 7.4%, lack of advanced MR techniques, dynamic study, inadequate scanning time, artifact, technique problems of CD copywriting, etc.

hospitals results were 20.9% and 68.2% respectively.

The major cause of unqualified technique was found as inadequate patient position at 75.2% range. The other reasons were inadequate contrast density as 33.8%, artifacts as 28.3%, absence of patient information on the mammogram CD as 16.6%, inefficient compression as 12.8%, incapability of patients as 4.9%, technique problems of CD copywriting as 3.3%, and bucky problems as 2.4%.

Marmara University, Department of Radiology, Istanbul), Dr. Alper Dilli (Assoc.Professor, Diskapi Yildirim Beyazit Training and Research Hospital, Ankara), Dr. Levent Altin (Numune Training and Research Hospital, Department of Radiology, Ankara)

Ministry of Health members:

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The team coordinators were Dr. Nevra Elmas from TSR and Dr. Irfan Sencan from the Health Ministry of Turkey.

The Canadian Experience: Assessing the Radiologist's Report

Multiple reviews of radiology reporting have taken place throughout the country, mandated by local health authorities, chiefs of staff or department chairmen. The process culminated in British Columbia (BC) a few years ago, when the CT reporting activity of two radiologists was reviewed, demonstrating high levels of discrepancy, with more than 30% significant errors, which could potentially harm patients.

This series of highly publicised radiologists' reviews in Canada has raised awareness of the need for a process to evaluate the quality and accuracy of the reports in the best interest of our patients and institutions. The American College of Radiology's RadPeer™ system has been in existence for more than 14 years, but does not answer to requirements any more, as the retrospective method on which it is based does not protect our community from errors, which may have disastrous consequences.

To address this issue, the BC Minister of Health Services requested in February 2011 an independent two-part investigation into the quality of diagnostic imaging, and asked Dr. Doug Cochrane, Provincial Patient Safety and Quality Officer, to lead this review. The first part of the report centred on the credentials and individual experience of the radiologists involved. The second part of the report provided a description of the events, a review of quality assurance and peer review of medical imaging, a review of physicians' licensing and credentialing, and issued 35 recommendations (Cochrane 2011). Among the recommendations pertaining to the provision of diagnostic imaging services, six were specific to quality assurance and peer review in diagnostic imaging as follows:

- That the health authorities and College develop a comprehensive retrospective review process that can be used in the health system or the private sector (recommendation 15);
- That the College and the health authorities develop a standardised retrospective

peer review process designed for quality improvement in the health authorities and private facilities (recommendation 16);

- That the Provincial Medical Imaging Advisory Committee (MIAC) establish a provincial management system for diagnostic imaging peer review in BC and that this system oversees both concurrent and comprehensive retrospective peer review processes (recommendation 17);
- That each health authority establish a Diagnostic Imaging Quality Assurance Committee to provide oversight for diagnostic imaging services provided by the health authority (recommendation 18);
- The British Columbia Radiology Society (BCRS) establish a teaching library of images reflecting difficult interpretations and common errors (recommendation 19);
- That BCRS, the Canadian Association of Radiologists (CAR) and the Royal College establish modality-specific performance benchmarks for diagnostic radiologists that can be used in concurrent peer review monitoring (recommendation 20);

This was the first initiative to implement a province-wide quality assurance programme for diagnostic imaging, focused on the quality of reports. It led to a provincial request for proposal (RFP) for a digital solution to enable the reviews. Three years after the vendor was selected, based on the Cochrane recommendations, only one of the six regions in British Columbia has a programme implemented. The solution implemented is based on the retrospective RadPeer™ system. A second province, Alberta, has also issued an RFP for a region-wide quality assurance solution based on the same requirements as in British Columbia.

There is no large-scale initiative in Canada otherwise and other jurisdictions are considering the opportunity to engage in such processes. The Canadian Association of Radiologists (CAR) has published a guide to peer review systems, which gives a list of recommendations for successful quality assurance implementation (O'Keefe

et al. 2011). The Ontario Association of Radiologists (OAR) has issued its own recommendations, similar to the CAR ones. Both support not only the current retrospective model, but also a new prospective concept that allows predistribution review of diagnostic imaging studies.

At McMaster University, we have initiated a prospective quality assurance pilot, the first in the country. The pilot's prospective nature allows for completion of QA activities before the report is finalised for the referring physician and made available in the Radiology Information System (RIS) and Picture Archiving and Communication System (PACS). The peer review solution combines the benefits of 'multi-ology' diagnostic peer review/quality assurance with the productivity benefits of single or cross-institutional workflow management/workload balancing, faster report turnaround time and improved overall healthcare system capacity into a single integrated platform. It has been developed based on previous large-scale reviews conducted in other provinces.

The pilot started in October 2013 with 11 radiologists participating across four sites, and features 400 CT, 100 MRI and 100 ultrasound cases across a four month timeframe. The reports made by a radiologist from a given hospital are not sent for review to a radiologist at the same site. For non-urgent elective exams, the maximum turnaround time is 48 hours. In case of discrepancy, the cases are referred to an arbitration committee.

The goals of this pilot are to:

- Determine the benefits in prospective QA workflows;
- Evaluate automated versus ad hoc QA sampling methodologies;
- Validate the feasibility of automated QA processes;
- Produce a recommendation report;
- Develop a centre of excellence in radiology peer review.

The expected pilot outcomes are:

- Proactive, pre-report distribution peer



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VIRTOPSY®

Photography, X-rays, Computed Tomography

Using photography (J.A.J. 1869) and taking plain X-rays are both techniques that were adopted by forensic scientists or forensic pathologists in a flash, as it appears.

Compared to this bush fire type adoption into forensic science, it is surprising to realise that the first adopters used CT (computed tomography) already in 1973 (Richmond 2004), but that CT remained largely unused throughout forensic sciences and medicine. Some scientific papers described methods as we use

so it appeared), the Russians demonstrated a ready-to-use arm dubbed the 'Russian Arm' (Kobriniski et al. 1950). After that, the Western Bloc countries, to their chagrin, had to send delegations to Russia to "learn about it" (Sherman 1964). Interestingly, the wider adoption of post mortem forensic imaging was preceded by a similar incentive: one institute charged ahead and just did it. **Virtopsy®**

“added value for the conventional autopsy results from improved planning and better diagnostics”

As far as plain x-rays go, first tests by the German physicist Wilhelm Röntgen were done around November 1885. Not much later, on 25 December 1895 in Montréal, Canada, a male victim suffered a firearm injury to the leg (Cox and Kirkpatrick 1896). Only three days later, the first scientific article was submitted by Wilhelm Röntgen (then in Würzburg, Germany) as a conference contribution, which immediately made headlines. That conference was the third meeting of the Physical-Medical Society in Würzburg, Germany. There Röntgen talked about "a new kind of rays" on 23 January 1896 (Röntgen 1898). With the goal to show the surgeon that was to remove the bullet of the aforementioned Canadian victim, a plain x-ray was taken on 7 February 1896 in Montréal, Canada. The patient was sent home ten days later. A court trial was held later, and the radiographs were presented as evidence there. Never has a new scientific or technological breakthrough been so quickly, internationally and universally adopted by the medical and scientific community (Brogdon 1998; Thali et al. 2011).

them in modern Virtopsy®, such as angiographic methods (Karhunen et al. 1989), CT scanning as such (Wüllenweber et al. 1977; Donchin et al. 1994), photogrammetry or 3D surface documentation (Brüschweiler et al. 1997) and MRI (magnetic resonance imaging) (Woodward et al. 1997). However, by 1998 – 25 years later – not one forensic medicine institute had added post mortem CT scanning or other 3D scanning methods to their everyday workflow.

Immediate adoption of a new technique by the whole wide world is not always the instantaneous result. It has been brought about by incentives every now and then though, such as the myoelectric prosthetic arm, whose wider adoption was somewhat forced upon the Western Bloc by their nemesis, the Russians. At the time, the technology to build myoelectric arms appeared to have been available, but no one seemed to bother with building products that amputees could use (eg. Schlesinger et al. 1919; Battye et al. 1955). In the middle of the Cold War, to the embarrassment of Western countries (Cohen 1955), out of the blue (or

The Virtopsy® research was in part initiated by a high-profile case (see Figure B1.1.3, p. 53 in Thali et al. 2009). The first body scans were started by our group in 1999, using project names such as 'digital autopsy' or 'scalpel-free autopsy'. With that, the Virtopsy® project was born (Dirnhofer 2001). This project was not the first attempt to use CT or MRI post mortem scanning worldwide (see references above), but it was undoubtedly the first to incorporate a broad range of technologies such as CT, MRI, biopsies (see Figure 1 overleaf) for an overview of the Virtopsy® system also containing a Virtobot®, 3D surface scanning (see Figure 2 for an example of surface data evaluation and injury matching), while also examining as many cases as possible over an extended period of time and in a systematic manner. A considerable number of traditional forensic pathologists expressed a 'dislike' for these new methods, but at the very same time this immediately was news all over the globe.

The targeted activity of the Virtopsy® research group around Richard Dirnhofer was widely communicated in conferences after 1999. The systematic approach and broad scope were unprecedented (eg. gunshot focused research (Thali, Yen, Schweitzer et al. 2001a), sharp force trauma (Thali, Schwab et al. 2001; Schweitzer, Yen, Thali et al. 2001a, Thali,



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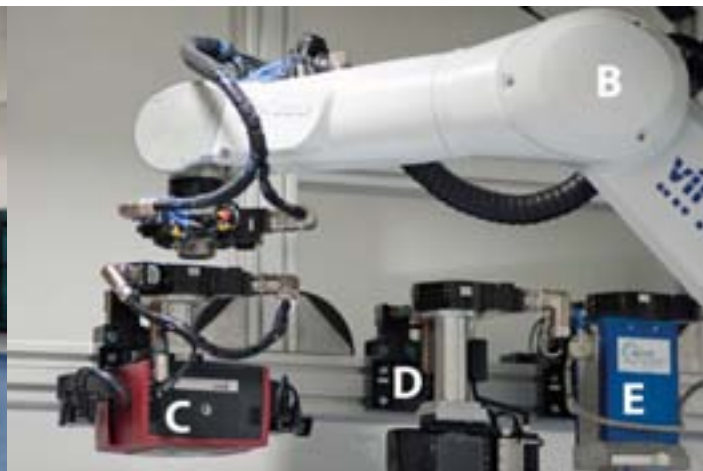


Figure 1. Virtopsy® system. The CT scanner (A) and its table are located within the reach of a ceiling mounted robot arm (B). The arm carries various tools, which are picked up automatically, such as a 3D surface scanner (C), a photographic mirror reflex camera (D) and a system to target and place biopsy needles (E).

Braun et al. 2001), heat and strangulation (Thali, Yen, Schweitzer et al. 2001b), post mortem interval estimation (Ith et al. 2001; Scheurer et al. 2001), skull and brain injury (Yen et al. 2001), heart-focused research (Schweitzer et al. 1998; Schweitzer, Schaepman et al. 2001; Schweitzer, Yen, Thali et al. 2001b) and 3D surface pattern matching (Brüschweiler, Braun, Thali et al. 2001a; 2001b)). Subsequently, results were made available also in compiled form (Thali et al. 2002; Thali et al. 2003; Thali et al. 2009).

Virtopsy® subsequently developed into a multi-tool documentation and analysis research project (Thali et al. 2009), combining 3D body surface imaging methods with merged CT and MRI data and 3D shape analysis (Thali et al. 2005; Buck, Naether et al. 2007; Buck, Albertini et al. 2007; Ebert et al. 2010; Schweitzer et al. 2013; Röhrich et al. 2012). The application of multi-detector or multislice (Ohnesorge et al. 1999) CT and MRI found continued interest (Aghayev et al. 2005; Bolliger et al. 2005; Jackowski et al. 2005; Yen et al. 2007; Buck et al. 2009; Ruder et al. 2012) also for problems specific to clinical forensic medicine (Yen et al. 2005; Yen et al. 2007), then for high-resolution micro-CT (Thali, Taubenreuther et al. 2001; Thali et al. 2003) and micro-MRI (MR microscopy) (Thali et al. 2004), magnetic resonance spectroscopy (time-of-death determinations) (Ith et al. 2002; Scheurer et al. 2005; Ith et

al. 2011), image-guided percutaneous biopsy (Aghayev et al. 2007; Aghayev et al. 2008; Ebert et al. 2010; Ebert et al. 2012; Ebert et al. 2014), post mortem angiography (Jackowski et al. 2005; Grabherr et al. 2006; Gyax and Grabherr 2009; Gyax and Grabherr 2010; Grabherr and Gyax 2012; Gyax et al. 2013; Ross et al. 2008), post mortem identification (Jackowski et al. 2006; Pfaeffli et al. 2007), post mortem ventilation (Germerott et al. 2010; Germerott et al. 2012), and non-invasive tool and data display control such as the integration of a Kinect camera (Ebert et al. 2013; Ebert et al. 2012) or 3D printing and rapid prototyping (Ebert et al. 2011). Added value for the conventional autopsy results from improved planning and better diagnostics. Some concise advantages are the identification and incorporation of bone bruises into accident reconstructions (Buck et al. 2009), the identification of gas (relevant in diving-related deaths (Plattner et al. 2003; Ozdoba et al. 2005; Wheen and Williams 2009)), the ability to identify pathology in decaying tissue (that can be difficult if not impossible to handle manually at dissection (Thali et al. 2003; Takahashi et al. 2013)), the ability to extract and use information related to (chemical) material composition (Persson et al. 2008; Alkadhi and Leschka 2013), documentation of medical installations (Oesterhelweg et al. 2009) and exploitation of digital data for reconstructive purposes (Thali,

Braun et al. 2005; Buck et al. 2007; Weilemann et al. 2008; Röhrich et al. 2012). Furthermore, advances in usage of reconstructive aspects of 3D CT reconstructions have led to routine integration of forensic aspects into clinical forensic medicine (see Figure 3). In the last 15 years, there have been numerous publications on forensic imaging (Baglivo et al. 2013). The significant technological step in forensic medicine can be described as the advancement from the 'forensic camera obscura' to 'Star Trek-like Virtopsy® and VirtobotQR technologies' (Thali et al. 2009). However, the core aim of the Virtopsy® project is not to eliminate the classical approaches, but to implement imaging techniques in forensic medicine that are at the level of the current technology (see figure 3).

Current Status and Outlook

Currently, there are a few centres that offer 3D model testing (such as the Institute of Forensic Medicine in Bern, Switzerland (Thali et al. 2002; Bolliger et al. 2010)) and 3D scanning (centres in Bern and Zürich, Switzerland) (Buck et al. 2007)). Post mortem imaging following the Virtopsy® approach is increasingly being employed around the world. This was apparent already a few years ago (Oesterhelweg and Thali 2009), while in the meantime major implementations seem to be underway at least in the United Kingdom as well as the United

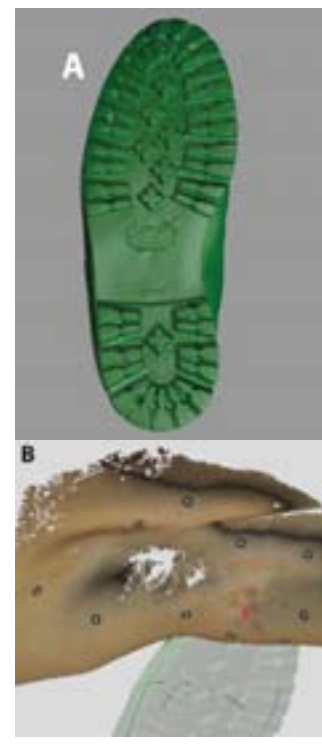


Figure 2. Footprint analysis: Middle-aged male was attacked. While lying on the ground, the perpetrators kicked him in the head and the trunk. One of the shoes left an imprint in the armpit. This injury, as well as the shoe, was documented using 3D photogrammetry and surface scanning. 3-dimensional reconstruction permits direct matching of the injury and injury-causing instrument.



Figure 3.

In this case, an initial forensic question was what type of violence had caused this man's head injuries leading to a significant nosebleed and a frontal epidural hematoma. The man had reported having fallen from his bicycle. He bled so much that he was admitted to a hospital where he was sedated, intubated and ventilated; so far he survived the injury. Clinical radiologists did report frontal, mid face and mandibular fractures, but no details as to their shape, distribution or relative size. Forensic assessment (see 3D reconstruction of clinical skull CT data) yielded a wide-spread fracture pattern spanning forehead, midface and mandible, containing a radial impression fracture of the frontal bone, with emerging burst lines towards the back of the head, across the mid face and with a partly comminuted fracture of the mandible. With this, the injury is consistent with massive blunt force as inflicted by a flat structure such as riding a bicycle straight into a bridge pillar that he must have overlooked.

States of America (Edwards 2009).

In forensic pathology, the following workflow emerges as standard: 3D surface scanning to document body surface and injuries in 3D and CT scanning to document any bone injuries and gross pathology.

The forensic imaging approach has the following potential:

- Recorded data are observer-independent, archived for later retrieval and can be reviewed by others or subjected to new analytical techniques, and possibilities for teleradiopathology are opened (second opinion).
- Material analysis is possible or approximated (Alkadhi and Leschka 2013).
- Scanning is non-destructive and does not tamper with the forensic evidence.
- Data provide a 1:1 match to the body and correct 3D geometry in xyz-axes or spatial documentation, which can be used as the basis of 3D scientific reconstruction.
- The approach provides an alternative or

additional examination that 'sees' different aspects of the body, as CT 'sees' with x-rays and MRI 'sees' chemical distributions (Jackowski et al. 2006).

- Difficult-to-examine body areas can be examined (eg, face, neck, spine, pelvis).
- The technique could be considered in cultures and situations where autopsy is not tolerated by religion or is rejected by family members (e.g., psychological reasons) (Goodman et al. 2011; Cannie et al. 2012).
- Bodies contaminated by infection, toxic substances, radionuclides, or other bio-hazards (i.e., bioterrorism) can be subjected to touch-free examination (more detailed requirements see eg, (Nolte et al. 2004)).
- 2D and 3D post-processing are provided for visualisation of the findings, which may be particularly relevant for people not present during the examination.
- A case's presentation in court may be understood better, more easily and in a more matter-of-fact way (Ampanozi et al. 2012).
- A new strategy option is introduced, specifically, examining a case stepwise. This is achieved by first doing an external inspection, then possibly a CT scan, then reading the data, then possibly an MRI, again evaluating the data, and ultimately deciding whether to do or not do to an autopsy. Thus, cases can be examined in a way that optimises quality and cost.

The forensic imaging approach (when applied alone) includes the following disadvantages:

- CT scanners have limited soft tissue contrast.

- Organ colours cannot be visualised (so that, eg, inflammation, tumour, scars, etc. can be hard to discriminate).

It is necessary for those interested in the future of forensic imaging to cooperate on an international basis at a high level, exchanging and sharing research results and acquired experience. There is a need for the education and teaching of highly trained professionals, which requires both financial support and enthusiasm. In light of global terrorism, it might be possible for the forensic field to acquire grant-based financing. Government institutions such as the United States Department of Homeland Security are already starting to consider funding research about this topic. As such, financial support seems more possible than in previous years. For that purpose, the International Society of Forensic Radiology and Imaging (www.isfri.org) was founded in 2011. Additionally, in 2012, the Journal of Forensic Radiology and Imaging (www.jofri.net) was born. A new 'Forensic Radiology' sub-discipline has opened up, bridging the worlds of Forensics and Radiology.

Because the Virtopsy® multi-tool approach will create a process of change in forensic medicine over the subsequent decades, teaching will be an important and core topic over the next few years. CSI television series have resulted in an increased interest in the forensic sciences (Schweitzer and Saks 2006; Knoblauch 2012). With the adoption of new imaging techniques, forensic sciences have indeed opened up a new area of research and a new area for service options. ■

Key Points

- Photography and x-rays were already used in the 19th century by forensic scientists
- In the 20th century adoption of CT in forensic sciences took longer
- The Virtopsy® research was the first project to systematically use a range of technologies (CT, MRI, biopsies and 3D surface scanning) in autopsy
- Forensic imaging has several advantages, including the ability to examine difficult-to-examine body areas, use when bodies are contaminated or when psychological or cultural reasons prevent autopsy
- Education in forensic imaging will be a core topic over the next few years

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Available on the website or on request

CONTRAST MEDIA AND RISK MANAGEMENT

DEVELOP SIMPLE RULES OF CONDUCT



Inherent in any technique of direct opacification (e.g. angiography), the injection of a contrast medium is common during routine examinations such as CT and MRI. The advantage of this injection is to improve the circulatory system and various organs, and thus help to individualise and characterise pathologies. Accidents, although rare and even exceptional for the most serious (i.e. death), are well documented. Risk factors are known, even if we know that certain reactions, including serious ones, are unpredictable.

The injection step is never trivial and remains a critical step for teams. Awareness of the risk, embedded in medical imaging, should facilitate management. Management is to know, prevent and organise, which implies, given the complexity of clinical situations and the different levels of education of stakeholders, proposing simple rules of conduct and ensuring that they are understood.

Main Risks

We distinguish schematically immediate manifestations, namely allergic reactions, which are quite common, and delayed reactions such as secondary renal failure due to iodinated contrast agents (techniques using X-rays) and the now well understood occurrence of nephrogenic systemic fibrosis after the injection of gadolinium contrast (MRI). The goal here is not to detail the various risks and how to prevent them individually,

but to list solutions aiming to mitigate these risks.

Prerequisites

These focus on knowledge and organisations. The messages are:

- Have a good overall knowledge of the risks associated with the use of contrast agents and more specifically those using specific molecules or those with specific uses (e.g. the intrathecal injection);
- Ensure knowledge is constantly updated. Good site management is to individualise the thematic contrast agents, and to agree on the name of a referring physician specifically in charge of monitoring the subject. The web accessibility of the recommendations of professional groups and societies not only greatly facilitates the monitoring process but the scalability of data from year to year is also faster;
- Be trained in the identification, characterisation, staging (classification by Ring and Messmer (1977)) and the control of intolerance reactions. On site scenarios are useful. Medical and non-medical staff should regularly receive practical training in the management of life-threatening emergencies. There is also labelled training for the staff of health facilities to qualify for a certificate valid for four years (French decree of 3 March 2006 on the certification of training actions and emergency care), such as training focused on

accidents with contrast agents proposed during the French Days of Radiology;

- Provide comprehensive, consistent and frequently and regularly verified support material, contained in a trolley in health-care facilities or a briefcase in an office. This equipment must be easily accessible, located in a central position, a place known to all staff, not locked but not open to the public. The verification of material is to ensure that, in relation to a predetermined list, the content is complete, and expiration dates are checked. The division of roles in the audit of the trolley must be established: we could for example do a check every day, performed by the potential users of the trolley (it is a way for them to know the content), with a logbook and also spot checks by the quality manager. It should also be clear about what action to take when using the equipment: update content, and then close with a small plastic seal - both show that a check was conducted and dissuade people from taking from this pseudo reserve. The promotion of the use of serum histamine and tryptase to characterise allergic reactions also calls for sampling kits to be made available with this equipment;
- Have effective means of communication (telephone with emergency numbers marked on or in the immediate vicinity of telephones, intercom), simple procedures (such as the code blue



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used in the U.S. for major emergencies) and defined procedures with external stakeholders (call an intensivist or emergency ambulance service) etc.;

- Display reminders of practical action in an immediate emergency as well as details on specific tasks: circuit blood samples to characterise an allergic reaction and make an appointment with the specialist allergist;
- Provide training for new personnel (medical and non-medical) upon taking up their post. Also, locums arriving on site must inquire about the means at their disposal and the plan put in place in case of an emergency.

Risk Management Throughout the Stages of the Examination

1. Making appointments

- Provide a framework so staff can easily identify, depending on the content of the application, the examinations for which an injection is needed. This pre-decision determines the later stages of the planning, is usually carried out by non-medical staff and will be reassessed when the patient is present;
- Be able to identify patients at risk of allergic reaction, the key question being whether there has been an intolerance reaction during a previous exposure to a contrast agent. A simple question such as: "Have you ever had a CT scan? An MRI? Did it go well? " will address the issue without creating anxiety;
- Be able to identify patients who warrant a dosage of creatinine, whether for a CT scan (risk of renal failure) or MRI (risk of nephrogenic fibrosis, varied depending on the products used). Attitudes can be systematic for all

patients, or on demand for financial reasons, particularly for outpatients and to exclude the use of risky products (hyperosmolar iodinated products and unsubstituted linear gadolinium). This is all based on risk factors collected at the patient interview and / or on forms filled out by applicants (patients older than 70 years, diabetics, history of renal disease, renal surgery, proteinuria, gout, heart failure, etc.). Access to a recent dose (less than two months or less than six weeks unless there is clinical deterioration in the meantime) will also limit withdrawals;

- Ban fasting, antinomic with the protection to be provided by adequate hydration (prevention of secondary kidney disease from iodinated contrast agents);
- Arrange appointments for injections when medical staff will be present;
- Do not expose the patient to repeated injections and so organise, when possible, the care of the patient in one sitting (the concept of a one-stop shop, unfortunately not valued by the French pricing system);
- In the event of necessary consecutive injections, ensure an appropriate interval adapted to the dose used, the renal function and the clinical situation (in a patient with normal renal function, rely on a half-life of around two hours for non-specific products).

2. Receiving and preparing the patient

- Check that the risk factors were investigated;
- Take them into account and, if necessary, challenge the injection: exploit the results of creatinine to express them as GFR (glomerular filtration rate) estimated by the MDRD formula*. If necessary and if it has not already

been done, find a substitution for another examination or correct any dehydration (protocols for rapid rehydration, delaying the procedure by less than an hour, are now available);

- Look into possible treatment with beta-blockers, knowing that it is a complicating factor in treatment of shock if it occurs. Similarly, identify the base blood pressure so vital signs can be interpreted under emergency conditions.

3. Carrying out the protocol and performing the act

- Use a licensed product suitable for the intended use (type, concentration), taking into account the potential risk factors of the patient;
- In the event that uncertainty remains on the characterisation of a prior reaction and where the examination could not be deferred, change the product;
- Use the minimum dose required for the diagnosis (and thus adjust the dose to the patient);
- Indicate the product and the dose used, and the batch number;
- Ensure that a doctor prepares the products used intrathecally (there is no room for error given the risks specific to certain products and stringent aseptic objectives).

4. Patient monitoring

- There should always be two carers, including a doctor close to the patient during injection: a nurse, familiar with the site, who knows how to provide immediate relief and call alerts, and a doctor ready to intervene. This doctor is not necessarily a radiologist and may be an accident and emergency doctor (a solution adopted in teleradiology);
- Ensure attentive monitoring during the critical phase that covers at least the first 15 minutes after the injection.

The patient should remain in a medical establishment for at least 30 minutes after an injection. In the case of hospitalisation, this precaution is automatically respected but for outpatients, it might be necessary to make them wait before allowing them leave.

5. Accident

- Identify it and act quickly;
- Remember to note the start time;
- Implement appropriate treatment;
- In the event of an allergic reaction, run blood samples as quickly as possible and organise consultation by a specialist allergist who can make recommendations for formal eviction or contrast agents to which the patient proves to be allergic.

6. The report

- Specifies the data on the contrast used (type and dose), states observed intolerance reactions, the people involved and successful management. The report is indeed an essential tool for traceability, simple letters being more randomly integrated into the patient's record.
- For patients with complex allergic histories, it is also important after a successful examination to include that tolerance was good without clinical intervention.

Concluding Messages

The relevance of the examination

It goes without saying that with respect to a risk review, the relevance (justification) of the latter has been verified. In case of complications, it is one of the first questions that will be raised.

Patient information

Risk management obviously involves much patient information

on the risks they are exposed to, when it is requested by the clinician and making the appointment. The appointment stage is often too late to give the patient the freedom to abandon or at least postpone the examination.

The overzealous

The unjustified refusal of the examination:

Taking into account the potential nephrotoxicity of contrast sometimes leads to extreme positions, not taking into account that, in assessing the risk / benefit ratio, denying or deferring an examination or to only perform it without contrast can be just as detrimental to the patient. For intravenous injections there is a risk threshold of glomerular filtration rate (GFR) estimated by the MDRD formula within 45 ml/min/1.73m². It is only above this threshold that it is recommended to search for an alternative technique, or if the indication is maintained, volume expansion and hydration. Case by case discussion with a kidney specialist as well as the patient must always be preferred to discharging a patient.

The untimely interruption of treatment:

In intravenous use, stopping metformin is now only proposed for a GFR less than 45 ml/min/1.73m².

Using MRI is also a risk

Allergic reactions, sometimes severe, initially discovered with iodine products, may also occur in MRI. The risk is even more important as this technique, erroneously, has a reputation for being harmless, but the scanner, increased physical isolation (narrow tunnel, room door tightly closed) and the length of acquisition makes patient monitoring more difficult. Hence the importance of quality audio

and video communications, solutions such as alarms and, if necessary, the real-time monitoring of vital signs.

The harmonisation of terminologies

The presentation of risk levels would benefit from being standardised, the frequency of reported effects on the basis of pharmacovigilance data, as specified by the following harmonisation proposals.

“ An undesirable side effect is:

- Very common if the frequency is $\geq 10\%$
- Frequent if the frequency is $\geq 1\%$ and $<10\%$
- Uncommon if the frequency is $\geq 0.1\%$ and $<1\%$
- Rare if the frequency is between $\geq 0.01\%$ and $<0.1\%$
- Very rare if the frequency is $<0.01\%$.”

Risk orphans

We must not forget the undesirable side effects related to the osmotic load of iodinated contrast agents (ensure to seek a prior pulmonary sub-oedema by cuts without injection during the exploration of dyspnea), iodine residues contained in the iodinated contrast product vials (an inappropriate injection in cases of hyperthyroidism), as well as the precautions to be taken during pregnancy.

* The MDRD (Modification of Diet in Renal Disease) equation allows calculation of the estimated glomerular filtration rate (GFR) from serum creatinine. ■

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QUESTIONS TO OUR EXPERT IN CONTRAST PRODUCTS: PROF. OLIVIER CLÉMENT

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Why did we settle for creatinine, abandoning the Cockcroft formula and express renal function in glomerular filtration rate estimated by the MDRD formula?

Creatinine is not good at estimating renal function as it depends on age and muscle mass. Historically, nephrologists encouraged us to use the Cockcroft formula which estimates creatinine clearance. This formula should not be used because it is not very accurate and the validity criteria are no longer respected (Jaffé dosage method replaced by enzymatic methods). The four MDRD parameters estimate the glomerular filtration rate; it is easier and probably a bit more accurate. The CKI-EPI is also usable. It is preferable for estimating renal function around 90 ml / min, but identical to the MDRD for the danger zone (30-45 ml/min/1.73m²) we seek.

What recommendations are there for the delay between an injected MRI exam and an injected scanner, in what order, and why?

There is no recommendation from agencies concerning the injection of two contrast media on the same day. The potential risk is an increased renal risk, but the amount of osmoles injected MRI is much lower than the scanner. Although there is no literature available, the injection of the two is possible in the same day, and there is in my opinion no specific time limit or order.

Prevention of nephrogenic systemic fibrosis: is it not excessive, when confined to the use of the most stable products, in single

doses, to use creatinine, knowing that if the disclosure is relevant the exam will not be challenged?

For products with low risk, the recommendations of the European Medicines Agency (EMA) indicate that an estimation of renal function by a biological test is generally recommended. The dosage of creatinine is therefore, unlike the high risk products, not mandatory. Indeed, if the GFR (glomerular filtration rate) is less than 30 ml / min, injection is possible, but at a single dose. This interpretation of the term 'generally recommended' may vary between centres and physicians. But effectively, if the indication is formal and the dose should be limited to 1 mmol / kg, the dosage of creatinine will not change the procedure.

At what grade of allergic reaction should you embark on further assessment (determination of histamine and tryptase, skin tests)?

The results of the CIRTACI study* that are currently being published show that the percentage of true allergic reactions (IgE-mediated) increases with the severity of the reaction, but it is still high in grades 1 (hives, angioedema). Apart from two small hive papules spontaneously resolved, we must explore all allergic reactions by blood (especially the dose of tryptase), because it is a major biological argument in the diagnosis of allergy.

Does premedication provide medico-legal protection in patients with an unclear allergy history?

All notions of 'iodine allergy' are unclear since this term does not

mean anything, and patients have never been properly examined. When a patient has an unexplored history of previous hypersensitivity reaction, the radiologist may be tempted to 'premedicate' before injecting. This attitude is a false security, and can certainly not be an argument in the case of an eventual legal case. What matters is to have a crash cart ready, procedures displayed, trained personnel and have successfully managed the patient if a reaction should occur. Routine premedication by the appointment secretaries is in my opinion a bad practice. Targeted premedication of patients which is medically focused, or after exploration by the allergist, can of course be considered, but in the knowledge that it may prevent symptoms of low intensity (urticaria, etc.) and can never prevent occurrence of severe anaphylactic shock. ■

* CIRTACI is the committee of interdisciplinary research and work on imaging contrast agents. Practical worksheets of recommendations for the use of contrast agents have been developed by a working group comprised of radiologists and specialists. They are available on the website of the SFR (www.sfrnet.org section Working Groups Contrast Agent - CIRTACI).

A REVIEW OF THE PLACE OF CONTRAST ENHANCED ULTRASOUND IN INTERNATIONAL DIAGNOSTIC GUIDELINES



Ultrasound (US) contrast agents are used extensively worldwide. In order to moderate their application, a first set of guidelines for contrast enhanced ultrasound (CEUS) was published in 2004 by the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB), focusing on liver imaging (Albrecht et al. 2004). In 2008, new EFSUMB guidelines (Claudon et al. 2008) reflected changes in available agents, updated liver indications and introduced extrahepatic applications. In 2012 a joint World Federation for Ultrasound in Medicine and Biology (WFUMB)-EFSUMB initiative resulted in updated liver guidelines (Claudon et al. 2013). A year earlier, another set of EFSUMB guidelines studied CEUS for non-liver imaging (Piscaglia et al. 2012). This article assesses the role of these guidelines in common CEUS indications, with the addition of other international guidelines when applicable.

1. Liver

1.1. Focal Liver Lesions (FLLs) Characterisation

CEUS is performed using three different agents:

1. SonoVue (sulfur hexafluoride with a phospholipid shell).
2. Definity/Luminity (octafluoropropane [perflutren] with a lipid shell).
3. Sonazoid (perfluorobutane with a phospholipid shell: hydrogenated egg phosphatidyl serine).

CEUS has high specificity for characterising FLLs (von Herbay et al. 2004; Bleuzen and Tranquart 2004; Ding et al. 2005; Leen et al. 2006), studying enhancement in the arterial, portal and late parenchymal phases. Sonazoid liver enhancement

is longer, following a postvascular 'Kupffer phase' (Yanagisawa et al. 2007). CEUS is the imaging examination that should be initially performed when a FLL is located on baseline US (Beaton et al. 2010), since it shows the highest sensitivity, specificity and accuracy (Trillaud et al. 2009). When enhancement patterns are typical for specific FLLs (haemangioma, focal nodular hyperplasia, focal fatty change/sparing, certain malignancies), these can be characterised (Claudon et al. 2013) with no additional imaging (see Figure 1). When atypical patterns are noted on CEUS, further examination is warranted.

contrast pharmacokinetics (Forner et al. 2008). Inconclusive CEUS does not exclude malignancy and should proceed to CT/MR. If these are also inconclusive, biopsy is performed. CEUS, as first-line investigation, is part of the Japanese HCC guidelines, (Kudo et al. 2001b; Kudo and Okanoue 2007), but has been removed from the AASLD guidelines (Bruix et al. 2011). This is partly justified by the still non-existent licence for liver CEUS in the USA and difficulty in differentiating CCC from HCC by CEUS alone, since both lesions show comparable dynamic perfusion patterns (Piscaglia et al. 2006). This risk is minimal

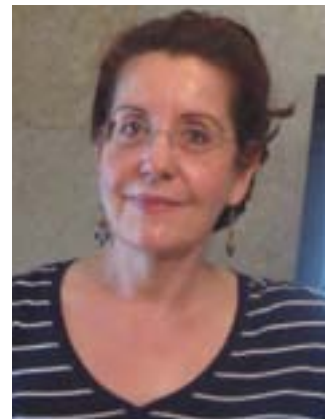
.....
“strict regulations on paediatric CEUS may inhibit the use of a very beneficial and simple technique”

For hepatocellular carcinoma (HCC) study, CEUS has a controversial role. The American Association for the Study of Liver Diseases (AASLD) guidelines (Bruix et al. 2011) suggest an US-based HCC surveillance protocol. In cirrhosis arterial hyperenhancement and late washout on CEUS is crucial for HCC characterisation (Bruix et al. 2011). This pattern corresponds to 97% of HCCs (Boozari et al. 2011; Fan et al. 2006; Foschi et al. 2010; Vilana et al. 2010), but is also seen in peripheral cholangiocarcinoma (CCC) and hepatic lymphoma. Late washout is observed more frequently in poorly differentiated HCCs. Well-differentiated HCCs are more isoechoic in the late phase (Boozari et al. 2011; Fan et al. 2006; Iavarone et al. 2010; Jang et al. 2007). CEUS HCC washout is observed less often than CT/MR, due to different

when CEUS is performed by skilled operators (Barreiros et al. 2012). CEUS is not included in the European Association for the Study of the Liver (EASL)-European Organisation for Research and Treatment of Cancer (EORTC) Clinical Practice Guidelines for HCC (European Association for the Study of the Liver and European Organisation for Research and Treatment of Cancer 2012), and CT/MR are recommended for noninvasive HCC diagnosis (Piscaglia et al. 2007).

Guidelines of CEUS for characterisation of FLLs in the **non-cirrhotic liver** include:

- Characterising routine US incidental findings;
- Lesions detected on US in patients with known malignancies, as a CT/MR alternative;



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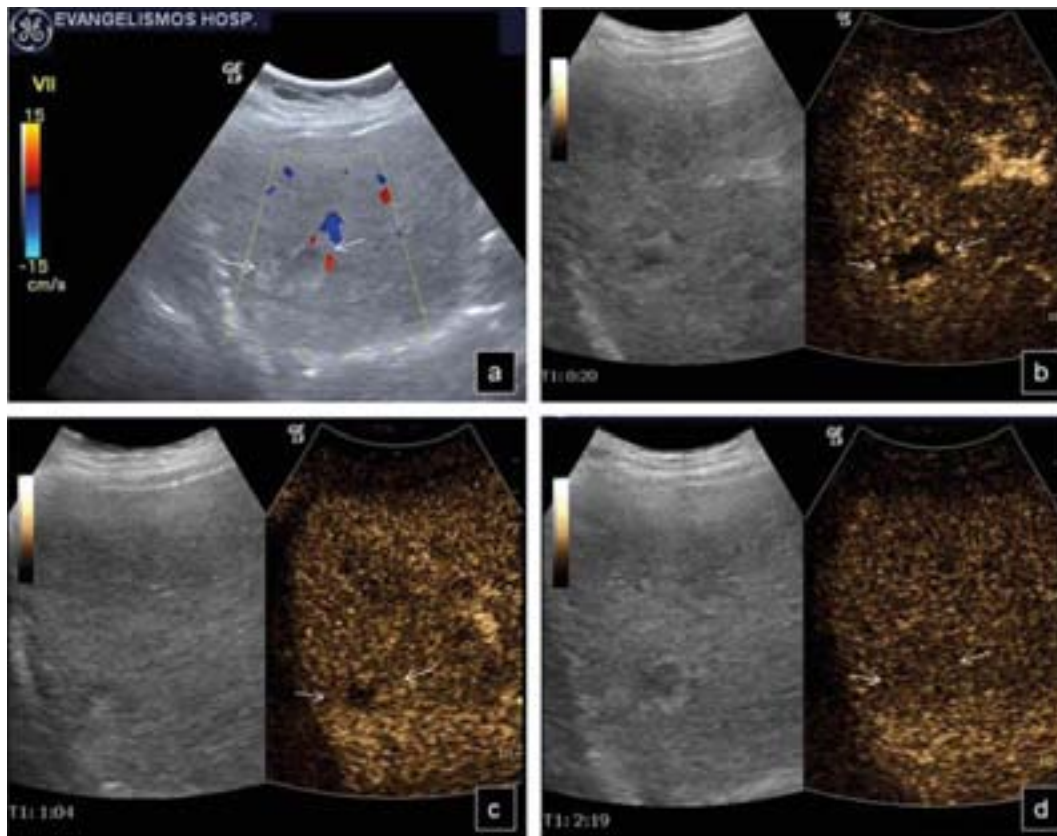


Figure 1. An ill-defined lesion is noted on segment VII of the right hepatic lobe on baseline US (between arrows in a). On CEUS, the lesion shows peripheral nodular enhancement in the arterial phase (b). In the portal venous phase (c) it gradually fills in. In the late phase, the lesion is isoechoic to the rest of the liver (d). This behaviour is typical for a haemangioma. No further imaging is needed.

- Contrast enhanced CT/MR contraindication;
 - Inconclusive CT/MR or cytology/histology;
- Guidelines of CEUS for FLL characterisation in the **cirrhotic liver** include:
- Characterisation of nodules found on baseline US;
 - Characterisation of nodules in cirrhosis. CT/MR are needed for pre-treatment staging;
 - Variable international acceptance as a first-line investigation for HCC at the same level as CT/MR;
 - Upon inconclusive CT or MR, especially in nodules unsuitable for biopsy;
 - Contribution to selection of nodule(s) for biopsy when these are multiple or show different contrast patterns;
 - Monitoring changes in size and enhancement patterns over time when a nodule is not diagnostic for HCC;
 - After inconclusive histology.

For Sonazoid, taken up by the

reticuloendothelial (Kupfer) cells, like superparamagnetic iron oxide MR contrast agents (Korenaga et al. 2009), with a late phase beginning 10 minutes post injection, guidelines include:

- Nodule characterisation in cirrhosis, assessing vascular and postvascular phases. This practice is adopted by Japanese guidelines for HCC management (Kudo et al. 2011; Kudo and Okanoue 2007; Kudo 2010);
- HCC screening in cirrhosis, although not proven so far as cost-effective;
- HCC staging when US imaging is satisfactory. No evidence exists so far that CEUS can replace contrast-enhanced computed tomography (CECT)/ contrast-enhanced MR (CEMR).

1.2. Liver Metastasis Detection

CEUS improves metastasis detection compared to baseline US (Piscaglia et al. 2007; Cantisani et al. 2010; Dietrich et al. 2006; Larsen et al. 2007; Quaia et al. 2006), showing portal venous and

late phase washout. With SonoVue and Definity/Luminity the examination lasts for at least 3-4 minutes. With Sonazoid, very late washout can be detected (Moriyasu and Itoh 2009). When a late phase enhancing defect is noted, a second injection shows arterial enhancement, confirming its metastatic nature.

Guidelines of CEUS for detection of malignant liver lesions include:

- Characterisation of indeterminate lesions on CECT-CEMR;
- Ruling out of metastases or abscesses;
- Treatment planning for assessing metastases' number and location;
- Oncology patients' surveillance;
- Replacement of unenhanced US for evaluating colorectal cancer patients post chemotherapy for metastases presence.

1.3. Portal Vein Thrombosis

Characterisation

Portal vein thrombus may be bland (benign intraluminal clot) or malignant, usually due to HCC (Piscaglia et al. 2010). On CEUS, bland thrombus shows no uptake (Piscaglia et al. 2010; Ueno et al. 2006; Rossi et al. 2006; Sorrentino et al. 2009). Malignant thrombus enhances parallel to the originating tumour (quick arterial hyperenhancement-fast washout (Piscaglia et al. 2010).

1.4. Liver Biopsy Planning

CEUS increases biopsy diagnostic yield and decreases the false negative rate, especially in large tumours with necrotic areas, differentiating high vascularity regions, which should be targeted, from areas of necrosis, which should be avoided (Wu et al. 2006).

1.5. Intraoperative CEUS

Intraoperative ultrasound (IOUS) is the gold standard for liver resection or transplantation (Conlon et al. 2003). Intraoperative CEUS (IOCEUS) shows higher sensitivity, specificity and accuracy compared to IOUS, CT or MR for

defining if metastasis/HCC resection is needed, altering surgical management in up to 30% of cases (Leen et al. 2006; Lu et al. 2008; Torzilli et al. 2007).

Guidelines for IOCEUS include:

- Metastasis detection in patients undergoing liver resection;
- Nodule characterisation in cirrhotic patients undergoing resection for HCC, especially if IOUS reveals new lesions;
- Targeting occult lesions for ablation.

1.6. Monitoring Liver Ablation

CEUS aids in selecting lesions to be ablated (Minami et al. 2007), depicting previously undetectable lesions and identifying still viable tumours post-therapy.

Guidelines of CEUS for monitoring liver ablation include:

- Complementing CECT/CEMR for pre-treatment staging and lesion vascularity assessment;
- Immediate ablation result estimation. Guidance for immediate re-treatment if residual unablated tumour is detected;
- Local tumour progression assessment for follow-up.

1.7. Liver Transplantation

Common transplantation complications are hepatic artery (HA) stenosis and thrombosis (Shaw et al. 2003). Portal vein (PV), hepatic vein (HV) and inferior vena cava (IVC) thrombosis are less common. CEUS is more sensitive than Doppler US in detecting these complications.

Guidelines of CEUS for liver transplantation include:

- Pre-transplantation assessment of PV patency and FLL characterisation;
- Post-transplantation confirmation of intrahepatic HA, PV, HV, IVC occlusion;
- If haematoma is present, searching for ongoing haemorrhage;
- Infarction exclusion;
- Monitoring success of thrombolysis post intervention for HA occlusion.

1.8. Contrast Quantification and Monitoring Hepatic Malignancy

Treatment

Neoangiogenesis is an important feature of tumour growth and a target for anticancer treatment. Dynamic CEUS (DCEUS) monitors therapy response, relying on quantitative features, if standardisation and strict scanner control settings are followed (Dietrich et al. 2012). Quantification software (time-intensity curves), background subtraction and specific calculations (time to peak intensity, mean transit time, peak intensity, area under the curve etc.) (Peronneau et al. 2010) are mandatory for this technique.

2. Spleen

Splenic CEUS is indicated for focal lesion characterisation (Görg and Bert 2005). Incidental hyperechoic lesions in asymptomatic people are usually benign. In cancer patients, multiple hypoechoic lesions are often malignant.

Guidelines of CEUS in the spleen include:

- Parenchymal inhomogeneity or suspected lesions on baseline US;
- Suspected infarction confirmation (see Figure 2);
- Suspected accessory spleen/splenules characterisation;
- Oncologic patient malignancy detection if CT/MR/PET are contraindicated or inconclusive.

3. Pancreas

CEUS is not helpful for focal lesion detection, but aids in their characterisation (Dietrich et al. 2008; D'Onofrio et al. 2007). Inflammatory lesions enhance along with, but malignancies are hypoechoic compared to adjacent pancreatic tissue. Pseudocysts show no enhancement, with CEUS sensitivity and specificity in their characterisation of 100% (Rickes and Wermke 2004).

Guidelines of CEUS in the pancreas include:

- Ductal adenocarcinoma characterisation;
- Differentiation between pseudocysts and cystic tumours;
- Differentiation between vascular (solid) and avascular (liquid/necrotic) areas of a lesion;
- Defining of lesion dimensions and margins;
- Distinction between solid and cystic lesions;
- Diagnosis when CT is indeterminate.

4. Kidneys

Renal infarction, traumatic injury or haemorrhage appear as enhancing defects (Nilsson 2004). Excellent results are observed studying atypical cysts with echogenic content, septa or nodules and classifying them with the Bosniak system (Robbin 2001; Robbin et al. 2003), with accuracy comparable to CECT (Quaia et al. 2008). Tumours enhance differently than the rest of the kidney at

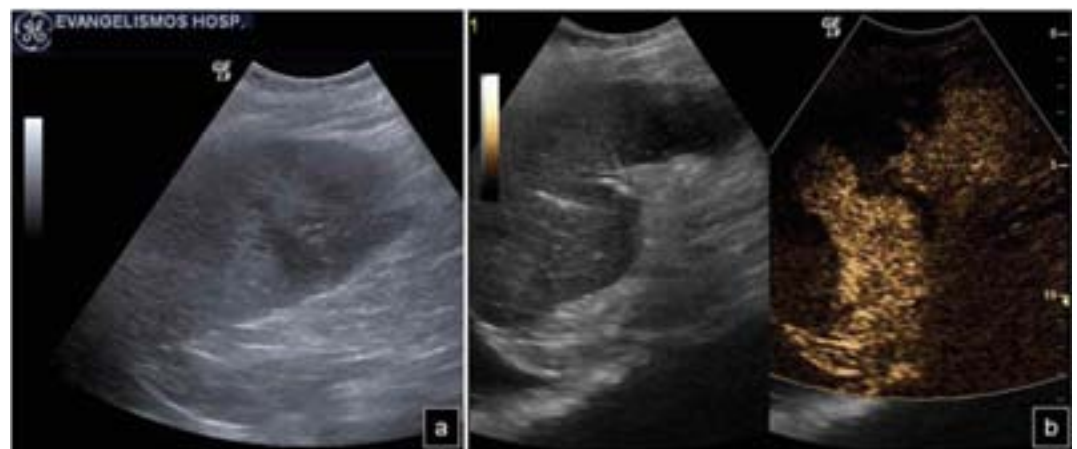


Figure 2. The spleen shows inhomogeneous echogenicity on unenhanced US (a). Post contrast injection (b), a large part of the spleen shows no uptake, due to extensive infarcts.

least in one phase (Correas et al. 2006). Normal variants, like a prominent Bertin septum ('pseudotumours'), enhance parallel to renal parenchyma. CEUS cannot differentiate between benign and malignant tumours (Correas et al. 2006), but can characterise enhancing renal vein thrombosis as neoplastic, as accurately as CECT (Igneer et al. 2010). Enhancing echogenic material in the pelvicalyceal system is characterised as neoplastic, while pus and blood do not enhance. Focal pyelonephritic oedematous areas show reduced enhancement. Abscesses appear as non-enhancing lesions with peripheral uptake.

Guidelines of CEUS in the kidneys include:

- Suspected infarction and cortical necrosis;
- Differentiation between solid masses and cysts with atypical appearance on baseline US;
- Differentiation between tumours and anatomical variations upon equivocal baseline US;
- Characterisation and follow-up of complex cystic masses;
- Abscess detection;
- Lesion visualisation and residual detection after tumour ablation.

5. Trauma

Blunt abdominal trauma is initially imaged with baseline unenhanced FAST (Focused Assessment with Sonography in Trauma) US (Kretschmer et al. 1997; Yoshii and Sato 1998; Healy et al. 1996), which is excellent for fluid detection, but has low sensitivity for revealing abdominal solid organ injuries (Pearl and Todd 1996). CECT (the best modality in this task) is often over-utilised and has its own disadvantages. Low energy

localised trauma is well imaged with CEUS, revealing injuries undetected by baseline US (Valentino et al. 2009). Solid organ lacerations and haematomas appear as non-enhancing areas (Afaq et al. 2012; Cokkinos et al. 2013). Although not replacing CT, CEUS is an alternative to reduce its use. Moreover, patients initially assessed with CT can be followed with CEUS with no additional CT performed (Cokkinos et al. 2013).

Guidelines of CEUS for blunt abdominal trauma include:

- Alternative to CT in stable patients with isolated moderate energy solid abdominal organ trauma, especially in children;
- Elucidation of uncertain CT findings;
- Follow-up of trauma managed conservatively, to minimise CT scanning.

6. Scrotum

CEUS is useful for ruling out torsion and differentiating solid tumours from non-enhancing testicular contusions. Abscesses appear as non-enhancing lesions with peripheral uptake. High frequencies (>7.5MHz) and high contrast doses (2.4-4.8 ml for SonoVue) should be used.

Guidelines of CEUS in the scrotum include:

- Discriminating vascular from non-vascular lesions;
- Imaging of non-viable tissue in trauma;
- Detection and characterisation of segmental testicular infarction;
- Detection of abscess in severe epididymo-orchitis.

7. Paediatric Applications

In the past, the only agent approved for paediatric use (only for vesico-ureteral reflux) was

Levovist, which is not produced anymore (Claudon et al. 2013). SonoVue, with equally good results for this and all paediatric indications, is administered off-label, since there is no current approval for children. This is a peculiar situation, since one of the primary CEUS advantages is reduction of ionising radiation, of grave importance for paediatric imaging. Strict regulations on paediatric CEUS may inhibit the use of a very beneficial and simple technique (Piscaglia et al. 2012).

8. Other Applications

Due to space reasons, this article cannot review all current CEUS applications in almost all systems (Mao et al. 2010). Breast cancer response to chemotherapy, carotid plaque characterisation, aortic aneurysms and endoleaks assessment, musculoskeletal, pleural, gynaecological, biliary tree applications and joints inflammation imaging, inflammatory bowel disease activity estimation and complications in Crohn's disease, endoscopic use to characterise internal vasculature and to differentiate benign from malignant pancreatic masses are some other CEUS uses. Besides intravenously, US contrast agents are administered orally or endocavitarily for assessing percutaneous drainage procedures (Mao et al. 2010; Ignee et al. 2012), abscesses, pancreatitis complications, intestinal or other fistulas, gastroesophageal reflux and GI lumen stenoses (Piscaglia et al. 2012). It should be noted that current on-label radiological indications in Europe include only liver, breast and vascular imaging. For all other applications, informed consent by the patient is needed. Disappointingly, in the USA ultrasound contrast agents are still being used only for cardiology studies. ■

Key Points

- Since 2004, European guidelines have been published for liver and non-liver applications.
- This article assesses the role of international guidelines in common contrast-enhanced ultrasound indications.
- It covers guidelines of CEUS for the liver, pancreas, spleen, kidneys, trauma and the scrotum.
- Current on-label radiological indications in Europe include only liver, breast and vascular imaging. For all other applications, informed consent by the patient is needed.

References

Available on the website or on request



TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2014 (PART 2)



CT Radiation Exposures in Pediatric Patients (no. 3)

Paediatric patients are inherently more sensitive to the effects of ionising radiation than are adults. While the risk has always been hard to quantify, newly published empirical studies add to the evidence that exposure to ionising radiation from diagnostic imaging at a young age can increase a person's risk of developing cancer later in life. (See the figure 1.)

CT scans make use of ionising radiation, which can damage DNA and other cellular structures. This in turn can lead to an increased risk of cancer. The potential for such damage is estimated by calculating the effective dose. The greater the effective dose, the greater the likelihood of harm. The effective dose delivered by CT is among the highest in diagnostic radiology. The level of risk is subject to considerable debate, the calculations being largely based on data collected following the atomic bomb detonations during World War II. However, retrospective studies are now being published that indicate an increased risk of future cancers for children exposed to CT (Matthews et al. 2013; Pearce et al. 2012).

Using safer diagnostic options when appropriate

Actions that healthcare providers can take to minimise a child's exposure to high doses of ionising radiation include using safer diagnostic options when appropriate, in consultation with a radiologist:

- **MRI** is considered the preferred choice for diagnosing problems such as ligament and tendon damage, spinal cord injuries, and brain tumours.

- **Ultrasound** is still effective at revealing the presence of soft-tissue abnormalities. Because ultrasound has difficulty imaging through bone and air-filled lungs, this technology is most commonly used for scanning abdominal organs.

- **X-rays.** Because radiography, including digital radiography, uses substantially lower radiation dose than CT, it should be considered as an alternative to CT when diagnosing children.

Some new digital techniques, such as digital tomosynthesis, are becoming available that improve the amount of information available with radiography without greatly increasing the radiation dose.

Avoiding repeat scanning

Obtaining the existing images from previous scans can greatly reduce the need for repeat scans, and thus decrease the amount of radiation paediatric patients are exposed to over the course of their diagnosis and treatment.

Following the ALARA principle

Care must be taken to use a dose that is 'as low as reasonably achievable' (ALARA) to acquire the desired diagnostic information. This can include avoiding the use of 'adult size' doses on children, as well as minimising radiation exposures to parts of the body that are beyond the area of interest.

Recommendations

- Implement appropriate use criteria for determining whether alternative methods could be used when urgency or symptoms do not necessitate CT. A radiologist should be consulted to determine the best method.

- Before initiating a new CT study, try to identify whether a scan has already been performed on the patient, perhaps at another institution. Obtain the results of these scans if possible, and consider whether they are sufficient for diagnosis and treatment without the need for further scanning.

- When CT has been determined to be necessary:

- ♦ Use the ALARA principle to minimise radiation exposure.
- ♦ Customise scanning protocols to the needs of paediatric patients—that is, recognise that settings designed for adults are not appropriate for children.
- ♦ Take care to avoid beyond boundary scanning (i.e., unnecessarily delivering the dose beyond the anatomical area of interest) and overexposure.
- ♦ Update your scanning protocols as necessary to reflect the latest guidance from professional organisations such as the American College of Radiology and the American Association of Physicists in Medicine.

Author

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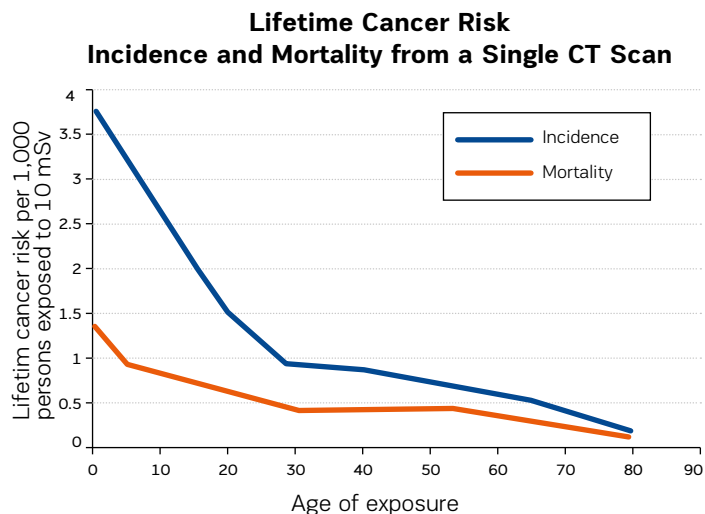
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The Top 10 Health Technology Hazards for 2014 (part 1) have been published in the previous issue of HealthManagement journal

Figure 1.

High cancer risk from paediatric CT. This graph of an individual's lifetime cancer risk based on a single 10 mSv CT exam shows a much higher likelihood of developing cancer for young patients: BEIR 2005, Tables 12D-1; sexes combined using 2005 estimates from the U.S. Census Bureau



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Risks to Paediatric Patients from 'Adult' Technologies (no. 8)

Healthcare technologies are often developed with the needs of adult patients in mind, leaving clinicians with little choice but to rely on 'adult' technologies in the diagnosis and treatment of paediatric patients. Due to their smaller size and ongoing physiologic changes, children may suffer adverse effects when subjected to adult-oriented healthcare techniques. Unfortunately, paediatric-specific devices can be slow to reach the market because of the small numbers of patients available to study, the devices' high-risk nature, and high development costs. Healthcare personnel must exercise particular care when this is necessary.

Electronic health records

A healthcare facility's EHR may not be configured to optimally support the care of children. For example, the system may not facilitate the recording and review of important paediatric-specific data, such as vaccinations, or may not allow both height and weight to be viewed on the same screen, which in turn can contribute to vital information being overlooked. To bridge the gap between the functionality present in most currently available EHRs and that needed to better support children's healthcare, the Agency for Healthcare Research and Quality (AHRQ) recently announced the development of the Children's EHR Format. The Format provides information to help EHR developers optimise their systems for the care of

using the incorrect weight led the physician to prescribe a drug at about twice the desired dose. Fortunately, the child's mother recognised the error before the child experienced significant adverse effects (Bokser 2013). Even advanced technologies intended to help decrease medication errors are fallible. For example, the authors of a 2012 study identified CPOE systems as an enabler of tenfold medication errors in paediatric patients. The authors cited the "overriding of recommendations, ignoring of alerts, and the inability of CPOE to recognize certain tenfold underdoses" as contributing factors, and they noted the need for CPOE systems to be "designed in a standardized fashion that incorporates paediatric-specific dosing logic" (Doherty and McDonnell 2012).



Discussion

The following are just a few examples of how the care of pediatric patients can be compromised when applying 'adult' healthcare technologies:

Radiation exposure hazards

Exposure to ionising radiation such as that used in CT and x-ray imaging has been associated with an increased cancer risk. Because they are still developing, children are especially susceptible to long-term damage from radiation exposure. To compound this problem, using adult scanning techniques on children can expose them to an unnecessarily large 'adult' dose and can potentially expose regions of the body outside the area of interest (see hazard number 3 in this year's list).

children, as well as criteria to help facilities select an EHR that supports children's healthcare needs.

Medication dosing errors

Children, because of their small size, are particularly susceptible to adverse consequences from incorrect dosing. This susceptibility to harm, coupled with the use of technologies that aren't optimised for paediatric patients, can lead to tragic results. A device as simple as a scale can contribute to significant harm. In one report to ECRI Institute PSO, a mix-up involving the use of pounds versus kilogrammes to record weight contributed to the death of an infant. In a similar incident, a toddler's weight was measured to be 25 lb (11.3 kg), but was mistakenly recorded in the EHR as 25 kg. Calculating the dose

Recommendations

- When assessing medical technologies and supplies for purchase or use, consider the extent to which the device, system, or accessory has been developed with the needs of paediatric patients in mind. For example:
 - ♦ When selecting an EHR, consider the extent to which the system complies with AHRQ's Children's EHR Format. (see <http://healthit.ahrq.gov/health-it-tools-and-resources/childrens-electronic-health-record-ehr-format>.)
 - ♦ Use electronic medication prescribing (e-prescribing) systems that include such features as child-specific medication libraries, normative references, and child-specific weight-based dose calculations and alerts.

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- ◆ For infants and children, use scales that can be set to provide weights in kilogrammes only, and verify that the scales are clearly labelled as such.
 - ◆ Whenever possible, use paediatric-specific technologies rather than using adult-oriented technology off-label or employing workarounds.
 - ◆ If obtaining paediatric-specific technology is not an option, investigate whether an available device can be safely and effectively used on children. Alternatively, ask if the vendor can refer you to current users of the technology who have implemented the system in a manner that addresses the needs of paediatric patients.
 - ◆ Consider identifying a paediatric technology safety coordinator to assess both the adult-oriented technologies and the adult-paediatric hybrid technologies that are being used on pediatric patients at your facility. Responsibilities may include:
 - Identifying devices, accessories, or systems that are appropriate for only a certain range of patients (e.g., adults but not children)
 - Identifying devices, accessories, or systems that must be used in a specific configuration to safely accommodate paediatric patients (e.g., restricting the upper flow rate for infusion pumps)
 - Where appropriate, clearly labelling any such devices
 - Educating staff about unique safety considerations or methods of use that are required when working with paediatric patients
 - Establishing protocols for setting medical device alarms to levels that are appropriate for paediatric
- patients and periodically verifying that these protocols are being followed.

Data Integrity Failures in EHRs and Other Health IT Systems (no. 4)

Reports illustrate myriad ways that the integrity of the data in an EHR or other health IT system can be compromised, resulting in the presence of incomplete, inaccurate, or out-of-date information. Contributing factors include patient/data association errors, missing data or delayed data delivery, clock synchronisation errors, inappropriate use of default values, use of dual workflows (paper and electronic), copying and pasting of older information into a new report, and even basic data entry errors.

Some of the mechanisms by which the information in an EHR or other health IT system could become compromised:

- Patient/data association errors
- Missing data or delayed data delivery
- Clock synchronisation errors
- Inappropriate use of default values
- Maintaining hybrid (paper and electronic) workflows
- Copying and pasting older information into a new report
- Data entry errors, e.g. entering incorrect information, selecting wrong item from a drop down menu, or entering information in the wrong field.

Recommendations

- Before implementing a new system or modifying an existing one, assess the clinical workflow to understand how the data is (or will be) used by frontline staff, and identify inefficiencies as well as any potential error sources.
- Test, test, and retest
- Phase out paper.
- Provide comprehensive user training.

- Provide support during and after implementation.
- Facilitate problem

Neglecting Change Management for Networked Devices and Systems (no. 7)

The growing interrelationship between medical technology and IT offers significant benefits. However, one underappreciated consequence of system interoperability is that updates, upgrades, or modifications made to one device or system can have unintended effects on other connected devices or systems. ECRI Institute is aware of incidents in which planned and proactive changes to one device or system—relating, for example, to upgrading software and systems, improving wireless networks, or addressing cybersecurity threats—have adversely affected other networked medical devices and systems. To prevent such downstream effects, alterations to a network or system must be performed in a controlled manner and with the full knowledge of the personnel who manage or use the connected systems. Unfortunately, change management—a structured approach for completing such alterations—appears to be an underutilized practice.

Discussion

In today's hospitals, initiatives that once may have been considered 'IT projects' must instead be viewed as 'clinical projects that require IT expertise.' Software upgrades, security patches, server modifications, changes to or replacement of network hardware, and other system changes can adversely affect patient care if not implemented in a way that accommodates both IT and medical technology needs. Consider the following examples:

- An ECRI Institute member hospital described an incident in which a facility-wide PC operating system upgrade caused the loss of remote-display capability for its foetal monitoring devices. The facility had configured its foetal monitoring system so that nurses could view the output on a PC located outside the patient's room. However, these displays became nonfunctional when the IT department pushed out a Windows 7 upgrade to the computers connected to the network. The PC application that allowed the display of the foetal monitor information was not compatible with Windows 7.
 - Another member hospital experienced problems displaying foetal monitor data on workstations at the nurses' station following an IT change. In this case, the problems began after the IT department moved the obstetrical data management system server off-site. No verification testing was performed to ensure continued performance after the change.
 - An update to the firmware for the wireless access points at a member hospital caused the loss of wireless functionality for some of the facility's medical devices. Some physiologic monitors, for example, required a wired connection for months until a fix could be implemented.
 - A recent article describes an incident in which an EHR software upgrade resulted in changes to certain radiology reports, causing fields for the date and time of the study to drop from the legal record. The fields remained in the screen display, so staff using the EHR system did not detect the change to the legal record. (See the June 2013 edition of ECRI Institute's Risk Management Reporter for details.)
- Appropriate change management policies and procedures, as outlined in the recommendations below, can help minimise the risks. Just as important, however, is to cultivate an environment in which IT, clinical engineering, and nursing/medical personnel (1) are aware of how their work affects other operations, patient care, and work processes—particularly clinical work processes—and (2) are able to work together to prevent IT-related changes from adversely affecting networked medical devices and systems.

Recommendations

Effective approaches to change management include the following:

- Facilitate good working relationships among departments that have a direct responsibility for health IT systems, medical technology, and change management. Involve the appropriate stakeholders when changes are planned.
- Maintain an inventory listing the interfaced devices and systems present within the institution, including the software versions and configurations of the various interfaced components.
- Take steps to ensure that changes are assessed, approved, tested, and implemented in a controlled manner. ECRI Institute recommends that, when possible, the changes and associated system functionality be tested and verified in a test environment before implementation in a live clinical setting. Change management applies to a variety of actions, including hardware upgrades, software upgrades, security changes, new applications, new work processes, and planned maintenance.
- Evaluate the facility's policies and procedures regarding change management. Care should be

taken to determine how technology decisions involving health IT systems, medical devices, and IT networks can affect current operations, patient care, and clinician work processes.

- Develop contract wording that is specific to change management. For example, contracts with vendors should require the necessary documents (e.g., revised specifications, software upgrade documentation, test scenarios) to be provided to the appropriately designated staff member(s) to facilitate change management. Stipulating that vendors provide advance notice of impending changes can give healthcare facilities time to budget and adequately plan for those changes.
- Ensure that any system updates do not jeopardise processes to maintain the privacy of patients' protected health information and the security of records with that information.
- When making changes to interfaced systems, closely monitor the systems after the change is made to ensure their safe and effective performance.
- Provide frontline staff members a point of contact for reporting problems related to change management and health IT systems. Education, training, and good escalation procedures (so that reports reach someone who can respond if the first person is unavailable or lacks the necessary competence) can help to ensure that problems are addressed with the appropriate urgency. In addition, consider applying risk management principles to change management as discussed in the IEC 80001-1 standard, Application of Risk Management for IT-Networks Incorporating Medical Devices— Part 1: Roles, Responsibilities and Activities. ■



HIFU'S ROLE IN CANCER TREATMENT



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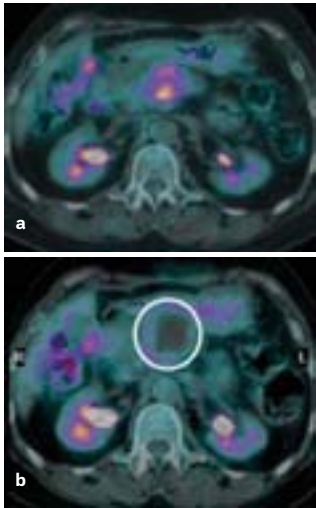


Figure 1.
a) PET scan shows FDG uptake at the pancreatic head, where tumour mass is located.
b) PET scan, performed one month after USgHIFU of the pancreatic tumour, is negative.

The clinical need for local tumour control, by means of a minimally invasive approach instead of traditional invasive, risky and expensive surgical ones, represents the main reason for the very fast development of new hyper-technological branches in oncology. Invasive local treatments are very often not fully indicated because of the poor general clinical condition or the short life expectancy that may not justify any aggressive therapy. When the invasiveness of therapies is reduced, indications can often become wider, and patients who might benefit from such a non-aggressive approach will increase in number. In oncology, because the majority of patients are unable to undergo surgical resection because of the tumour sites, advanced stage of tumours, or poor general condition, novel treatment techniques, such as radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, and laser-induced interstitial thermotherapy have been introduced in daily practice. Among these techniques, HIFU is the only 'nominally' non-invasive technique, and this is the main reason of the fast-growing interest in its development and evaluation for clinical use.

High-Intensity Focused Ultrasound

High-intensity focused ultrasound (HIFU) is a highly precise medical procedure, which uses focused ultrasound energy for burning and destroying the tumour tissue at depth within the body, selectively and without harming overlying and/or adjacent structures within the path of the ultrasound beam. The

possibility that focused ultrasound therapy could be developed as a result of controlling local heating phenomena was introduced by Lynn et al. in the 1940s (Lynn et al. 1942), but the technique was not developed at that time because of inadequate targeting methods. The advent of more sophisticated imaging has led to a resurgence of interest in HIFU. Unlike percutaneous ablation, HIFU is completely non-invasive and can be used to reach tumour targets that are deep within the body, if there is an acoustic window for allowing for the transmission of ultrasound energy. Preliminary reports underline a reduced toxicity with HIFU ablation compared with other ablation techniques because of the non-invasive nature of the procedure. The first devices, which were never used widely in clinical practice, were transrectal probes, used predominantly to treat prostate cancer. Extracorporeal devices are significantly larger, and can be used to treat a variety of problems, most commonly intra-abdominal solid tumours. As a result, these extracorporeal devices use transducers with a longer focal length and use either US (USgHIFU) or MRI (MRgHIFU) for targeting the organ.

Advantages and Limitations

Both technologies have pros and cons, relating to the specific characteristics of the two imaging modalities. US guidance may allow for real-time images, which is very helpful in the treatment of abdominal tumours located in moving organs, such as the liver, pancreas and kidneys. As the same form of energy is used

both for guidance and treatment, it is usually much easier to foresee the feasibility of the treatment. However, MRI provides a much better imaging detail with a wider multiplanar view of the region where the tumour is located. Moreover, thanks to specific sequences, MRI may provide the temperature at the focal spot with the so-called 'thermal map'. In the meantime MRI cannot produce 'real-time' imaging during treatment, and moving organs still represent a big challenge both for safety and effectiveness (lack of temperature monitoring).

In order to overcome such limitations, dedicated ultrasound probes and devices are being developed for improving USgHIFU and respiratory-gated techniques are under evaluation for approaching abdominal organs with MRgHIFU devices.

However, due to the aforementioned limitations, up till now liver and pancreatic tumours have been mostly, if not exclusively, approached by USgHIFU devices, with wider experience coming from authors in Asia. Bone tumours, and, more recently, brain lesions are conversely better treated with MR-based technology. Breast cancer represents a very appealing target for both the modalities and several research projects (ablation and resection) are ongoing in order to define the efficacy in terms of radicality.

Challenging Tumour

Among those several fields, pancreatic and breast tumours are now the most challenging HIFU targets in oncology:

Pancreatic Tumours: Pancreatic

cancer has the worst outcomes among all malignant tumours, with a one-year survival rate of less than 10% and a median survival time of only 3-5 months. Surgical resection is considered the only option for such patients, seeking long-term survival, but no more than 20-30% of patients with pancreatic cancer are eligible for resection because of metastatic or locally advanced disease. In the meantime surgical resection is reported to have a high morbidity and re-operation rate, with a postoperative survival of around 19 months. In patients with no surgical option, their

quality of life is influenced by cancer-related pain. HIFU has been demonstrated to be feasible, effective and safe in those settings, both for pain and for tumour control, in patients ineligible for resection.

Breast Cancer: Over the past decades there has been a radical change in surgical treatment for breast cancer, moving towards a more conservative approach and achieving the same clinical efficacy aimed at maintaining the integrity of the woman's body.

Many papers have reported the results on HIFU treatment for breast

cancer. Although the results are very encouraging and significant, the small number of cases and the non-homogeneous enrolling criteria and post histological and/or instrumental post HIFU evaluation leave enough room for further scientific speculation. The inherent advantage of HIFU in this field is the total absence of any cosmetic damage to the woman's breast and, due to the relatively superficial site of tumours, targeting and treatment are both easier and not time-consuming. It represents one of the most exciting fields of research for HIFU. ■

Key Points

- Among novel oncology treatments, high-intensity focused ultrasound (HIFU) is the only 'nominally' non-invasive technique.
- Extracorporeal devices can be used to treat a variety of problems, most commonly intra-abdominal solid tumours.
- The advantages and limitations of both ultrasound-guided HIFU and MR-guided HIFU are outlined.

>> continued from page 33

review;

- Anonymised radiologist input and feedback of reporting;
- Establishment of cross-institutional peer review;
- Demonstration of cross-system applicability of the solution.

To measure the success of our pilot, we will assess the perceived impact of prospective quality assurance methods on radiology practice, and the perceived impact on report accuracy both

by radiologists and by referring physicians. An important component of our study is the elapsed time from receipt of QA work item to submission of QA result and the elapsed time from receipt of the primary report to report completion / release to RIS/PACS.

We will also measure volumes by modality, by radiologist, by sub-specialty, and by result (report amended; disagree with discrepancy; sent to arbitration). Sampling rates by modality, by radiologist and by sub-specialty are easily

configurable.

Our pilot has already highlighted a number of discrepancies, which have been resolved before distribution. Results will be published after the end of this first phase, which is planned to run until the end of July, but we are confident that this solution is already bringing tangible benefits, and we look forward to a regional implementation, which will allow us to reach out and include isolated sites with no resource available for QA. ■

Key Points

- The Turkish Society of Radiology and the Turkish Health Ministry carried out an evaluation of the quality of CT, MR and mammography examinations.
- The appropriateness of the exam, radiological technique and reporting were evaluated and results from the pilot study on adequacy of the exams are presented.
- McMaster University in Canada is piloting a prospective peer review system for radiology reporting.
- The system allows completion of QA activities before the report is finalised for the referring physician and made available in the Radiology Information System and Picture Archiving and Communication System (PACS).

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“TRIPLE RULE-OUT” CT ANGIOGRAPHY: 3 FOR THE PRICE OF 1?

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Chest Pain in the Emergency Department (ED)

Chest pain is a very common presenting complaint to EDs across the United States, accounting for up to 20% of all visits. Recent studies have reported suspected coronary artery disease and chest pain as the most common reasons for direct hospital admission from the ED. Many factors account for such high admission rates, including the lack of a quick, accurate exam to diagnose a myocardial infarction (heart attack), as well as the potential morbidity and fatality danger of missing this diagnosis. As a result, patients are often admitted for an array of diagnostic testing to rule out acute coronary syndrome (ACS), including serial ECG, cardiac enzymes, nuclear stress testing, and cardiac catheterisation. The cost of negative inpatient cardiac evaluations is high, estimated at \$6 billion annually in the U.S. Despite this extensive workup, 2-5% of patients who actually have ACS are still unfortunately misdiagnosed and discharged home; typically these are younger patients with atypical symptoms. Missed ACS is a major source of medicolegal burden for ED physicians, comprising about 20-39% of all malpractice liability.

Triple Rule-Out CT Angiography (TRO-CTA)

To complicate the problem further, the differential diagnosis for a patient presenting with acute chest pain is not simply limited to heart disease, but includes other serious, life-threatening diagnoses such as pulmonary embolism (PE) and aortic dissection (AD). Triple rule-out CT Angiography (TRO-CTA) was developed as a potential method to aid

the ED physician and radiologist in tackling the complex diagnostic uncertainty of chest pain. TRO-CTA is a specialised computed tomography (CT) imaging exam tailored to evaluate for pathology within the coronary arteries, pulmonary arteries, and the aorta in a *single* CT study, hence the name ‘triple-rule out’.

All sounds dandy, but what exactly is the role of TRO-CTA in the workup of chest pain in the ED? A study by Takakuwa et al. (2008) demonstrated that TRO-CTA has a high negative predictive value of >99% for ACS at 30 days in patients with mild or absent coronary artery disease, and provides additional diagnosis of non-coronary causes of chest pain in up to 11% of patients. Additionally, TRO-CTA precluded the need for additional diagnostic testing in over 75% of patients with low to intermediate risk of ACS. These advantages translate into decreases in patient anxiety, time spent in the ED, and overall radiation exposure accumulated during a hospital stay. Most importantly, it may save both the patient and hospital from a costly inpatient admission and workup.

Like any imaging study, proper patient selection is the key to correct utilisation and cost-effective application. Selection criteria for TRO-CTA include patients with low to moderate risk for ACS based on the Thrombolysis in Myocardial Infarction (TIMI) score, non-coronary pathologies among the diagnostic considerations, negative cardiac biomarkers (i.e. troponins), and normal or nonspecific ECG changes. In other words, patients who qualify for TRO-CTA do not have risk factors or laboratory/ECG evidence to suggest a clear cardiac source as a cause of their symptoms. The rationale is that if these patients

are unlikely to have ACS, why admit and subject them to further testing and hospitalisation? On the contrary, patients who are at high risk for ACS or have elevated cardiac biomarkers or abnormal ECG changes should be appropriately triaged from the ED and admitted for further workup and possible cardiac catheterisation and intervention.

No Walk in the Park

While TRO-CTA is conceptually and intuitively appealing, there are notable pitfalls and problems with its use and implementation. First, substantial resources and training are necessary to carry out TRO-CTA on a routine basis. Since a ‘triple rule-out’ is designed for diagnosing the aforementioned three most serious aetiologies of chest pain, adequate and simultaneous contrast opacification of the coronary, pulmonary, and systemic vasculature is critical to accurate image interpretation. Obtaining optimal contrast opacification is challenging and requires specific injection protocols to be carried out by highly-trained CT technologists and nurses. Additionally, CT scanners need to be equipped with ECG gating and have at least 64 detector rows in order to scan the chest in a single 15 second breath hold. Without appropriate contrast injection timing and CT technology, the study will be suboptimal for the evaluation of one, if not all three, of those diseases, limiting its usefulness and diagnostic accuracy.

Second, significant patient preparation is necessary to adequately image the coronary arteries. As with dedicated CT coronary angiography studies, an ideal heart rhythm is a sinus bradycardia at 50-60 beats per minute. To

achieve sinus bradycardia, beta-blockers are often administered prior to the exam. It is important to make sure the patient has no contraindications to beta-blockers, such as high degree heart block or asthma. Additionally, sublingual nitrates can be given to dilate the coronary arteries for optimal imaging. The effects of these medications in a patient suffering an acute PE is unknown, but it certainly raises concern that these patients may become haemodynamically unstable with alterations in cardiac output and vascular tone.

Third, the extensive area of the body covered by a single TRO-CTA study has led to a substantial amount of incidental and arguable clinically irrelevant findings. A study by Lehman et al. (2009) demonstrated that incidental findings were detected in about 45% of patients, with pulmonary nodules and liver cysts comprising the majority of these findings. Yet only 1.3% of these findings actually affected inpatient clinical management and 20% led to further follow-up imaging tests. The more we look, the more we see – and what to do with these incidental findings will have important ramifications.

Radiation Dose

As a brief note, since the initial development of TRO-CTA, there have been numerous concerns over radiation exposure. As a result, newer techniques have evolved over time to decrease the radiation exposure to more acceptable

levels. Technological advances such as prospective triggered high pitch ECG gating, tube current modulation in retrospective ECG gating, and 100 kV scanning are amongst the techniques available on most new CT scanners, and can significantly minimise radiation exposure to be in line with other imaging tests.

Controversy and Conclusion

Despite the potential benefits of an 'all-in-one' study to evaluate chest pain in the ED, widespread application of TRO-CTA in EDs across the U.S. remains controversial. In addition to the technical issues with implementation discussed above, there is, most importantly, a lack of rigorous scientific trials to justify the routine use of TRO-CTA. Opponents of TRO-CTA argue that a dedicated CT coronary angiogram should be performed when clinical suspicion is truly limited to ACS as opposed to subjecting patients to a 'triple study'. Dedicated CT coronary angiography provides superior detail and higher quality images of the coronary vasculature as compared to TRO-CTA. Just as important is the fact that dedicated studies are technically easier to perform and are rarely susceptible to artefacts. Oftentimes TRO-CTA is diagnostic in some vessels at the expense of other vessels, if the contrast bolus and motion factors are not absolutely timed right. In the only randomised controlled trial comparing TRO-CTA to a dedicated coronary

CT angiogram for evaluation of PE, AD, or ACS, TRO-CTA was not shown to improve efficiency in managing patients in the ED and in hospital with respect to length of stay, rate of hospital discharge without additional imaging, cost of care, and number of repeat visits. Also, other studies have shown that the incidence of PE and AD is extremely low in patients with chest pain, comprising just <0.5% of diagnoses in these patients. So one must wonder – is TRO-CTA cost-effective or even necessary? At this point, the jury is still out, even amongst the experts. In 2010 a review of the appropriate use of cardiac CT, jointly issued by several medical societies, including the American College of Cardiology (ACC), American Heart Association (AHA) and the American College of Radiology (ACR), concluded that while dedicated coronary CTA had sufficient evidence for use in the ED, TRO-CTA did not, and was classified as an uncertain diagnostic method.

Overall, TRO-CTA has developed into a wonderful innovation, which has added to the ED physician's armamentarium of exams to work up chest pain. It has proven to be a safe and effective exam. However, given its high technical demand, as well as controversies regarding its utility relative to dedicated coronary CT angiography, further refinements will be necessary before this high-end exam can be adopted by the mass medical community. Further research will be necessary to ultimately determine the most effective application of TRO-CTA. ■

Key Points

- Chest pain is a common chief complaint presenting to emergency departments.
- Missed diagnosis of chest pain is major source of liability for ED physicians, but inappropriate hospital admission can be costly to both patient and hospital.
- Diagnostic possibilities for chest pain include life-threatening conditions such as acute coronary syndrome, pulmonary embolism, and aortic dissection.
- Triple Rule-Out CT Angiography (TRO-CTA) is a special CT study to evaluate for all three diseases in a single study.
- In selected patient populations, TRO-CTA can be used to rule out coronary disease, diagnose non-coronary causes of chest pain, and preclude a majority of patients from additional diagnostic studies.
- Controversy exists whether TRO-CTA is truly necessary and cost-effective.

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IMPLEMENTING BALANCED SCORECARD IN A PORTUGUESE HEALTHCARE ORGANISATION



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The Balanced Scorecard

Belonging to an organisation is like being on a journey. We have to ask some essential questions: Where are we? Where do we want to go? When do we want to go? With which resources or means? How far have we travelled? Are we going in the right direction? In fact, the organisation does not exist, only its people do. This journey is commonly called **Strategic Planning**, and it embodies the definition of a **strategic challenge** (vision, mission and values), even at an unconscious level. Defining a strategic challenge involves the definition of what we want to be in the future (**Vision**), why we exist (**Mission**) and what are our fundamental beliefs about the organisation's behaviour to its stakeholders (**Values**).

How can we turn Vision, Mission and Values into our game plan or our strategic goals and establish measures for evaluating the achievement of those goals? With a **Balanced Scorecard**.

The balanced scorecard (BSC) is a strategic planning and management system, which is used extensively in private, public and third sectors worldwide. It aligns business processes to the vision and strategy of the organisation, improves internal and external communications and monitors organisation performance against strategic goals.

This tool was created by Robert Kaplan and David Norton. They felt that traditional management approaches, such as control

systems, were very restrictive, because organisations measured their performance only by financial indicators, and focused on the short term, so these systems were not able to measure the organisation's ability to create future economic value.

Balanced Scorecard is a performance measurement framework that adds strategic non-financial performance measures to traditional financial metrics in order to give managers and executives a more 'balanced' perspective of organisational performance. It aims at a balance between short and long term goals, financial and non-financial goals, result and process indicators, historical and prospective indicators, and internal and external performance. BSC has evolved into a full strategic planning and management system. It provides a framework that not only offers performance measurements, but also helps planners identify what should be done and measured. It enables managers to truly execute their strategies.

As a management system that enables organisations to clarify their vision and strategy and translate them into action, the BSC provides feedback around both the internal business processes and external outcomes in order to continuously improve strategic performance and results. It helps to translate organisational vision and mission into four perspectives: the **customer** perspective, the **financial** perspective, the **business process** perspective and the

learning and growth perspective.

BSC induces people involved in the strategic planning process to think about strategic goals in an integrated way:

1. If we succeed, how will we look to our shareholders? (**Financial Perspective**)
2. To achieve my vision, how must I look to my customers? (**Customer Perspective**)
3. To satisfy my customers, at which processes must I excel? (**Business Process Perspective**)
4. To achieve my vision, how must my organisation learn and improve? (**Learning and Growth Perspective**)

The Financial Perspective: Kaplan and Norton do not disregard the traditional need for financial data. This will always be a priority for a manager.

The Customer Perspective: Organisations must know what they need to assure as strategic in the service offered, and how they want to be seen by their clients.

The Business Process Perspective: This refers to internal business processes. Organisations must identify the critical processes so that they can fulfil the financial and client objectives considered strategic.

The Learning and Growth Perspective: Which intangible support must the organisation have to assure that the whole strategy is aligned? How can the organisation create and improve value? Learning and growth constitute the essential foundation for success of an

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organisation. It includes employee training and corporate cultural attitudes related to individual and corporate self-improvement.

The next step is to draw up a strategy map. It is the visual representation of all critical success factors and of the cause-effect relationship between the strategic goals.

Measuring is essential to whether the set objectives are achieved. Without it, we can neither know if we are on the right path, nor find the origin of deviation of unwanted pathways. So we have to define adequate indicators.

Frequently we have to evaluate whether the strategy continues to be adequate, if the critical success factors should remain the same, if the indicators continue to be pertinent, and whether the monitoring process can be improved in order to be more efficient and effective.

Which indicators are not necessary? Which other indicators are strategic? Do the indicators

measure what we want?

The process is simplified, which means that indicators need to be straightforward and fast to calculate, so that management time can be dedicated to result analysis.

Implementation of BSC in ULSM

Unidade Local de Saúde de Matosinhos (ULSM), located in the Northern region, is a local health unit, created in 1999. ULSM is a public institution of

the Portuguese national health-care system that integrates Pedro Hispano Hospital, Matosinhos Primary Health Care Centres and a continuous care unit. It was the first of its kind in Portugal, and has since inspired the creation of others.

In 2009 the ULSM's new Board made a fundamental structural reorganisation, creating departments with administrative autonomy that aggregate several services. The strategy was based on the promotion of decentralisation

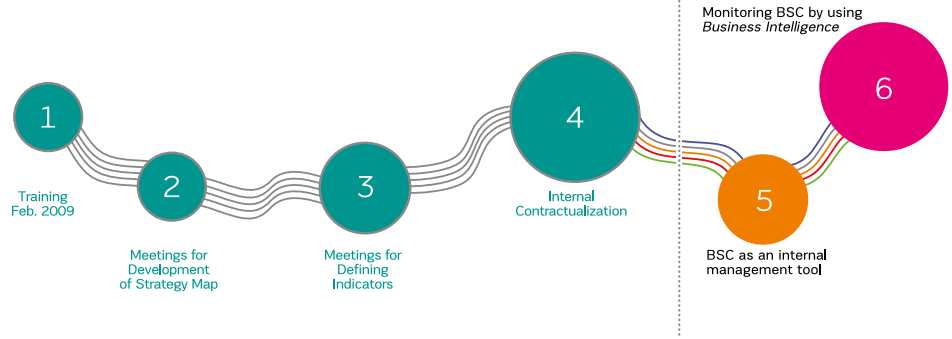


Figure 1. Implementation Schedule



Image 1. Annual Negotiation Meeting

Strategic Map

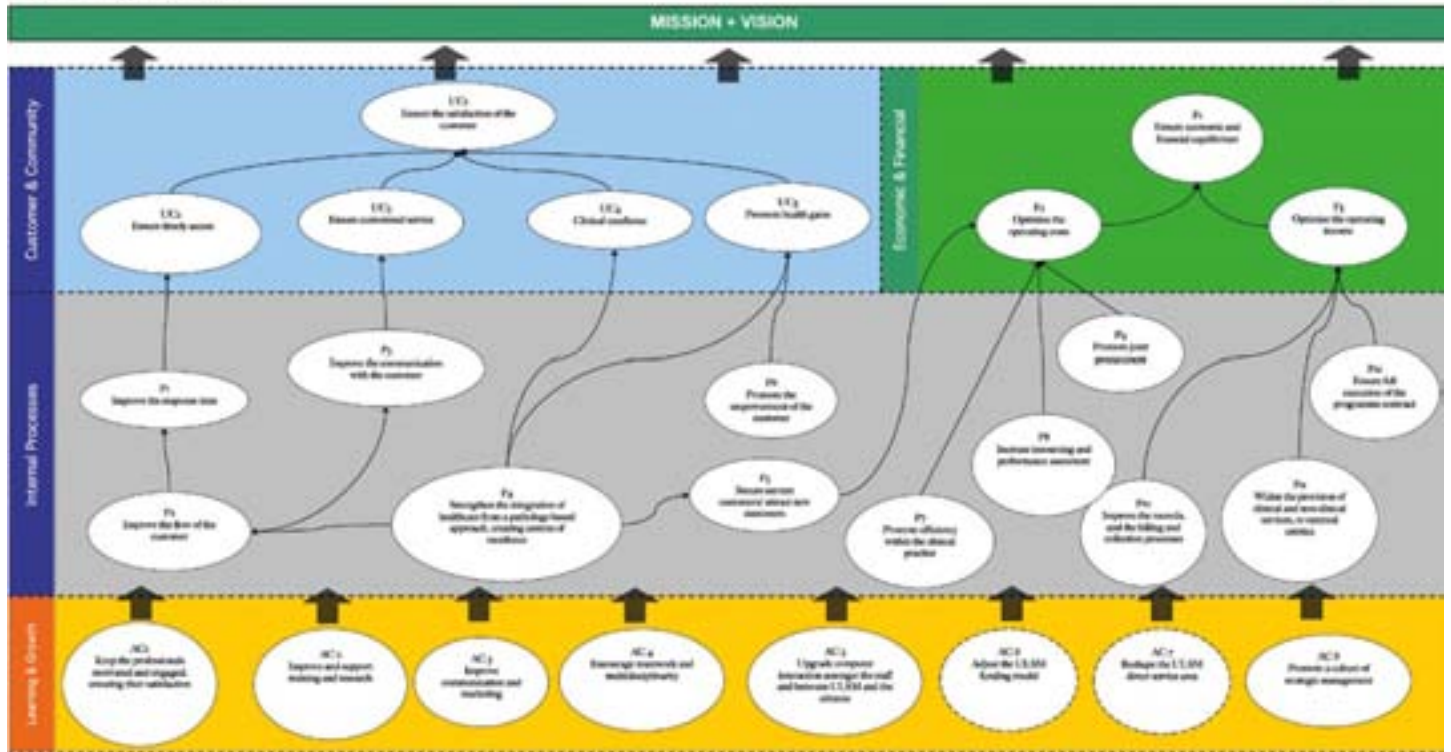


Figure 3.
Strategy Map After Meetings

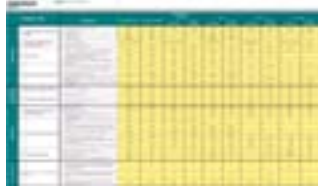


Figure 4.
Indicators Map of Woman and Child Department.

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and accountability through contracting, so that ULSM could improve accessibility, quality, productivity and efficiency in healthcare services. This means that the Board establishes and negotiates strategic goals with each department on an annual basis.

The Board chose to implement a new methodology, especially innovative in the public healthcare sector: The Balanced Scorecard (see Figure 1 on page 55).

To start this project, it was important to increase middle management skills, and a partnership with a Business School was established. This training outside the institution provided a strategic reflection on the role of each department in the development strategy of the institution as a whole.

The next step was to meet with each department to analyse their strategy and to align it with the strategy of the Board. The result of these meetings was the design of the strategy map (see Figures 2 and 3).

Subsequent meetings were held to define the indicators for each strategic goal. It was important to ensure that the information was available when the indicator was being built (see Figure 4).

With this work done it was possible to start the internal contracting. Once the strategic objectives were defined, aligned and the indicators chosen, the Board negotiated the annual goals (see photo) and a contract was signed establishing rights and duties, further integrating the strategy map and

the indicators map.

On a monthly basis departments and the Board receive the monitoring reports that allow them to identify deviations, analyse the causes and define action plans so that the strategy can be executed. The BSC is monitored by using business intelligence software. This application allows top and middle management to know in real time how they are performing. It simplifies the process and makes it automatic, so that management time can be dedicated to result analysis.

As described, the ULSM's BSC implementation was a strategic objective in the learning and growth perspective of the BSC.

Figures and more images are available in full at <https://healthmanagement.org/c/healthmanagement/issue/volume-14-issue-2-2014> or scan the QR code



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IT SECURITY AND PRIVACY IN HEALTHCARE

THE NEED FOR QUALIFIED PROFESSIONALS



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Global Healthcare Trends

Delivery of healthcare is extremely reliant on skilled and motivated people. Patients' natural need for human contact means that people, not machines, will always play the primary role in healthcare. In countries with effective healthcare systems each person is likely to receive care from many healthcare professionals over the course of his or her life. Many healthcare staff may be involved, even in a single healthcare episode, and their need to access each patient's records means that if anyone ever breaches security or privacy, whether accidentally or intentionally, the consequences could be severe. Patient trust in healthcare organisations is highly dependent on everyone involved playing their part in protecting information.

There are many good reasons for increasing medical use of information technology (IT):

- Electronic records are simpler and quicker to access and cheaper to maintain than paper records;
- Electronic records can be richer and more useful than traditional records. For example, digital images can easily be enhanced and annotated. Video interviews and voice notes can capture information that historically would not have been retained;
- Machines can deliver more detailed, accurate and consistent measurements than people can;
- Automated monitoring systems can operate continuously day and night without breaks;
- Computers can assist skilled

medical practitioners in different countries to collaborate and to build expert systems based on their combined knowledge and experience;

- Videoconferencing and telemetry can overcome the delays and costs of travel, putting patients in contact with medical experts more quickly and economically;
- IT can improve both the quality and the accessibility of medical training and continuous professional development.

However, increasing use of technology within healthcare means that information security and privacy arrangements effective when almost all medical records were kept secure using strong physical and personnel controls are no longer sufficient.

Other trends are also shaping the ways in which IT is being used within healthcare, for example:

- More data is being collected about each patient;
- Unit costs of electronic information storage and processing are falling;
- Medical records are being aggregated into ever larger databases to support epidemiological research;
- Medical records are being accessed more frequently and by more people;
- The "Network Effect" is encouraging ever greater levels of healthcare information sharing (Hillestad et al. 2005; Miller and Tucker 2009);
- Reduction of administration costs enables reallocation of funds to care delivery;
- The use of outsourcing to third

party organisations is increasing, even in countries where most healthcare is provided by public institutions.

Healthcare is also becoming increasingly international. People travel more and require care outside their home country. Perhaps even more significantly, the sector attracts talent from around the world, creating a workforce that in most countries is highly internationalised.

Taken together, these changes are making it increasingly difficult to establish and sustain consistent security and privacy controls.

Growing Information Security and Privacy Risks

A significant barrier to ever-increasing medical exploitation of IT is that medical information security and privacy risks are growing in impact, frequency and variety.

There are frequent stories in the news about physical or electronic break-ins resulting in stolen data, or about mistakes, perhaps a significant data entry error or accidentally losing an electronic data storage device. Occasionally a medical device manufacturer reports a security or privacy vulnerability in a product that went through rigorous design and testing so would routinely be trusted. It is not uncommon to read of legal and regulatory fines and other penalties for data breaches.

Increasingly there are also news stories about:

- Risks associated with cloud computing that mean physical location of data is not controlled by the

organisation and access to data is dependent on external networks also not controlled by the organisation;

- Risks associated with increasing use of personal computing devices such as smartphones and tablets, the so-called 'Bring Your Own Device' (BYOD) phenomenon;
- Risks that pseudo-anonymised medical records released to researchers may be linked with other information to re-identify individuals, invalidating assurances given to patients that their personal information is being safeguarded...and more.

Importance of Information Governance

Effective clinical risk management relies heavily upon effective information risk management. If information needed to support medical processes is not available or is inaccurate, there will inevitably be negative impacts on clinical outcomes.

In healthcare organisations that manage information risks effectively, delivery of positive clinical outcomes rests heavily on all aspects of information security, including:

- **Availability** - information needed to support clinical decisions is there when needed;
- **Integrity** - information needed to support clinical decisions is complete and accurate; and;
- **Confidentiality** - ensuring that sensitive personal details are handled appropriately.

Only by providing patients with robust assurances of sustainable privacy will the quantity and quality of complete and accurate healthcare information be maximised.

Establishing clear lines of accountability and responsibility for information risks is a growing priority

at the organisational level. Within many organisations frontline staff feel unclear about who is responsible for which aspects of information risk. Because many partner organisations may be involved in delivering healthcare and many information exchanges occur between staff working for different organisations, it is frequently extremely difficult for people without specific competence in information risk management to determine:

- What security and privacy policies are applicable;
- Which country's laws have precedence;
- Who has primary responsibility for information security and privacy;
- What their own responsibilities are for supporting information security and privacy.

By nominating appropriately qualified and experienced individuals to perform information governance duties, usually alongside their primary role, management can do much to support their frontline staff and minimise uncertainty.

Embedding effective information security controls into clinical working practices across multiple organisations requires both an understanding of the prevailing culture and experience in establishing and sustaining an appropriate information governance regime. Broad consensus needs to be reached between all parties about:

- Which roles within which organisations have responsibility for which aspects of information security and privacy;
- Which stakeholders need to be consulted about changes to information security and privacy policies;
- Which stakeholders need to be informed (educated) about information security and privacy controls.

In any information governance negotiation involving multiple healthcare organisations, it is only possible to achieve broad consensus if a good proportion of the parties involved:

- Understand the unique challenges of the healthcare sector;
- Can effectively explain to their colleagues why information security and privacy matters;
- Are competent in the specifics of implementing information security and privacy controls within healthcare sector organisations.

Building Information Governance on a Firm Foundation of International Standards

One of the best ways to achieve the consensus required is to meet or exceed internationally recognised minimum standards. Implementing processes and controls that meet or exceed national standards may also be necessary, but organisations involved in any international activities need to identify common processes and controls which meet the needs of multiple countries.

When it comes to building effective information governance regimes and standards for healthcare organisations it has historically been difficult for managers to identify suitable international standards to build on, because many industry security and privacy standards have been:

- National and/or;
- Focused on particular technologies; and/or;
- Tightly controlled by proprietary commercial interests.

The (ISC)² Healthcare Information Security and Privacy Credential

In recognition of the void in established international personnel standards the International

Information Systems Security Certification Consortium, Inc (ISC)²®, best known for its cross-sector professional certifications in information security, pulled together a diverse team of subject matter experts from multiple countries to develop the Healthcare Certified Information Security and Privacy (HCISPP) certification.

they need to study and learn new material in order to pass the exam, because of the diverse range of practice standards.

Candidates for certification must have healthcare sector work experience and have made an effort to study the specifics of information security and privacy in some depth and breadth. Good knowledge of

- Preserving the confidentiality and privacy of the medical records of a victim of crime is essential to protect the victim from further harm from the perpetrator.

To reflect the breadth of perspectives required, HCISPP candidates are examined to ensure that they meet minimum standards of knowledge in six domains:

- Domain 1 - Healthcare Industry;
- Domain 2 - Regulatory Environment;
- Domain 3 - Privacy and Security in Healthcare;
- Domain 4 - Information Governance and Risk Management;
- Domain 5 - Information Risk Assessment;
- Domain 6 - Third Party Risk Management.

“security and privacy measures of yesteryear are no longer sufficient”

The HCISPP sets a credible minimal international standard of knowledge and experience for anyone working in healthcare to whom management assign information security and/or information privacy responsibilities. The initial goal is to establish a broad base of competence spanning multiple countries and organisations. It is hoped that these HCISPP-certified individuals will in turn contribute significantly to the establishment of effective information governance arrangements in numerous healthcare organisations.

The HCISPP certification standard has intentionally been set at an accessible level that does not require degree-level education or prior experience in any specific medical or IT specialism. Nevertheless, even knowledgeable and experienced candidates will probably find that

just one country's laws and regulations is unlikely to be sufficient. Successful candidates will have needed to study a wide range of references and be aware of international differences in security and privacy laws and regulations.

Healthcare organisations can expect someone with the HCISPP certification to understand how information security directly impacts specific scenarios, for example:

- The timely availability of information about an individual's allergies is important to ensuring that no further exposure to the allergen occurs during treatment;
- The integrity of the information used to configure a radiotherapy machine determines whether many patients receive the correct dose - too much or too little radiation could be fatal;

The HCISPP Candidate Information Bulletin is a good resource, even for those who do not wish to take the HCISPP certification examination, for understanding more about these topics or seeing the underlying references for the syllabus.

The core data security and privacy knowledge base will evolve and expand over time. However, healthcare organisations looking for confirmation that an individual is ready to start playing an active part in developing an effective information governance regime would be hard pressed to find better evidence than that they have studied for and attained the HCISPP certification. ■

Further information

(ISC)²® <https://www.isc2.org/>

HealthCare Information Security and Privacy Practitioner (SM) (SM) Candidate Information Bulletin
https://www.isc2.org/uploadedFiles/%28ISC%292_Public_Content/Exam_Outlines/HCISPP-CIB.pdf

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Key Points

- Information technology is instrumental to efficient delivery of services.
- Currently, no comprehensive national or international professional good practice standards exist.
- Foundational credentials for healthcare IT professionals are being introduced, which aim to improve care, safety and workflows, and reduce risks of institutional liabilities.

MOLECULAR IMAGING

A PROMISING FUTURE?

The European Society of Molecular and Functional Imaging in Radiology (ESMOFIR) was founded in 2010 to provide a scientific forum for molecular and functional imaging and to promote education, research and recommendations in these fields among the radiological community. It is a subspecialty society of the European Society of Radiology. HealthManagement Managing Editor, Claire Pillar, spoke to ESMOFIR's President, Prof. Nicolas Grenier about the future of molecular imaging.

What do you see as the most promising applications of molecular imaging?

I think there are two main applications. Actually, we are able to detect many pathologies, but not all of them, and most of our imaging techniques and most of our contrast agents are unspecific. So, one of the most promising applications of molecular imaging is to be able to specifically identify most of the diseases by using targeted agents and to obtain their main biological characteristics.

The other main application is in the field of therapy. There are many techniques, which are developing to be able to provide targeted therapy. Based on these new specific imaging techniques, it becomes much easier to target non-invasive therapy. This is why the development of specific diagnosis and non-invasive target therapy is very complimentary. That's what we call theragnostics, combining specific agents with a physical effect like a thermal, a mechanical or a magnetic activation. For example, nanovehicles sensitive to heat (eg. thermosensitive liposomes) can be covered by fragments of antibody to reach chosen pathological cells and loaded with a therapeutic agent released once the temperature is increased externally. Microbubbles can also be targeted and loaded and disrupted by application of transcutaneous ultrasound.

How far away are we from wide-spread use?

I think we are quite far away. Targeting the lesions with specific agents is really on the way. However, the problem will be money, because in the market the real problem is not knowledge of how to develop a specific agent for specific diseases. It is whether it is profitable. For example, if the agent is

dedicated to a specific type of breast tumour the market will be very small. We need to find a middle situation where we would be able to target a certain type of disease that has a quite large spectrum, probably larger than we would expect, but it would be a trade-off between specificity and the cost-benefit ratio.

Molecular breast imaging has shown some promising results. What place do you see for this technique?

What I would say, as a non-specialist in breast imaging, is that we need to better characterise breast tumours. Some of these tumours can be sensitive to specific therapies, others not, depending on the expression of the cells. Therefore, depending on the category of tumour, the prognosis and the sensitivity to treatment will not be the same. Identifying its different sub-types related to genomics using imaging phenotyping will improve probably management of these tumours, and then these could be combined with targeted therapies in patients.

The European Society for Molecular and Functional Imaging in Radiology's ESMOFIR slogan is "towards personalised medicine". Can you expand on that?

To my point of view, imaging has to contribute to this typing of the different types of genomes in oncology. Tumours are better and better characterised due to proteomics and genomics. To be able to make the link between imaging characteristics and genomics could allow us to participate in the phenotyping of the tumour in a given patient, non-invasively. By doing this type of imaging, which could be functional or molecular or both, we would be able to characterise an individual patient's tumour, and this will have an impact on prognosis

and management. 'Radiomics' is a mix of genomics and radiology.

Imaging plays the core role in the management of every phase of the patient journey. The advantage of imaging is that it can give patient information in vivo and non-invasively, and it can follow that with time. For example, we know that tumours are changing even their genotype during evolution and different phases of treatment. So, if we could follow that with imaging in the future, I think imaging will keep a major role, a growing role in management.

What do you see as the challenges in bringing functional imaging into radiology?

The challenges are to find quantitative, but also reproducible, biomarkers of organ functions or any type of tissue. The challenge for functional imaging is to have reproducible techniques and effective usable tools for post-processing. Functional imaging of the heart, kidney, liver, and tumours has to be optimised in terms of protocols and reproducibility. ESMOFIR's main role is to validate accurate biomarkers in this context. The tools have to be reinforced and then evaluated for effectiveness. This will take time.

ESMOFIR is holding a workshop on clinical functional imaging in July 2014. Please tell us more.

The workshop will include lectures on the importance of validating functional biomarkers and on the objectives of techniques in molecular and functional imaging. There will also be practical sessions on how to do repetitive acquisitions, how to do reproducible quantifications, and with which tools. We really need to emphasise the role of radiology in modern patient management. ■



Interviewee

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Further information

<http://www.esmofir.org>



FRANCIS ONE YEAR ON



Harry Cayton

Chief Executive

Douglas Bilton

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www.professionalstandards.org.uk

A year on from the Francis Report (Francis 2013), several further reports have followed from the government, mostly on strategy and safety: its own response *Hard Truths* (Department of Health 2014), and the Berwick (National Advisory Group on the Safety of Patients 2013), Cavendish (2013) and Clywd (2013) reports. Some real steps have been taken in particular towards greater transparency, for example, quarterly reports on complaints, the professional and organisational duty of candour, the publication of 'never events', and the proposed new criminal offence of wilful neglect.

Far less progress, it seems to us, has been made on accountability. For example, it seems that the fit and proper person test will apply formally only to trusts, but not to clinical commissioning groups or to NHS England. Whistleblowing remains challenging, despite the progress we have made in understanding the reasons that people do not speak up when they know that something is wrong. Less progress still has been made towards achieving patient-centredness; the debacle over Care.data (Triggle 2014) is a case in point – using patient data without consent is hardly an example of 'nothing about me without me.' Real

paper *Asymmetry of Influence*, published by the Health Foundation last year (Bilton and Cayton 2013), we reviewed the regulatory landscape, starting with Berwick's observation that "the current regulatory system is bewildering in its complexity and prone to overlaps of remit and gaps between different agencies. It should be simplified" (National Advisory Group on the Safety of Patients in England 2013). Professional health and care regulation demonstrates this complexity admirably.

Professional Regulators

There are nine UK health professional regulators, one of which also regulates social workers in England. Three other organisations regulate social workers in Scotland, Wales and Northern Ireland. Some regulate single professions, some regulate multiple professions. The Health and Care Professions Council regulates 16, including social workers in England. Some are huge – the largest is the Nursing and Midwifery Council (NMC) with a register of nearly 700,000; some are tiny – there are around 2,800 chiropractors registered with the General Chiropractic Council. Some are old

standards, receiving and investigating complaints, and quality assuring courses of higher education that lead to registration. However, they have different legislation, standards, approaches and sanctions, and different levels of efficiency and effectiveness.

It is not of course just people who are regulated, and different kinds of regulation have different influences on outcomes, which is why we called our paper *Asymmetry of Influence*. The array of regulators of different aspects of care, in addition to the professional regulators, is enormous. It includes the Medicines and Healthcare Products Regulatory Agency (MHRA, regulating products), the National Institute for Health and Care Excellence (NICE, regulating processes), Monitor (regulating health sector), the Competition Commission (regulating prices), the Care Quality Commission, Healthcare Improvement Scotland, the Regulation and Quality Improvement Authority and Healthcare Inspectorate Wales (CQC, HIS, RQIA and HIW in England, Scotland, Northern Ireland and Wales respectively) regulating places.

Despite this array of regulators, in public discussion more regulation is often invoked as if it will make the world a better place. Regulation is often described as if a Utopian enterprise; regulation is cited as the answer to all sorts of problems. However, in reality regulation is endlessly utilitarian, seeking the adequate good of the greatest number. The various regulatory functions require staff to work patiently and accurately with vast quantities of detail. The last doctor or nurse added to the GMC's or the NMC's register is the last to have been deemed just good enough to practise.

Here we find the source of one of the great fallacies in the debate about the role of regulation – the conflation of the good enough with quality improvement. This confusion of regulation, quality improvement and additionally inspection has been

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“The real lesson from Francis is still to be learned...we need more personal responsibility, more professionalism and more decision-making near to patients”
.....

change in the NHS has, as usual, come from within, rather than from the top.

There is no doubt that the Francis report came as a shock and a challenge. We looked into the mirror and we didn't like what we saw. That has certainly been the case with health and care regulators. In our

– the General Medical Council (GMC) was established by the Medical Act 1858 - while some are only a decade old. The General Optical Council regulates students, but no one else does.

The organisations have common functions of keeping the register, setting out

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manifest in the past confusion in role of the Care Quality Commission. The new Chief Inspectors have made a real difference, in part because of the real concentration, thought and engagement of CQC, but also because of personality and style, and the quality of the people involved.

One of the practical consequences of the multiplicity of regulatory organisations is the plethora of advice, guidelines and standards telling people and organisations how to act. Carthey and colleagues (2011) found that the NHS Library had a list of 152 publishers of guidelines and 17 references to guidelines about how to develop guidelines. They also found over 3,000 guidelines on the Department of Health's website and 1,000 on the NICE website. The authors conclude that "clinical guidelines are undoubtedly an essential foundation of high quality patient care. However, their extraordinary and uncoordinated proliferation in the NHS confuses staff, causes inefficiencies and delay, and is becoming a threat to patient safety. We need to recognise the problems caused by current approaches and introduce greater rationalisation and standardisation at both national and local levels."

Lessons to Learn

The real lesson from Francis is still to be learned. We don't need yet more rules, regulations and guidelines. We need more personal responsibility, more professionalism, and more decision-making near to patients. We also need to treat health and social care professionals with dignity, respect and compassion, for how else can we expect them to show dignity, respect and compassion to patients and their families? There is much evidence that people behave well, and do high quality work

when they are engaged, empowered and respected. To achieve this we need more management and less administration. As the King's Fund said in a 2011 report, "there is appreciable evidence that the NHS is over-administered as a result of extensive, overlapping and duplicating demands from both regulators and performance managers", and the report cited evidence pointing to a conclusion that "the NHS, particularly given the complexity of health care, is under- rather than over-managed (King's Fund Commission on Leadership and Management in the NHS 2011).

We are slowly learning more about how regulation and humans interact – what might be called the social psychology of regulation. The more we learn, the more it becomes apparent that more regulation is seldom the answer, because all regulation has unintended consequences which may be the opposite of the intended outcome. In an excellent editorial in the BMJ Goldacre and Spiegelhalter (2013) looked at the evidence relating to cycle helmets and safety. Although a number of studies have shown that people wearing helmets are less likely to have a head injury, they point to evidence that suggests other, less desirable effects of making helmet wearing compulsory. For example, drivers may give more room on the road to somebody who is not wearing a helmet. Making helmets compulsory may reduce the number of people who wish to participate in cycling, thus resulting in individuals losing out not only on the health benefits of cycling, but also the 'safety in numbers' effect achieved by increased cyclist density on the road.

We have also been interested in research which has looked at the consequences of taking regulations away, leaving people to make their own

judgements about the best way to proceed. The most striking example of this is the 'shared space' treatment of Exhibition Road, in South Kensington, London, where street signs and markings have been removed, requiring pedestrians, cyclists and drivers to focus on what is in front of their eyes to avoid collisions and accidents (Moore 2012). It introduces an element of uncertainty, which requires everyone to be more vigilant for their own safety. While the success of the project may be contested, it seems clear to us that if people are given responsibility for self-management, mostly they will behave responsibly.

Personal responsibility is central to professionalism, is empowering and is an important motivator for safe practice. This includes personal responsibility for error; while the Berwick report observed that fear in the workplace is toxic both to safety and improvement, this should not be at the expense of people being responsible for their own actions and mistakes. The role of regulation in relation to professionalism is to provide a framework in which it can flourish, not to be a substitute for it.

There has been much done in the last year by the CQC, GMC, NMC and others to identify common objectives and values and a shared model of regulation, but progress is hampered by inconsistent legislation, and a lack of clarity from government as to what regulation is for, as policy swings between red tape cutting and regulating everything that moves. In the year ahead we need focus on working hard at achieving a culture of professionalism and responsibility. That includes how we behave personally, for all of us are the makers of the culture in which we work. ■

Key Points

- *The Francis Inquiry report was written by lawyer Robert Francis QC and published on 6 February 2013.*
- *It examined the causes of the failings in care at Mid Staffordshire NHS Foundation Trust between 2005-2009.*
- *The report makes 290 recommendations, including:*
 - *openness, transparency and candour throughout the healthcare system (including a statutory duty of candour), fundamental standards for healthcare providers;*
 - *improved support for compassionate caring and committed care and stronger healthcare leadership.*

Note

This article is based on a speech given by Harry Cayton to the Kings Fund conference on 18 March 2014.

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