

IMAGING

Management

Promoting Management
and Leadership
in Medical Imaging

Volume 11 Issue 5
2011 / 2012 – € 22

ISSN = 1377-7629

RADIOLOGY • CARDIOLOGY • INTERVENTION • SURGERY • IT • MANAGEMENT • EUROPE • ECONOMY • TRENDS • TECHNOLOGY

TRENDS IN DATA MANAGEMENT



INSIDE:

- Contrast Media in High Risk Patients
- Radiation Safety Awareness Training for Cardiologists
- Pros and Pitfalls of Paediatric CEUS
- Cost-Effectiveness of Interventional Radiology

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Data Management

Dear readers,

In the daily life of the leader of a medical imaging department, we are called on to wear many different hats: that of problem-solver, manager, scientist, clinical expert, and often, IT specialist. As is well known, radiology is a discipline that is steeped in fast-paced, highly effective, though often challenging new technology, which is speeding developments in patient care, but demanding much from the leader of clinical IT and those responsible for running the department.

With that in mind, our cover story in this edition has been inspired by not only the increasing dominance of cloud computing as a potential solution of serious challenges for cost-effective data storage and management, but also coverage of the European Society of Radiology's recent publication of a white paper on the use of lossy compression as one way in which data can potentially be managed without needlessly diverting finances from the primary goal of patient diagnosis and care.

Trends in data management will always be challenging to keep abreast of, given the explosion in areas like 3D imaging, hybrid imaging and complex studies that aid us in better caring for patients, but which are so advanced that the management system for that data sometimes arrives after the technology itself. I would urge those of you who are engaged in such matters to draw the attention of industry and vendors for the ever growing need for integrated, smart and cost-effective data management solutions. Without pressure from their clients, we risk losing out on the opportunity to set up new technology in a smart way that is adapted to our needs.

Our big focus in the features section this issue is on patient safety. We can all agree that this is a fundamental duty of any physician: to carry out the exams paramount for excellent diagnosis in

such a way as the least possible impact is made on the patient. The first of these, authored by Carpeggiani et al, addresses a lack of awareness amongst cardiologists on basic radiation safety for patients. As she states, "Cardiologists prescribe and/or directly perform >50 percent of all imaging examinations, accounting for about two thirds of the total effective dose to patients". With this in mind, her team successfully demonstrated how a brief training course can have a positive impact on the approach with which cardiologists carry out necessary imaging exams. Secondly, we bring you a very interesting paper by Esposito et al, which examines the pros and cons of more widely introducing contrast-enhanced ultrasound in the paediatric population. As well as highlighting the particular challenges in doing so, he and his team provide a compelling argument on why more needs to be done to promote this type of exam in certain cases.

We are delighted to continue our ongoing editorial collaboration with the CIRSE organisation throughout 2012, which continues to provide our readers with focused updates on relevant advances and developments from the world of interventional radiology. This edition we feature a paper by Dr. McLean and Dr. Thomas on the economic aspects of interventional radiology, and focuses on the value of IR as an investment.

I welcome your correspondence on any of the topics covered in this issue by contacting me at: editorial@imagingmanagement.org

Sincerely,




Prof. Iain McCall

Editor-in-Chief
editorial
[@imagingmanagement.org](mailto:editorial@imagingmanagement.org)

Trends in Data Management

The speed at which technology in medical imaging makes advances has always been remarkable. Inspired by the European Society of Radiology's recent publication of a white paper on the use of lossy compression, it is becoming evident that this rapid growth is creating gaps in other areas of IT management. In particular, new ways are being sought to manage increasingly numerous and complex imaging studies. In this cover story, we examine the cloud computing revolution, looking at the challenges faced, such as proving return on investment, as well as the related trust and data privacy issues. Other papers provide innovative models, such as lossy compression in Canada, and email as an easily implementable mode of data sharing.



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ASSOCIATION NEWS



MANAGEMENT IN RADIOLOGY: BOOK NOW FOR JANUARY WINTER COURSE!

Taking place this year in the winter ski resort of Schladming, Austria, from January 14 – 16 2012, the annual MIR winter course programme will be interactive and informative, and build a practical skill set over a three-day period. The aim of this course is that each delegate will leave with new insights and practical solutions they can implement immediately. Two trainers from "Inspire Change" will explore the following five key topics:

- *Chairing national & international meetings;*
- *Advanced presentation skills;*
- *Negotiating;*
- *Dealing with difficult people, and*
- *Influencing.*

Chairing National & International Meetings

Chairing a large national or international meeting may seem like a daunting task when you are first asked, but it is also a great challenge, which if met successfully can add to your management and leadership skills.

We have all been to meetings where the Chairman was not as skilled as they might have been, and we clearly understand from that experience what it is we don't like about large meetings – speakers running over time, a lack of leadership or direction from the Chairman when re-

quired and little information about what is meant to be happening next. This workshop is about getting you to think about what will be required of you in your role as a chairman. If you do it well, it will be a seamless operation, which passes uneventfully, but do it badly and you will certainly be remembered for all the wrong reasons. We will look at what you need to take into consideration before, during and after the meeting.

Advanced Presentation Skills

This workshop takes your presentation skills to the next level and builds on what you may have already been taught. The objective of this session is to provide delegates with the opportunity to improve their skills in presenting complex findings to large and small audiences at international meetings. In this workshop delegates cover:

- *Making yourself understood;*
- *Interacting with a multi-lingual audience, and*
- *An opportunity to be recorded giving a short presentation.*

Each delegate will have the time to practice a presentation of their choice with tuition and learn the key rules for presenting to an international audience, understanding how to make a real difference when they present to their peers.

Negotiating

Many of us think that we know how to negotiate, but we fall down on four main points:

- *We consider what it is we want, but forget to think in detail about the other side;*
- *We don't ask enough questions;*
- *We fail to plan our strategies, and end up getting less, and giving away more, than we really should, and*
- *We get "thrown" when negotiators on the other side use tricky techniques.*

In this workshop delegates cover:

- *Planning for negotiation and how it pays you back every time;*
- *When to carry on and when to walk away;*
- *The power of adjournments;*
- *The benefits of a structured system, and*
- *How to avoid dropping your price.*

The trainers from "Inspire Change" will teach you how to spot the professionally trained negotiator; the tricks they sometimes play and how to handle them and keep the negotiation fairly working for all parties.

Dealing with Difficult People

The objective of this session is to provide delegates with the skills they need to deal with colleagues or patients whose behaviour compromises effective working or care planning. The workshop provides practical skills for confronting challenging behaviour without creating conflict. Any physician who finds themselves challenged by the behaviour of others in the care setting will find this session beneficial. In this workshop delegates cover:

- *Recognising the reason for behaviour change;*
- *Discussing behaviour openly, and*
- *Encouraging reflection.*

Influencing

The objective of this session is to provide delegates with the skills they need to put across their arguments and new ideas clearly and precisely, in a way that will gain support from colleagues in the hospital setting and patients during care planning. The session will include:

- *Recognising the difference between negotiating and influencing;*
- *Being clear about your message;*
- *Getting buy in for your ideas, and*
- *Respecting others points of view.*

Delegates who have to persuade colleagues and patients to accept treatment pathways, which might be challenged, will

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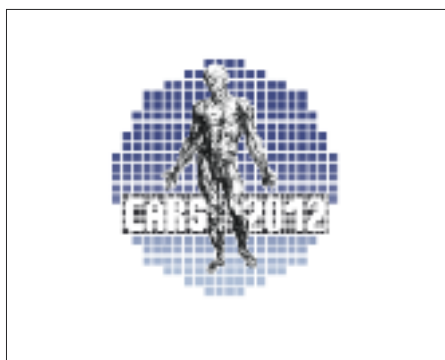


The annual meeting of  **myESR.org**

find this session beneficial and will learn how to deliver effective service development, by understanding resistance to new ideas and how to encourage colleagues and patients to embrace them.

This well-received leadership course has proven extremely beneficial to previous attendees and is predicted to attract high level leaders in healthcare.

Visit www.mir-online.org now to ensure you register in time.



ABSTRACT DEADLINE FOR CARS 2012 CONGRESS APPROACHING

Taking place in Pisa, Italy, from June 27 – 30, the annual CARS congress is the yearly occasion where medicine and technology meet to present and discuss the key innovations that shape modern medicine on a worldwide basis. As is traditional, the ISCAS, EuroPACS, CAR, CAD and CMI societies will join CARS holding their own meetings are part of this large event. The congress will also be part of the Bioengineering Week, which starts in Rome on June 24 and moves to Pisa to join with CARS.

At CARS you will have the opportunity to meet scholars and experts in the fields of radiology, surgery, engineering, informatics and/or healthcare management who have an interest in topics, such as:

- *Image- and model-guided interventions;*
- *Advanced medical imaging;*
- *Image processing and visualisation;*
- *Computer aided diagnosis;*
- *Medical simulation and e-learning;*

- *Surgical navigation and robotics;*
- *Model-guided medicine, and*
- *Personalised medicine.*

New PACS applications, including IT-infrastructures adapted for the operating room as well as related results from the DICOM and IHE working groups are also within the scope of CARS.

Please note that the deadline for paper and abstract submissions for CARS 2012 in Pisa is January 10, 2012. More information is available on www.cars-int.org



CIRSE FOUNDATION EDUCATIONAL GRANTS DEADLINE

The Cardiovascular and Interventional Society of Europe have announced that applications for the CIRSE Foundation 2012 education grants will be possible until March 1st, 2012. Applicants are asked to send all documents required to valentinitsch@esir.org. Late applications will not be accepted.

The purpose of the education grant is to advance training and education in interventional radiology. The grants are available for CIRSE Members, particularly fellows or junior faculty, who wish to train or experience new procedures at a different European institution. Grants can be used to learn a new procedure and/or skills that may be needed at the applicant's institution or to undergo training not available at the applicant's own institution. More information on the type of grants available can be found by visiting www.cirse.org



IHE TECHNICAL FRAMEWORK AND PROFILES IMPLEMENTED BY NATIONAL INITIATIVES

IHE Europe today counts national initiatives in Austria, France, Germany, Italy, Spain, Switzerland, the Netherlands, Turkey, and the United Kingdom. A national IHE initiative promotes, supports and implements IHE activities within the respective country, and often at the regional level within the country. National IHE initiatives also assume the responsibility to represent the needs and requirements of their respective healthcare systems within activities of IHE-Europe.

National initiatives are sponsored by professional associations and include membership and staff of these groups, as well as local hospital and vendor representatives.

A key role for a national initiative is to coordinate the deployment of the IHE Technical Framework and Integration Profiles and to then give input to development of this documentation relevant to local needs and issues. Specific IHE documentation relevant to individual European countries is contained within the national extension annexes to the Technical Framework documents accessible through the respective IHE National Initiatives.

A key requirement for the establishment of an IHE National Initiative in a country is the support of one or more IHE sponsors. The role of a national IHE Sponsor, typically an association or user organisation committed to the promotion of IHE, is to provide support, direction and resources to the newly formed IHE national initiative.

For further updates please visit www.ihe-europe.net

Management in Radiology



European Society of Radiology



MANAGEMENT IN RADIOLOGY

Annual Scientific Meeting

October 11–12, 2012, Milan/IT



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MIR is a subcommittee of the ESR Professional Organisation Committee.



ALLIANCE FOR MRI REACTS TO REVISION OF EMF DIRECTIVE

Threat from Council to Proposed Derogation for MRI

On November 8, a reception of the Alliance for MRI was jointly hosted by MEP Elisabeth Morin-Chartier and MEP Sylvana Rapti at the European Parliament. Since the adoption of the European Commission proposal for a new EMF-Directive in June 2011, it has become clear from the discussions in Council that there is opposition from a number of member states to the proposed derogation for MRI from the limit values. Mr. Jerzy Galeziak, representing the Polish Presidency, outlined that the objections are primarily ideological, as there is a reluctance to grant an exemption to any category of worker from the EU health and safety legislation.

Dr. Patricia Reilly, representing Commissioner Geoghegan-Quinn, DG Research, emphasised that the proposed derogation for MRI is crucial to boost the use and further development of MR technology without compromising the safety of workers and patients. She outlined the European Commission's commitment to fostering the development of the technology within the context of the EU 2020 strategy. MRI has been in use for over 30 years and MR research in Europe is vital to improve diagnosis and treatment for Europe's patients.

Ms. Morin-Chartier MEP, Rapporteur of the European Parliament's report, outlined that she will seek to achieve the best solution for Europe's patients in the new Directive prior to the expiry of the April 2012 postponement deadline of Directive 2004/40/EC.

Ms. Morin-Chartier explained that she planned to work closely with the Presidency of the Council in finding a workable solution, taking into account concerns regarding worker safety whilst ensuring the future of MRI. She concluded by assuring the Alliance for MRI that she will work to bring about a satisfactory solution for Europe's patients. Ms. Sylvana Rapti MEP stressed the importance of taking all views into account in order to find the best solution to ensure unhindered patient access to MRI in the future.

ESR Vice-President Welcomes Commission Proposal

Prof. Gabriel Krestin, Vice President of the European Society of Radiology, welcomed the European Commission's proposal to address the unintended impact of the current Directive on MRI. It is based on sound scientific evidence, which must be taken into consideration in the current discussions. He explained that the derogation would exempt MRI from the exposure limits only, not from the legislation, and MRI workers are already protected in other ways, including existing international standards relating to equipment safety and that MRI is used in a very controlled environment. He outlined that the MRI Community welcomed the development of European guidelines to support the current Directive.

Stephen Pickard, representing the European Parkinson's Disease Association (EPDA) pleaded for decision-makers not to forget the importance of unhindered access for patients to MRI. He outlined the progress which had been made with the European Commission in explaining the need for workers to accompany patients near the scanner and the importance of research in this technology in order to find ways to treat and cure major neurological diseases. MRI offers new insights into serious and widespread conditions such as bipolar depression. Whilst the EU adopts 2013 as the European Year of the Brain, it must not curtail the use of such a vital technology, which is used so effectively to improve and save lives.

Alliance for MRI's Position

- The Alliance for MRI requests that the new Directive provides for a derogation for MRI from all limit values for all workers including medical, research, maintenance and cleaning personnel.
- The Alliance fully supports the development of binding user guidelines for MR workers for all EU countries.
- The Alliance does not see any possibilities for compromising on this position without putting the use of MRI for the benefit of Europe's patients in danger.

Alliance for MRI Campaign needs your Help Now!

This Directive is complex and there is still disagreement about the scientific basis for the exposure limits. There is also a clear lack of understanding regarding MRI technology and how the scanners are developed and used to ensure the safety of patients and workers. It is our mission to ensure the unhindered use of this technology which is at the cutting edge of patient care and the diagnosis of life threatening diseases in Europe. It has been used for over 30 years with no evidence of harm to patients or workers.

The Alliance will be pleased to:

- **Provide expert witnesses to support discussions on the rationale for a derogation**
- **Support all our members who can write letters to their MEPs, ministers of health and ministers of social affairs/ health and safety to communicate the importance of this derogation**

We would like to thank all members who attended the reception and look forward to working with you.

For information on the Alliance for MRI please visit [visit www.alliance-for-mri.org](http://www.alliance-for-mri.org) or contact the Alliance Secretariat at eu-affairs@myesr.org ■



September 15-19
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CIRSE 2012, Europe's most comprehensive forum for minimally invasive image-guided therapy, will offer more than 250 hours of educational and scientific presentations streamlined around seven major topics, hands-on workshops, foundation courses, learning centres, industry symposia, an all-electronic poster exhibition and the largest CIRSE exhibition ever.

www.cirse.org

MAIN TOPICS

- Vascular Interventions
- Transcatheter Embolization
- Non-Vascular Interventions
- Interventional Oncology
- Neuro Interventions
- IR Management
- Imaging

Congress Review: RSNA 2011

Innovation in the Face of a Transforming Health Landscape

This year's 97th edition of the Radiological Society of North America (RSNA) Scientific Assembly and Annual Meeting both celebrated the continuing drive for innovation and novel ways to provide faster, sharper and safer medical imaging exams, as well as reminding its audience that in the face of anticipated and hotly debated cuts to the health system in the United States, belt tightening looms large.

Health Management on the Agenda

This year saw a growing focus on topics such as Health Policy Management, Quality Assurance and Quality Improvement, and Professionalism, and offered sessions that drew wisdom from experienced radiologists from an international spectrum that shared their practical management experience with the audience. More and more, attention is sharpening on these extra-clinical leadership-related roles, and residents and young radiologists are being encouraged in particular to devote some of their training to management related activities. Leaders of radiology departments urged the younger generation to remember that radiology is a vibrant, exciting profession, and that with an investment in extra curriculum activities ranging from social gatherings, to committee work and a general proactive attitude in this respect, that the sky's the limit for their

careers, negative reports of potential cuts in residency programmes and to reimbursement at large notwithstanding. The message is clear: opportunities in radiology have never been better and it continues to attract a high level of intelligent and competent professionals.

Best practice was another hot topic at this year's congress: topics ranged from "Critical Issues Facing the Profession of Radiology", to "Shaping Your Future Practice", and an exciting debate on the differences in recruiting and staff retention between public and private practice stood out as focusing on a present-day job market crisis in radiology.

Technology was certainly not forgotten in the mix of all these exciting practice and clinical based sessions. This year, several companies such as Hologic, Philips, Merge, Siemens, Carestream and GE Healthcare announced new products, new upgrades and technological innovations aimed at improving

outcomes and image quality and processing. Below, you can find a summary of the main industry highlights.

RSNA 2011: Celebrate the Image Speech Kicks off Congress

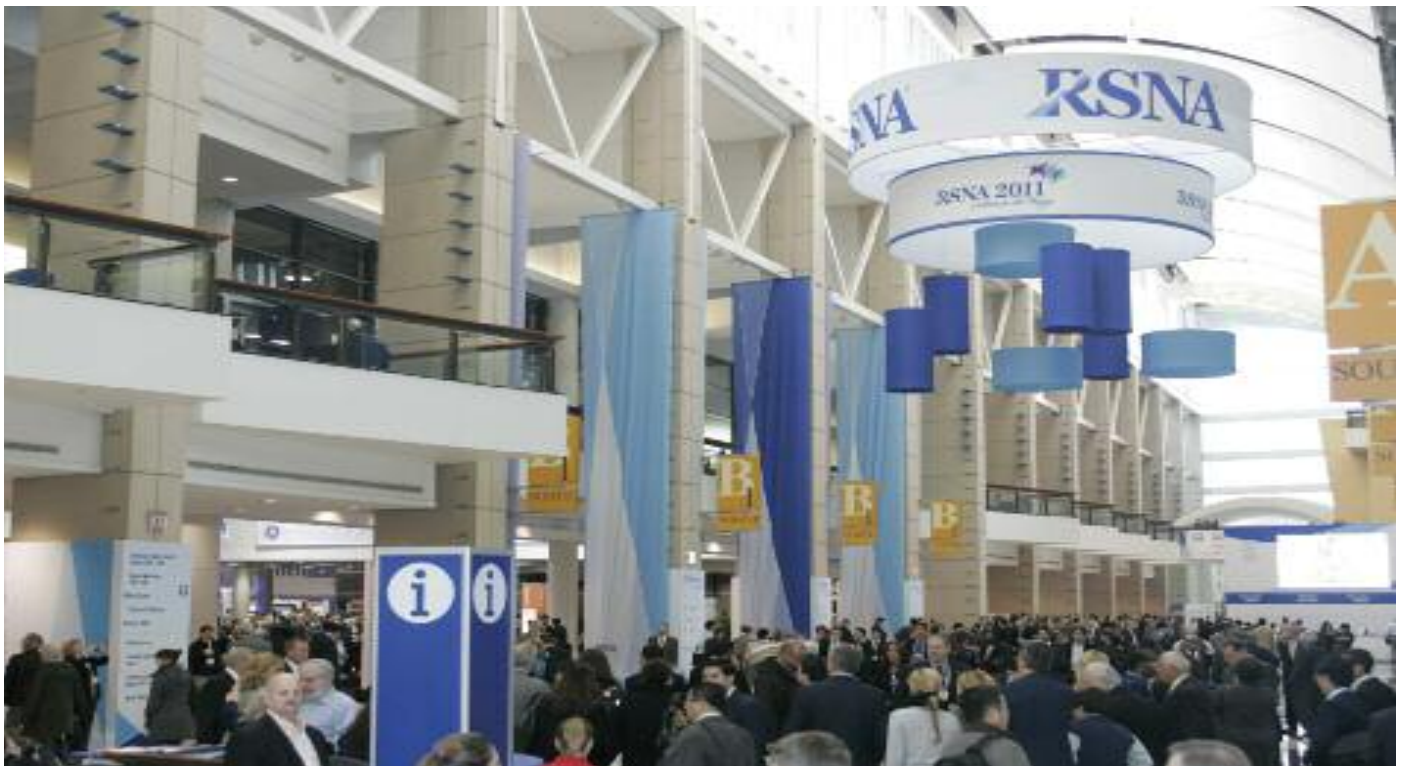
"You know you're under the economic microscope when a CT scanner adorns the cover of a Congressional budget office report," Dr. Drayer said during his President's Address, "Celebrate the Image: How We Changed the Face of Health Care," on Sunday of the RSNA congress.

"In addition to our image interpretation expertise, we're expected to prove comparative effectiveness and carefully oversee dose and utilisation management and work symbiotically with all," said Dr. Drayer, the Dr. Charles M. and Marilyn Newman Professor and chair of the Department of Radiology at The Mount Sinai School of Medicine and executive vice-president for risk at The Mount Sinai Medical Center in New York City.

But radiologists also have reason to be optimistic, Dr. Drayer added. "I believe that innovative radiologists and clinicians, working collaboratively with physicists and engineers, have spurred corporate innovation and competition to create better, faster and safer images to the benefit of our patients."

There is proven value in medical imaging, said Dr. Drayer, as a physical examination. With almost one billion office visits in the U.S. every year, there is no evidence-based study to even verify the accuracy of abdominal palpation or lung





auscultation. "CT is done in a resounding 14 percent of emergency department visits, and it's been the subject of much discussion and many explanations, but maybe it's just good, accurate clinical care," he said.

If radiologists are to continue relying on the diagnostic accuracy of CT, however, they must be strong advocates of dose reduction, Dr. Drayer said. Image acquisition, post-processing techniques and the use of dose registries are among the new ways to lower dose for patients, he said, while the best methods remain "not doing unindicated studies, using decision support and having ready access to prior imaging exams."

With increasing life expectancies comes increased disease burden, and progressively increasing healthcare cost, Dr. Drayer noted. "It seems clear that a key strategy to bend the cost curve of healthcare created by this aging population is to support the research needed to develop innovative new protective technologies and pharmaceuticals," he said, pointing to precise image phenotyping, early detection and prevention

using low-dose and more accurate imaging solutions, evidence requirements using statistical predictor models, and more use of biomarkers to quantify therapeutic response, as well as unique new imaging applications.

RSNA 2011: 3D Modeling Offers Hope to Facial Injury Victims

Results of a new study on human face transplantation, led by Darren M. Smith, M.D., plastic surgery resident at the University of Pittsburgh Medical Center (UPMC), were presented during the annual meeting of the Radiological Society of North America (RSNA).

Devastating injuries or defects of the face are extremely challenging, if not impossible, to satisfactorily reconstruct by traditional surgical techniques. In face transplantation, facial tissue from a donor is transferred to reconstruct the defect, restore essential life-sustaining functions—such as breathing, chewing and speaking—and, above all, reestablish normal human appearance.

"This surgery is for patients with dev-

astating injuries to the face, who have lost their ability to smell, eat and engage socially and have no other conventional treatment options," said Vijay S. Gorantla, M.D., Ph.D., administrative medical director of the Reconstructive Transplantation Program at UPMC.

Clearly defining and understanding the complex tissue deficits and defects that accompany devastating facial injuries like electric burns, blast wounds and accidental trauma are critical for both technical success and objective analysis of the return of function after face transplantation.

Medical imaging plays a major role in the entire spectrum of face transplantation, ranging from patient selection, donor and recipient surgical planning, and postoperative assessment of returning motor and sensory function. Face transplantation is a lengthy, complicated procedure that involves reconstruction of multiple tissues—such as skin, muscle, blood vessels, nerves and bone—by a team of surgeons.

Using sophisticated computer modeling software, Drs. Smith and Gorantla,

along with Joseph Losee, M.D., integrated information from 3D CT, CT angiography, MRI and high-definition tractography to create a 3D model of the patient's head and neck anatomy. The same type of modeling technology is often used in movies to animate computer-generated characters with detailed three-dimensional human features and realistic expressions.

Industry Highlights

Swedish university to improve medical education with Sectra's visualisation table

The Faculty of Health Sciences at Linköping University in Sweden has invested in the Sectra Visualisation Table. The faculty will use the table for training and instruction purposes in all of its seven education programmes.

The Sectra Visualisation Table is a large medical multi-touch display, allowing students and medical professionals to interact collaboratively with the life-size 3D images generated by CT and MRI scanners. The possibility to work with a virtual body allows for deeper understanding and insight into the anatomy, and functions and processes inside the body. In this manner, Sectra Visualisation Table improves medical education, surgery planning, clinical conferences and virtual autopsies. The table is powered by a tailored Sectra PACS workstation (Picture Archiving and Communication System). Linköping University is renowned as an innovator in medical education.

"With Sectra's Visualisation Table, we will have new opportunities to use medical images in our education and teaching," says Pia Tingström, Head of the Centre for Educational Development and Research at Linköping University. "Integrating advanced clinical imaging technology into our education provides students with a learning tool that will contribute to improved patient safety."

Siemens Unveil Somatom Perspective for CT

At the RSNA, Siemens Healthcare unveiled the Somatom Perspective, a new computed tomography (CT) scanner that is particularly efficient in operation. This scanner is their first to offer eMode functionality, which determines the best correlation between dose, financial efficiency, and image quality and adjusts the required scan parameters automatically. The system's operation can thus be optimised for the individual scan, for example in terms of tube current or scan velocity. This option relieves wear and tear on the CT and increases its life cycle. Special service offerings and even the design of Somatom Perspective are said to help keep down overall operating costs. Being suited to cover all clinical fields, including cardiovascular studies, this CT scanner reportedly allows clinics and practices to extend their range of available examinations even where budgets are tight. With the new scanner, Siemens further extends its portfolio for the middle price segment in the course of the initiative Agenda 2013. The Somatom Perspective will be available from the second quarter of 2012.

Philips receives FDA clearance to market its first whole body PET/MR imaging system in the United States

At this year's meeting, Philips announced 510(k) clearance from the Food and Drug Administration (FDA) for the company's first commercially available whole body positron emission tomography/magnetic resonance (PET/MR) imaging system, the Ingenuity TF PET/MR which was on display at the RSNA this year. This platform will help clinicians and researchers investigate novel personalised medicine and treatments for oncology, cardiology and neurology.

It was previously thought that PET and MR scans were incompatible; however, Philips overcame the enormous

technical hurdles, through advances in technology, to create a new class of hybrid imaging that they hope will push the bounds of what's possible in imaging. The system is designed to provide a state-of-the-art platform well into the future by facilitating the addition of new technologies as they become available.

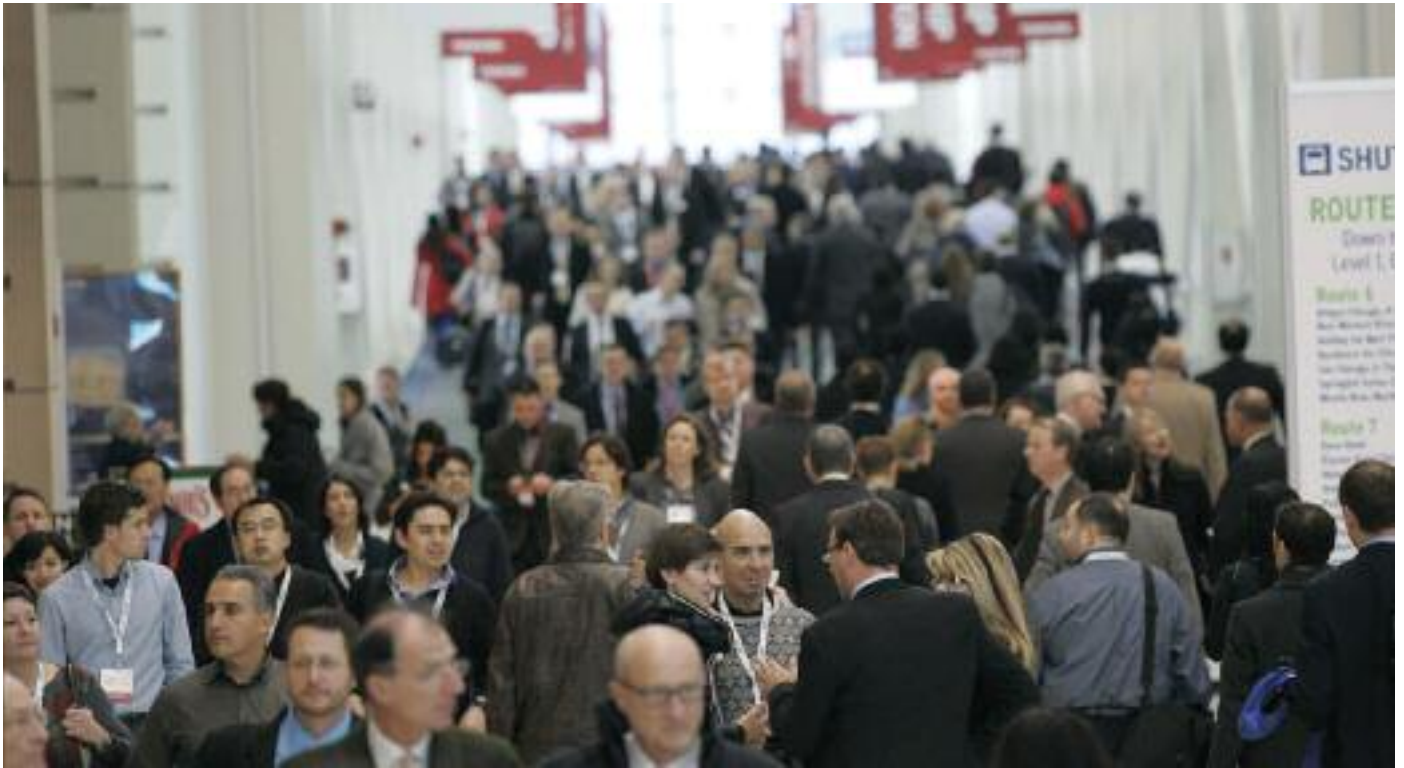
The Ingenuity TF PET/MR delivers increased economic value, as it is a sequential imaging system that has a similar clinical workflow experience to PET/CT, the current benchmark for hybrid imaging. In addition, the system is designed so the patient table rotates between each modality to scan a patient, thus enabling the system to perform both standalone MR and hybrid PET/MR studies. This aims to deliver added flexibility by eliminating the need to invest in multiple scanners while cutting down on throughput time and improving patient comfort since the patient can remain on the same table for both tests.

Merge Healthcare Launch Honeycomb Cloud Service; Shares Skyrocket

During the RSNA, Merge Healthcare announced Merge Honeycomb, a new cloud-based service that will enable users to upload, download, view, and share medical images - at no cost. "With Merge Honeycomb, we're harnessing the cloud in a way that encourages and enables faster collaboration among all healthcare stakeholders, resulting in a true improvement in the delivery of care and reduction of costs," said Jeff Surges, CEO of Merge Healthcare. "

First announced at the Merge Live 2011 Client Conference in October, attended by over 500 healthcare professionals, Merge Honeycomb will be the nation's largest medical imaging sharing network and is open to anyone. It was officially launched at the RSNA prompting a spike in share prices.

Merge Honeycomb aims to reduce the need for duplicative scans, which



costs the industry an average of 35 billion USD a year and exposes patients to harmful and unnecessary radiation. (According to a 2010 study by the Center for Devices and Radiological Health and the U.S. Food and Drug Administration, the radiation level in one CT scan of the abdomen is approximately the same as 400 chest X-rays.) It also aims to eliminate the archaic practice of using patients as transport vehicles. The need to burn X-rays, CT Scans, MRIs and other images onto CDs will be a thing of the past. When a physician needs to view images, they can log into the image-sharing network via any web browser.

Hologic feature new algorithm for Selenia Dimensions Breast Tomosynthesis System

At this year's RSNA, Hologic featured a new algorithm along with the Company's Selenia Dimensions breast tomosynthesis system, announcing the commercial release of its C-View synthesised 2D image reconstruction algo-

rithm that eliminates the need for a conventional 2D mammogram as a component of a 3D mammography(tomosynthesis breast cancer screening) exam. C-View software is approved for sale throughout the European Economic Area and in other countries recognising the CE Mark.

For users of Hologic's 2D plus 3D tomosynthesis breast cancer screening system, C-View software creates a 2D image from a single tomosynthesis scan and

eliminates the need for the acquisition of additional 2D exposures. Dr. Stephen Rose, a board certified radiologist with Houston Breast Imaging stated "Hologic's synthesised 2D image reconstruction algorithm is very impressive. C-View provides the information contained in a conventional 2D mammogram without the need for additional exposures while maintaining the superior clinical performance of Hologic's combo-mode (2D plus 3D) imaging."



STRENGTHS AND WEAKNESSES OF USING CLOUD COMPUTING

Data Ownership & Protection Issues



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Technological advances have created great opportunities for society to develop new products and services, and to communicate and share data. A tremendous amount of ubiquitous computational power and online services are used every day as a normal commodity. These new facilities allow data storage and exchange of information anytime and anywhere, at high speed. In recent years, cloud computing is the new term that has emerged to define these services. The main idea is to merge computational power and storage in a dynamically scalable infrastructure, i.e. the system capability grows as needed, which allows decoupling of the business service from infrastructure. This new buzzword is changing the computing paradigm and has given rise to vendors dedicated to providing this new utility in a pay-as-you-go business model, offering customers huge computational power and storage. The offer is diversified, including virtual operating systems and basic services, for instance, storage, database and signaling.

It is evident that the computing-as-utility business model is becoming prevalent in the electronic world and numerous industries are adopting it. So this new paradigm ought be of interest to the healthcare industry in various ways and may likely be increasingly adopted in the coming years. The medical imaging sector will not be an exception, despite its special requirements. The main advantages of cloud computing are cost savings, wide availability and high scalability. However, this new technology also brings new challenges regarding data ownership, trust, privacy and interoperability with healthcare standards. In this article, we will stress the applicability of cloud computing solutions to support medical image repositories, addressing the existent problems and point out possible solutions to solve these issues.

Trust and Data Privacy

The outsourcing of data records can be a good solution, depending on the type of information transmitted to the cloud providers. The privacy of medical information is a vital requirement and a very sensitive issue, especially when medical digital images and patient information are stored in third parties and transmitted across public networks. Healthcare institutions often insist on safeguarding the privacy of involved actors to avoid data being tampered with by provider companies (i.e. cloud services suppliers).

Medical image repositories usually deal with outsized data volumes, regularly including an ever-growing list of files. Apart from medical exams, PACS also supports a database with textual information corresponding to those exams. Both are relevant and only authorised parties should access them. Thus, a challenge in outsourcing medical images over the cloud is how to protect the privacy of patients and physicians, including protection against misuse of data.

“Storage of patient data in the cloud will be very difficult to implement in countries like Spain, France or Italy”

A possible way to minimise those risks is the use of a hybrid cloud solution, i.e. a combination of public computing utility with a local infrastructure retained by institutions. The idea is to keep critical mechanisms inside institutions and outsource the heavy computational resources. The hybrid cloud approach allows outsourcing of medical records without losing control, which means that only authorised entities can access the data. The third party entity, located within the institution's control, provides the core element of privacy. This huge amount of medical information is stored across public cloud providers, granting patient privacy through data encryption. Possible unauthorised access to the cloud repository does not jeopardise data privacy, since access to the repositories requires the right key to get medical imaging records. Moreover, an additional strategy of splitting ciphered chunks of the same image across different storage providers could be used to provide an even higher level of privacy.

Data Ownership and Protection

Data protection in the outsourcing of medical images is required because these records are important assets for data holders. Medical institutions need to be aware of legal aspects when storing data in outsourced repositories. The first concern should be the SLAs (Service Level Agreements), giving special attention to the problem of data security. Another topic to be considered is the permanence of patient data. Data protection laws in several countries, require knowledge of where data is stored. For this reason, storage

of patient data in the cloud will be very difficult to implement in countries like Spain, France or Italy. However, several cloud providers allow obligatory data storage in a specific geographic location. Thus, the problem addressed can be minimised and even countries with higher restriction laws might accept the solution.

Economic Aspects

Healthcare institutions need to reap certain benefits in terms of service quality and financial impact to be motivated to outsource their medical repositories. To analyse if cloud computing is economically viable in the imaging context, the following cost variables of the current solution are crucial:

- Server hardware;
- Network equipment;
- Licenses;
- Energy;
- Air conditioning;
- Maintenance, and
- Technological obsolescence.

A medical image repository based on the cloud does not require high initial investment compared to traditional archive solutions, which require purchase and maintenance of a data centre. It is well suited to a small centre because it does not require initial investment. However, for medium-to-large image centres there is a point of operation where it is economically more rational to have data centre storage in co-location. It is very difficult to define this tipping point because it is dependent on department workload and processes, and the cloud services market is rapidly changing, providing more resources at lower cost.

Furthermore, the cloud solution can facilitate multi-centre collaborative environments, including the sharing of medical records across medical institutions. So it will reduce duplication of medical exams, on one hand reducing the costs of patient care, and on the other, reducing the dose of exposure to radiation.

Interoperability with Healthcare Standards

There are many standards in the medical community (DICOM, XDS-I, IHE, HL7, etc.) that need to be interoperable with current cloud providers' interfaces. Historically, healthcare communications standards were thought to operate inside an institution's intranet. However, new standards are starting to follow a service-oriented architecture (SOA), which allows inter-institutional communication. Nevertheless, the compatibility with cloud services' interface is not directly supported due to data privacy and confidentiality.

For instance, in medical imaging, communication between medical devices follows the DICOM standard. However, the

cloud data store and database interfaces are not DICOM compliant. Most public cloud providers supply access to their services through a proprietary web service interface. Thus, we need a middleware component to provide interoperability between DICOM equipment and cloud repositories solution compatible both with medical practice and pre-existing medical information systems (Bastião et al., 2011). To access cloud medical image repositories we need a cloud broker, which will carry out the communication with healthcare standards (for instance, DICOM), as well as cloud services.

Data Availability

The availability rate of cloud services is very high, which means that services are always ready and reachable. However, availability in the medical imaging scenario is linked to the performance of access to the repository. Due to latency associated with service access and communication with public cloud providers, the retrieval process can be slower. This process is extremely important for the overall quality of the solution because there is real-time interaction with end-users, i.e. the professional is at the computer waiting for images. In order to reduce latency in data transmission, a caching mechanism can be placed on the cloud broker inside the medical institution. This mechanism is a local storage area that temporarily stores studies that are very likely to be requested in future operations. Moreover, the usage of pre-fetching mechanisms associated with the cache is fundamental to the solution's viability.

Conclusion and Future Perspectives

The use of cloud computing utility has increased significantly in recent years and it appears to be a natural evolution of the data centre to execute computing and storage in a more scalable way. With such a significant increase, the market is growing quickly and more companies are providing new services with better features, including isolated services. We strongly believe that in the near future, cloud computing will be widely used in the healthcare sector. Several companies are already adopting this kind of solution, offering PACS and RIS services in private clouds.

Medical images are very important records, and so the storage repository needs redundancy to be a reliable system. Cloud providers offer this data security and backup system without any worries or additional charges for customers. Medical institutions can reduce the costs of local storage maintenance with PACS archive outsourcing. Moreover, outsourcing is an opportunity for small image centres that purchase modality equipment, despite not having the financial resources to buy software and hardware to keep up a PACS repository as it grants a redundancy/backup system. ■

References:

- BASTIÃO, L., COSTA, C. & OLIVEIRA, J. L. 2011. A PACS archive architecture supported on Cloud services. *International Journal of Computer Assisted Radiology and Surgery*. Springer.

200 Terabytes of Patient Data

syngo.share: TILAK, an association of hospitals in the Austrian state of Tyrol, is implementing one of Europe's largest medical multimedia archives.



"*syngo.share* offers a high-performance, centralized infrastructure that lets us manage the enormous amounts of data handled by TILAK."

Dr. Georg Lechleitner,
Head of the Information
Management Department
for TILAK

With 150 imaging modalities, 400 million objects and 3,300 workplaces, as a multimedia archive solution for TILAK, *syngo.share*^{®*} defines superlatives. Efficient data management helps doctors and nurses worry less about administrative tasks, giving them more time to focus on their patients. The Innsbruck University Clinic and Innsbruck State Hospital are members of TILAK, an association of hospitals in the Austrian state of Tyrol, with 2,200 beds and 100,000 inpatient stays per year. The amount of data that flows through here every day, data that must be managed, stored and easily accessed, is understandably large. The State Hospital also collaborates with Innsbruck Medical University, with the same requirements for efficient communication across institutions. *syngo.share* has been in use here as a universal multimedia archive since 2002. In just a short time, the everyday lives of medical and care personnel have changed in terms of communication, efficient data management and patient care.

Everything is manageable

Overall, around 150 different imaging modalities are used to input data into the *syngo.share*

archive, adding up to two to five terabytes per month – an amount clearly in need of efficient management. Nearly 400 million objects – from DICOM studies to JPEG images to videos – are archived. Numerous subsystems are also linked. This is where the strength of *syngo.share* in processing not just DICOM but other formats as well, including multimedia files, pays off.

From DICOM to multimedia files

A couple of examples show the variety of data that is input and processed. Images from gamma cameras, PET scanners and ultrasound machines, for instance, are uploaded to the *syngo.share* archive from the University Clinic for Nuclear Medicine. At the University Clinic for Radiodiagnostics, the link to an external PACS plays a key role. Radiology data from PACS are stored in the *syngo.share* archive, allowing all 3,300 *syngo.share* workstations to potentially access it. Last but not least, the multimedia archive is linked to the Tirol GNT health care network through an eHealth solution as an IHE XDS repository. Variety, clarity, ease of access – that's the experience that *syngo.share* offers every day. With Soarian[®] Health Archive and *syngo.share*, Siemens now offers a compre-

hensive portfolio for managing digital images and documents in hospitals and other health care institutions. While the focus of *syngo.share* is on images and multimedia, Soarian Health Archive (SHA) is a comprehensive archiving and document management solution.

tilak
Universitätskliniken
LKH Innsbruck

at a glance

6 distributed sites, >2200 beds

26 departments connected

150 different subsystems of
>50 vendors integrated

4.5 million objects per year, therein
520k procedures per year DICOM

>300 million objects in total, therein
5 million DICOM procedures.

"*syngo.share*? It would be simply impossible to manage 150 GB of data produced daily, adding up to a total of 200 TB storage volume online, without such a powerful tool and all its centralized functionalities."

Dr. Dietmar Reiter



"*syngo.share* is our digital multimedia archive. It allows us to manage image data in all formats across modalities stably and reliably."

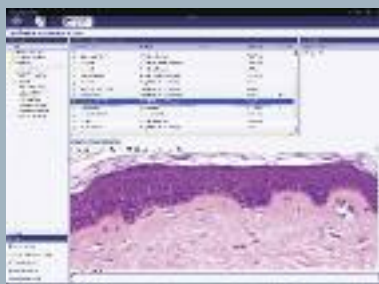
Dr. Dietmar Reiter

Information:
www.siemens.com/syngo.share

syngo.share Top 3 Use Cases

Native non-DICOM and multi-media information management

syngo.share empowers healthcare institutions to efficiently manage and share clinical imaging data comprising DICOM, non-DICOM and multimedia data formats (photo, US, endoscopy, ECG, video, microscopes, scanners, sleeping labs ...). "*syngo.share* makes imaging data available in a patient-centric approach and provides a comprehensive overview of available image information, regardless of the format," said Dr. Arthur Kaendl, CEO of the SYNGO Business Unit, Siemens Healthcare.



syngo.share web-based universal viewer for sharing, importing, exporting and routing of clinical data

A multi-PACS or multi-ology long-term archive

syngo.share unifies the data management and archiving tasks beyond classical departmental or enterprise boundaries. It can serve as connector between multiple Picture Archiving and Communication Systems (PACS), such as *syngo.plaza*. When combining *syngo.share* with *syngo.plaza*, you combine smart data management with state-of-the-art reading of DICOM cases, all over the enterprise. *syngo.plaza* is the agile PACS solution for the clinical routine. It is the first PACS from Siemens where 2D, 3D and 4D reading comes together in one place. In addition, *syngo.share* supports cross vendor connectivity – the customer can leverage already installed archiving solutions, and thus protect the initial investment.



Smooth combination of *syngo.share* (left) and *syngo.plaza* (right), providing same look-and-feel, context-sensitive call-up.

A full IHE XDS and XDS-I compliant repository

syngo.share's flexible interfaces support all major standards to integrate with and exchange information between separate stakeholders and systems. In addition, the system features a modular and scalable architecture which allows you to pick from departmental, enterprise-wide up to regional sharing deployments, providing an IHE-XDS and XDS-I compliant repository. *syngo.share* can act as the formation management backbone for the entire enterprise, potentially addressing all imaging data types in a single archive strategy.



syngo.share offers a unified patient-centric view on all imaging data of a patient beyond classical department boundaries, even across multiple locations of a hospital.

**syngo.share* is a medical device of ITH icoserve technology for healthcare GmbH, Innsbruck, Austria. *syngo.share* currently is not available in all countries.

HOW THE CLOUD WILL REVOLUTIONISE SHARING MEDICAL IMAGE DATA



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Improving Cost Effectiveness & Patient Outcomes

As the global healthcare landscape undergoes monumental change, healthcare IT is becoming a primary enabler of collaboration and cost management. Medical imaging, particularly the ability to move imaged data to the cloud, will create an opportunity for integration of existing technology into a new paradigm. Technological advances, such as the move to digital rather than analogue, are changing medical imaging as an infrastructure, with the potential to create cost savings within the organisation. The challenge is how providers can maximise their imaging systems in order to deliver additional services others cannot provide.

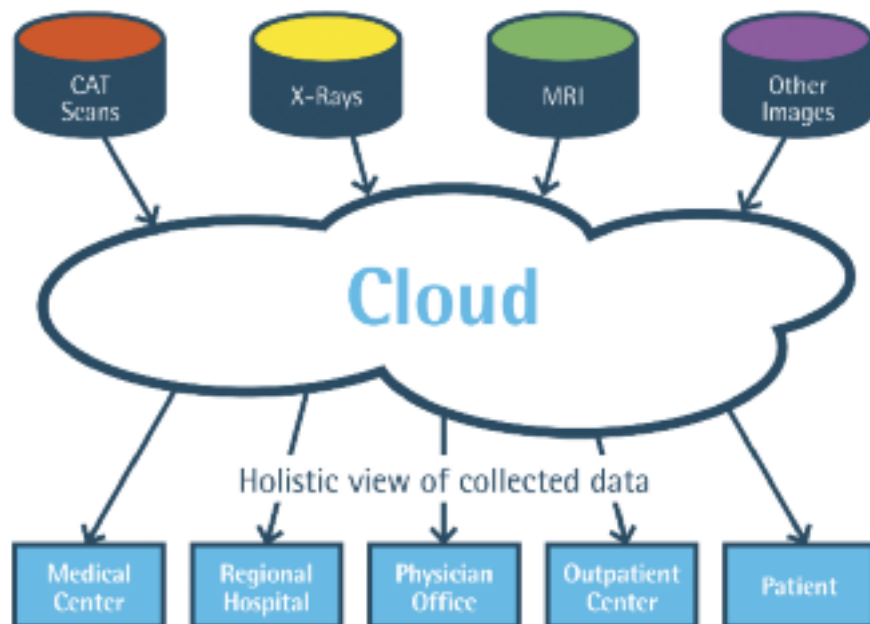
Providers Face Long-Term Issues With Imaging Technology

The use of imaging technology in medicine has exploded since the 1970s, with the introduction and spread of sophisticated CT and MRI systems. As the technologies have moved to digital formats, they create vast amounts of digital image data. While this has revolutionised diagnostics and treatment, it has brought its own problems — the cost of the latest equipment, the volume of image data to be stored and the proprietary nature of the im-

aging systems used. Throughout 2010, five billion imaging studies were conducted worldwide, according to Wikipedia, and a study can include anything from three to 30 images.

Vendors who create the software and hardware used for imaging equipment do so based on knowing the diagnostic problems that need to be solved. But their use of proprietary tags on the imaging data also makes it difficult and very expensive for practitioners to move to a different vendor's products, even if the capabilities to be gained will provide substantial benefits to patients and doctors alike. The cost of data conversion can be prohibitive all by itself, and practitioners ought to avoid maintaining two or more databases with incompatible formats that would make it impossible to maintain one set of records per patient.

For example, administrators at a major university hospital in a European country recently solicited proposals for migrating their information to a centrally managed cloud-service. They had encountered the dilemma of whether to pay their imaging technology vendor a sizable fee to cleanse the data of proprietary tags, so the data could migrate to the new system, or to stay with that vendor's platform even though it would limit their ability to use the data in the future.



In addition, many hospitals today are faced with the growing expense of being required to maintain records for a longer time than they planned. When participating in care studies, for instance, they were paid once for that participation, but now need to maintain the data for 20 years. The problem is even larger for studies using images. The files don't get smaller, they only get bigger, leaving practitioners with terabytes, if not petabytes, of data they have to maintain.

Practitioners can consider new vendors in the future without being trapped in specific data architecture.

Moving medical imaging to the cloud solves the question of long-term viability for both information and budgets, since the data will remain in place and accessible regardless of the imaging vendor. In fact, by separating the data from the specific applications and platforms, providers will be able to consider new technologies without being concerned that they

Roadmap to a Cloud Enabled Business

Organizations are starting their cloud journey with various different initiatives and at various different entry points. Eventually they will need to complete all these actions.

- 1 Develop Strategy including Cloud.
- 2 Design and implement new Governance, IT Organization, and Enterprise Architecture. Select strategic ecosystem partners.
- 3 Select and implement chosen SaaS solutions.
- 4 Replace/ replatform legacy applications. Build new applications.
- 5 Design and implement an agile infrastructure.
- 6 Establish integration services for on-premise and cloud services.

Cloud Solutions Provide Answers

Among the many pressures facing the healthcare industry, reducing costs without impacting patient care remains at the top. A major emphasis in some global healthcare reform efforts is to increase the availability of medical data to several constituencies, which requires standardised access and the ability to exchange health data through electronic medical records. Cloud solutions can provide that shared access.

Economies of scale in sharing data are not available to individual hospitals or practices in the current siloed environment. Cloud solutions offer economic survival through a “buy what you use” structure that lowers the cost of accessing and archiving data-intensive images. Separating the data from proprietary imaging systems also allows importing data from, and exporting to, other sources, whether or not the data was generated by the same imaging technology. Practi-

tioners are backing the wrong horse. This helps create a new, cost-effective clinical infrastructure — an important consideration at a time when costs are becoming one measure included in criteria of the quality of care delivered to patients. Finally, by using data-centric rather than platform-oriented solutions, practitioners can use superior cost performance and streamlined infrastructure to capture a larger share of the healthcare market.

Bring on the Revolution

Cloud computing will revolutionise the sharing of patient medical data and improve both health outcomes and providers' bottom lines. Those who move first to capitalise on this potential will find themselves rewarded with greater operating efficiency and larger market share. Those who don't will find themselves unable to serve their patients effectively. ■

Breast Tomosynthesis Increases Confidence and Reduces Recalls

Clinique Saint Pierre Ottignies Hospital, Belgium

The Breast Clinic in Ottignies, Belgium, about 30 km from Brussels, is equipped with two Hologic Selenia® Dimensions® mammography systems, one of them allowing breast tomosynthesis. The tomosynthesis system, the first in the region, has been available at the Clinic since September 2010.

“Our Breast Clinic hosts a multidisciplinary team, allowing patients to consult specialists in radiological diagnosis, surgery, oncology, and reconstructive surgery within the same premises, which is highly appreciated both by the patients and the medical team. Likewise, psychological support (including talk groups) is available on the site,” declares Dr. Anne-Pascale Schillings, Radiologist and Founder of the Clinic.

Not just a gadget

“It took me awhile to get used to tomosynthesis. My first impression was that the tool was more of a gadget,” confesses Dr. Schillings, “but with time and experience, I discovered that it is

obviously not the case: tomosynthesis is a real help in diagnosis.”

Radiologist and Breast Specialist, Dr. Schillings did not hesitate much before embracing the Hologic system. “I looked at other devices, but I decided swiftly because I liked the Hologic images, Hologic’s customer service and the local Hologic account team. The quality of diagnosis is there, with all the advantages of Hologic,” she says.

“Tomosynthesis allowed us to detect in less than a year a dozen small cancers that otherwise would have been missed, especially for cancers appearing as a stellar structure or as a structural disorganization in dense or heterogeneous breasts.”

“The Clinic does over 7,000 mammograms a year, excluding stereotactic breast biopsies which are done in a medical center attached to the Clinic,” Dr. Schillings says. “We perform breast checkups as individual screenings, follow-up examinations and update diagnosis. The warm welcome that

characterizes our ‘brand name’ is highly appreciated by our patients and improves their compliance to screening and follow-up.”

The breast radiologists at the Clinic view the images generated by the Selenia Dimensions tomosynthesis system on a Hologic SecurView® diagnostic workstation and store the cases on the radiology common PACS system, without any digital overload.

Tomosynthesis for screening & diagnosis

At the Saint-Pierre Clinic, tomosynthesis is used for both screening and diagnosis. For screening, Dr. Schillings believes breast density alone should not influence the choice of performing a tomosynthesis exam.



Dr. Anne-Pascale Schillings (6th from left) and the team of the Breast Clinic at the Saint-Pierre Clinic are proud of the human and personal approach offered to every patient, and of the capacity to offer a treatment of the highest quality on the physical and psychological aspects of breast cancer.



In the first year of use, Dr. Schillings says the Clinic discovered a dozen cancers that would not have been found with common mammography. "Breast tomosynthesis significantly improves our sensitivity, our sense of detail and therefore our performance. We sleep better as we have more confidence in our diagnoses."

"It is obvious that for clear breasts type BI-RADS® 1, tomosynthesis is less useful than for denser breasts. However, we have already diagnosed cancer through tomosynthesis in clear breasts by showing the stellar character of a small opacity appearing banal on standard mammography. However, tomosynthesis is the most useful for breasts of BI-RADS 2 and 3 densities".

And Dr. Schillings goes on: "For us, tomosynthesis has come to be indispensable for diagnosis. Indeed, I do not like to work any more on the second Hologic system, which is not equipped for tomosynthesis. Furthermore, when a patient comes to the Clinic for therapeutic management with an external medical report, even of a very good quality, we now tend to perform an additional tomosynthesis. That allows us to better specify the tumour extension, and sometimes to discover additional abnormalities".

An advantageous technology

"The main advantage of tomosynthesis in our daily practice is to simplify the constructed images, which create opacities on regular pictures," notes Dr. Schillings. "With tomosynthesis, the superposition of tissues disappears. Before tomosynthesis, we had to call back patients with opaque images to take additional pictures in oblique position or centered in a magnified view. Now, tomosynthesis allows us to get the answer with a single click, releasing the patient from the stress of going back to the examination room for additional pictures."

"Besides its usefulness in resolving false positives, tomosynthesis also helps avoiding false negatives. Tomosynthesis allowed us to detect in less than a year a dozen small cancers that otherwise would have been missed, especially for cancers appearing as a stellar structure or as a structural disorganization in dense or heterogeneous breasts."

No increase in working time

The Clinic radiologists do not use the automatic scrolling of images, but scroll them manually. With a little bit of practice, it takes less than one minute to view the additional images. Moreover, the radiologists gain time by avoiding having to repeat studies. Tomosynthesis also allows the radiologists to view lesions in space while searching for anomalies through echography, further reducing the search time.

An enthusiastic team and thrilled patients

The Clinic technologists have rapidly mastered the tomosynthesis technique. During the examination, they explain to the patients that this cutting-edge technology enables a finer analysis of the breast tissues. The patients are reassured and accept easier, that in the case of clear breasts, a traditional echography is not necessary any more.

IS A ZERO CAPITAL EXPENDITURE, MANAGED SERVICE MODEL THE WAY FORWARD?

Trend for Cloud Computing On the Rise



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With decreasing healthcare reimbursement and increasing economic uncertainty, there is a growing trend for hospitals to opt for a zero capital expenditure, managed service model with the purchase of IT systems in healthcare. As the application of managed service models emerges in the PACS market, it paves the way for cloud technology to finally have a significant impact in medical imaging.

“As the UK renews its national PACS programme in 2013, InMedica forecasts that up to 20 percent of revenues will derive from hosted managed models, whereby the storage of images will be cloud-based”

Managed services refer to a model where the vendor owns the IT infrastructure, with the hospital paying a fixed fee per month based on projected examination volumes. The vendor is also fully responsible for maintaining this infrastructure, providing data storage and software on a subscription basis. The benefits of managed services include reducing the need for heavy capital investment in PACS, such as costly in-house IT support staff and IT infrastructure in-

vestment. It also provides regular access to the latest software upgrades and allows flexible storage capacity to suit end-user’s needs.

In any managed service model, the underlying factor is the pay-per-service and third-party hosting or ownership of PACS. There are then different forms of managed services depending on the server location of the two components of PACS - software and storage (see table 1, below).

Cloud storage refers to the storage of the client’s data resting with the vendor or third party. However, PACS incorporates a viewing component (software), as well as the storage of images; the viewing system is actually what many consider as PACS. Hence, the question is, at which point does one begin to class PACS as being cloud-based?

- Is it the moment the software is at a third-party server, onsite?;
- Is it when the storage is remotely available on the third-party server, as in hosted managed services? or
- Is it only when both software and storage components are hosted by the third party, whereby the software as a service lies off-site?

Companies offering cloud-based PACS tend to fall into one of these three categories. It therefore depends on whether the system being offered is considered cloud-based from a software or storage point of view. A pure cloud-based PACS

Table 1

Definitions of Managed Service Models. The terms ‘On-Site’ and ‘Off-Site’ refer to the location of storage server relative to the end-user

Source: InMedica

Managed Service Models	Software Location	Storage Location
Remote Managed	End-user	End-user
Software as a Service On-Site	Vendor/Third-party	End-user
Hosted Managed	End-user	Vendor/Third-party
Software as a Service Off-site	Vendor/Third-party	Vendor/Third-party

may be described as a system where both software and storage components are vendor-hosted.

More important than definitions, of course, is the adoption of this technology. Both the technology and the business model have to work for suppliers and end-users. On the technology side, one might be more confident that vendors will resolve the technical hurdles, such as the quality of the data when transferred between locations and servers, as well as the quality of the interfacing. On the business model side, however, confidence is much lower and many questions remain. These include:

- Will hospitals be completely comfortable with third-party hosting of patient data, regardless of regulatory compliance?
- Will patients be comfortable with this arrangement?
- What about the cost-savings? Is the total cost of ownership over a product's lifecycle significantly different from traditional PACS models?

The major draw for managed service models are their stated cost benefits. Once the return on investment is clearly established penetration of this remote storage model will increase and there will be strong demand for further technological advances in the field. This phenomenon is already taking place in the UK and the Netherlands, for example, where remote managed service models currently account for most managed

service installations being currently provided. However, now that the cost savings from vendor ownership and management of PACS have been realised in these countries, the next wave of demand is for further cost savings, which may be obtained by completely moving storage and/or software to the vendor's site. Indeed, as the UK renews its national PACS programme in 2013, InMedica forecasts that up to 20 percent of revenues will derive from hosted managed models, where the storage of images is cloud-based.

“Despite any technological benefits that cloud technology may provide in medical imaging, what hospitals need to see, and what suppliers need to work on, is an enhanced return on investment”

As such, vendor-hosted PACS and cloud technology in healthcare will emerge strongly by proving an ability to reduce the cost of ownership to the end user. Despite any technological benefits that cloud technology may provide in medical imaging, what hospitals need to see, and what suppliers need to work on, is an enhanced return on investment. ■

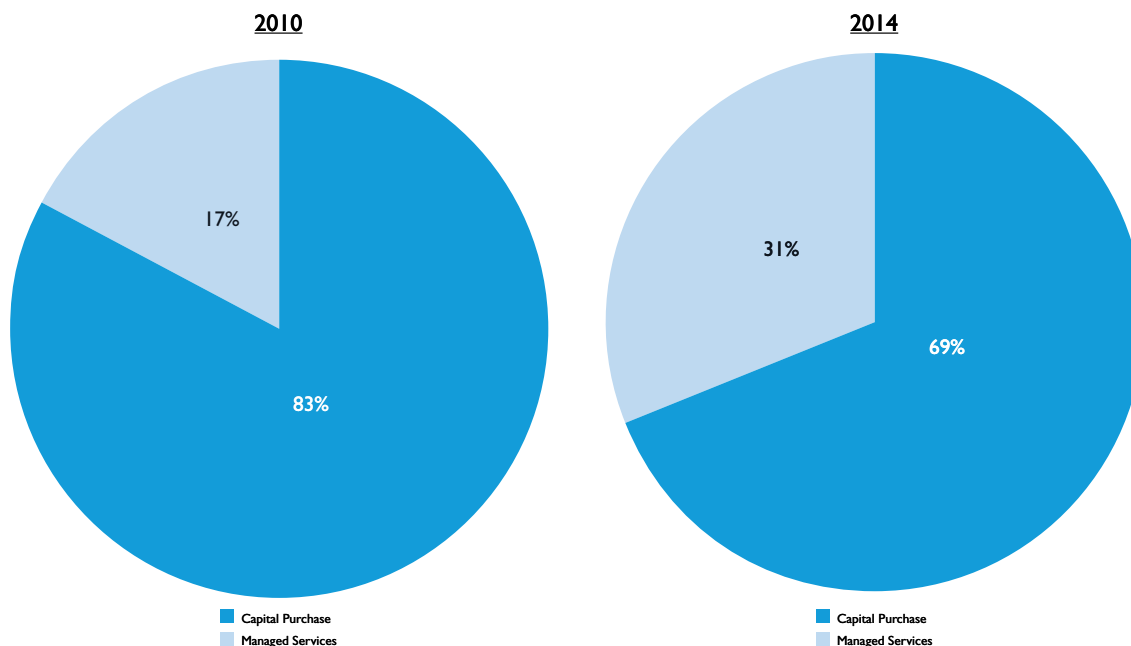


Figure 1
World PACS Revenues by Business Model
Source: InMedica

IMPLEMENTING LOSSY COMPRESSION

The Canadian Story



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Canada is implementing a network of large data repositories designed to store all diagnostic imaging studies generated in hospitals and clinics across the country. There will be 18 such storage units covering all provinces, called DI-r (Digital Images Repositories). The goal of this project is to make all imaging studies available to healthcare professionals, wherever they are, increase efficiency and decrease redundancies in facilitating comparison to previous.

The DI-r will be integrated with the Electronic Patient Records (EPR) and their architecture is based on accepted standards. They will store images for the life of the patient. This will result in a considerable amount of images and therefore drive the need to use lossy compression to decrease the volume of data, to save money and improve transmission times.

Steps Taken for Successful Implementation

1. Assess the need for lossy compression:

Even if the cost of storage is dropping, the savings are surpassed by the increasing amount of data. If we consider a typical radiologist interpreting 40 CT studies per day, assuming 800 images per study with three windows, in three planes (axial, coronal and sagittal), he may review 300,000 images per day, which means 150 GB of storage. If we add comparison to previous, our radiologist may have to review more than 600,000 images in a single day, which would represent 6.6 images per second for 24 hours, which is impossible. This also means that if the cost of storage may have dropped 200 times in 15 years, the amount of data has increased 200 times, and that at the end of the day, there is no savings.

We also have to take into consideration the high cost of operation and time-consuming data migration, which consumes most of the ongoing maintenance budget. We estimate that an average 45 million diagnostic imaging exams were performed last year in Canada, and that the rate of increase has been a steady 5 percent a year. Canada Health Infoway (CHI) is implementing large data storage units (DI-r) across the country to archive all medical images generated in hospitals and clinics and the intent is to retain these images for the life of the patient. Using irreversible compression at 10:1 could save 100 million Canadian dollars per year.

But this is not all; if access to high bandwidth becomes increasingly available in local hospital networks, it is still premature to expect any health professional to use 100 mbps connections on their computers. EHR networks cannot support large medical images and timely access to diagnostic images requires adequate level of compression. This applies also to teleradiology, where turnaround times for report delivery must be as short as possible.

2. Review the types of compression to use:

There are two ways to compress images: lossless or reversible where the decompressed image is numerically identical to the original, such as RLE (Run Length Encoding), or lossless JPEG or JPEG-LS (where JPEG stands for Joint Picture Expert Group), but where only low compression ratios can be obtained, usually no more than 2 or 3:1; lossy or irreversible, where redundant data are discarded during the quantization phase and cannot be recovered, but allowing much higher ratios.

We considered two of the most popular algorithms supported in DICOM, lossy JPEG and lossy JPEG 2000. Technical specificities are not in the scope of this article, but it is worth a reminder that JPEG 2000 is more flexible than lossy JPEG as it supports more image formats, when lossy JPEG is limited to 8 and 12 bit images.

“Canada is in the process of implementing lossy compression of medical images on a large scale”

3. Prove the usability of lossy compression:

To prove the usability of lossy compression, Canada Health Infoway looked at official statements, did an extensive review of the literature, asked for legal assessment from two reputed lawyers, and last but not least, in conjunction with Canadian Association of Radiologists (CAR), asked us to conduct a large-scale clinical evaluation.

None of the official positions we looked at prevent the use of lossy compression: the Foods and Drugs Administration



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(FDA) asks for the compression schemes to be identified by name and the compression ratios to be specifically stated; FDA only excludes lossy compression for mammograms. The American College of Radiology (ACR) endorses the use of compression to increase transmission speed and reduce storage requirements under the direction of a qualified physician, with no reduction in clinically significant diagnostic image quality. DICOM supports lossy compression, but has no position as to particular use of compression.

The literature review covered hundreds of articles published in reputed medical and engineering journals and all concluded that lossy compression could be used with no significant impact on image quality and no loss of diagnostic accuracy within acceptable ratios; some authors even demonstrated a gain in diagnostic accuracy linked to the denoising effect of low level lossy compression. But these articles covered only limited areas of imaging and the evaluation techniques were different from author to author, therefore a need exists for more consistency.

The legal opinions converged to state that lossy compression can be used provided that appropriate ratios are used, there is no clinically significant loss of data, lossy compression is used in primary reading (avoid altering records after primary reading), the technology is not adopted recklessly and due diligence is applied, such as: literature reviews, education, supervision, and finally that technology is used appropriately.

Our large scale evaluation was designed to standardise the disparate evaluation techniques that we encountered in the literature and we opted for a methodology based on two accepted techniques:

1. Diagnostic accuracy with ROC (Receiver Operating Characteristic) analysis where the reader is presented with an image, not knowing if it is compressed or not, and asked to identify a pathology, state in which quadrant of the image s/he sees the pathology and give a confidence rating;
2. Subjective assessment where the compressed image is compared to the original and ranked on scale of 1 to 6.

We covered five modalities (computed and digital radiography, ultrasound, computed tomography, magnetic resonance and nuclear medicine) and seven anatomical/radiological areas (angiography, body, breast, chest, musculoskeletal, neurology and paediatrics). We looked at the two most commonly used compression algorithms, JPEG and JPEG 2000, at three different ratios of compression.

We gathered more than 2,500 exams and enrolled more than a hundred radiologists from coast to coast, with all Provinces represented by one, and had 23 reading sessions with at least five radiologists per session, in order to have enough statistical power. We had designed a dedicated viewer and the radiologists received the images on a CD, that they had to display on the workstations they used for reporting, but the results were collected on-line on a specially designed server application. After two years, we developed a set of recommendations demonstrated in table 1.

4. Publish Canadian standards:

The Canadian Association of Radiologists (CAR) had endorsed the use of Irreversible Compression at its April 2004

Table 1
Recommended Compression Ratios for each Modality and Anatomical Area Investigated.

	CD/DR	CT	US	MR	NM	MG
Angio		10-15		16-24		
Body	20-30	JPEG 10-15 J2K 10	8-12	16-24	9-11	
Breast			8-12	16-24		15-25
Chest	20-30	10-15				
MSK	JPEG 20-30 J2K 20	10-15	8-12	16-24		
Neuro		JPEG 8-12 J2K 8		16-24		
Paediatrics	20-30	10-15	8-12	16-24	9-11	

General Assembly, but waited for the results of our evaluation to be presented to the Executive Committee for approval. The Canadian Standard was issued in June 2008.

This standard validates the use of irreversible compression under certain defined circumstances and for specified examination types. It gives indications for operational implementation, and stipulates among others that irreversible compression, when used, must be considered part of image processing and as such the compressed images are those that are used for interpretation and become the legal record. The compressed images used for interpretation are those that are subject to the requirements for archival storage for the legal retention periods. There is no requirement to maintain raw or uncompressed images.

Which means that radiologists will have to report on compressed images, which they do anyway when they use tel-radiology or report from home.

The standard was modified when validation of the use of irreversible compression for thin slice CT was completed in early 2010. More updates are expected when more validation is completed, mainly for 3D imaging.

“A literature review concluded that lossy compression could be used with no significant impact on image quality and no loss of diagnostic accuracy within acceptable ratios”

5. Implement and identify issues:

We have started to implement lossy compression in different settings, such as several hospital systems and a large tel-radiology network, and of course we started to encounter issues, for which some had not been anticipated. Here are just a few, but no doubt more will appear when adoption of lossy compression becomes more universal.

Implementation of lossy compression would be much easier if we had allowed radiologists to report on the original image and then apply compression when sending the images for long-term storage, but the Standard specifies that images stored must be the same as images read. Therefore, is the PACS able to lossy compress right away, those images received from the modalities for display on the workstations, or should we compress at the modality or between the PACS and the modality? We are currently assessing the ability of multiple vendors to perform compression this way.

There are also compatibility issues, as we need to make sure that there is enough standardisation between PACS vendors to visualise the images on any platform, which means supporting the various algorithms used. This will be even more critical when we start importing images from the DI-r into the local PACS.

The adoption of irreversible compression by an organisation or group of radiologists must be subject to the supervision of a qualified radiologist who must ultimately determine whether the image quality after compression has been applied is acceptable. But how will the radiologist perform quality control? He must be aware of the type of compression used, ensure that the vendor has extensively tested compression after implementation and that recompression is not applied to already lossy compressed images. This is easy, but it becomes more complicated when it comes to access the original image and compare with the compressed image to ensure consistency. More testing is required as modalities evolve, with more advanced processing, new sequences, and new technologies.

Conclusion

Canada is in the process of implementing lossy compression of medical images on a large scale, as it is required to optimise the use of the DI-r, for storage and communication. Even if the CAR published its Standard in 2008, there are still a number of issues that we are addressing with the support of Canada Health Infoway. International collaboration will certainly help greatly to foster adoption of lossy compression thanks to initiatives like the one led by the European Society of Radiology; the International Workgroup on Lossy Compression which met under the auspices of ESR and decided to rename Lossy Compression as Diagnostically Acceptable Irreversible Compression (DAIC) and which has since issued a white paper. ■

DOWNLOAD THE FINAL CANADIAN STANDARD FOR USE OF LOSSY COMPRESSION

www.car.ca/uploads/standards%20guidelines/201004_EN_Standard_Lossy_Compression.pdf

USING EMAIL TO EXCHANGE MEDICAL DATA

German-Wide Pilot Project Proves Operability of Email Based Network



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Introduction

The technological revolution that took place in radiology departments across the globe was first made easier by the implementation of viable Radiology Information Systems, followed by Picture Archiving and Communication Systems, while the DICOM standard was introduced in 1985 to help users communicate. By the end of the century, DICOM had become a matter of course for dealing with medical images - especially those deriving from a radiological background.

“Apart from the relevant DICOM-based email-capable PACS components, all it takes to communicate is a standard email server configured for a high throughput of large amounts of e-mails in shorter times”

While simple, vendor-independent exchange of data among the countless imaging systems was dealt with by DICOM, IHE facilitated a user-led demand for technological implementation based on the more complex, real life scenarios they encountered in their own work. Workflow became the goal for the first decade of this century; at first inside one's own organisation, but soon after also for the integration of external partners. The IHE profile family Cross Enterprise Document Sharing (XDS) underlines that development. As these profiles required a rather complex infrastructure, not all countries have been able to provide the necessary means for establishing that infrastructure. Taking Germany as one of these negative examples, users and vendors took it into their own hands to provide an innovative solution of practical use to overcome these shortcomings.

A Novel Use for Email

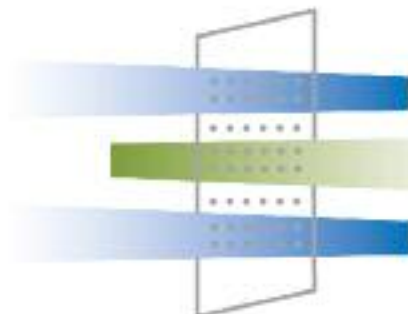
In 2003, a group of users and vendors under the auspices of the German Roentgen Society, created a recommendation for using email as described in the MIME standard,

with attached but encrypted DICOM data as proposed in Supplement 54 of the DICOM standard. Backed by a growing number of vendors who supported this recommendation, DICOM email enables users to build vendor independent networks with moderate requirements for the necessary infrastructure. Apart from the DICOM-based email-capable PACS components, all it takes to communicate is a standard email server configured for a high throughput of large amounts of emails over a short time. Figure 1 (see pg. 30) outlines the principle of a DICOM email communication. The payload (DICOM object) is encrypted using a Pretty Good Privacy (PGP) compatible Public-Key Encryption (Fig. 1 a). All e-mails with the attached encrypted data (Fig. 1 b) will be stored on an email server accessible through the Internet (Fig. 1 c). From this email server, the receiver polls its post-box and downloads the emails. Providing a successful signature check which guarantees the data integrity, the payload (Fig. 1 d) will be decrypted (Fig. 1 e) and the resulting DICOM objects are ready to be integrated into the image workflow on the recipient's side (Fig. 1 f).

Origins of the Project

Considering the experiences and the success of the at present largest DICOM Email Network in Baden-Württemberg, Germany linking 100 participants, the idea was born, to establish a communication platform for the Ruhr region based on the DICOM email standard recommendation of the Teleradiology Network Ruhr. Organisations including Contec, Fraunhofer ISST, MEDECON Ruhr, VISUS and ZTG designed this platform for the vendor-independent support of radiology in the Ruhr region. Due to the involvement of industry in the project, it was clear that the administration of such a network must be neutral. Therefore, an independent operating company was established.

In contrast to its counterpart in Baden-Württemberg, the Teleradiology Network Ruhr planned to be centrally administrated in order to provide as much service as possible. To achieve this, the use of a kind of central directory service managing all information necessary for setting up a communication link was planned for the time the network enters its normal operation phase.



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A Project in Two Phases

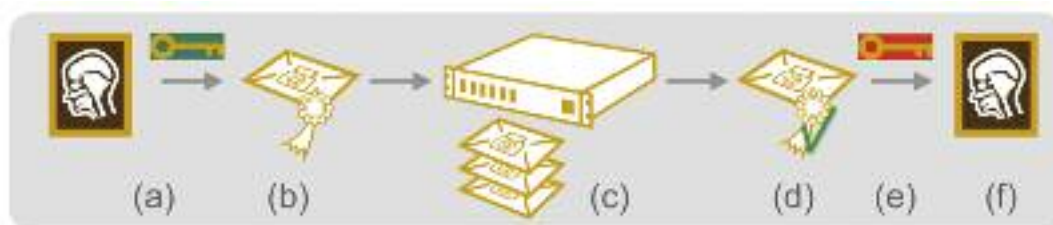
The whole project was divided into two phases; a sponsored pilot phase and a self-supporting routine operation phase. The pilot phase was planned with 20 participants starting in October 2010 and ending on December 31, 2011. In order to actually reach the critical number of necessary participants for such a network, all participants of the pilot phase have been granted a DICOM email gateway, together with project management, configuration and usage of the email server free of charge throughout the pilot phase. The

Pilot Installations of DICOM Email Gateways

The pilot installations of the DICOM email gateways went smoothly. The idea of opening ports from inside the firewalls in order to grant access to the email server on the internet caused no problems with any of the administrators. The greater challenge has been to actually get the necessary signatures from participants as their administration sometimes slowed the process down. That affected the whole rollout process of the gateways. Nevertheless by April 2011, the number of gateways installed reached 28.

Figure 1

Schematic DICOM Email Transmission



objectives for the pilot were for the participants to test the usage of the platform as a mail replacement, for the network administration to execute the testing of the platform itself and the fine-tuning of the different workflows such as deployment, building the Public-Key Infrastructure and establishing the support.

It became obvious that this was the "critical mass" for a healthy network. Suddenly, the mark for gigabytes being sent was pushed from around 10GB to 60GB per month.

The pilot phase was also designed for developing the software for the directory service as described above. However, as we did a survey prior to the kick-off of the network, it was obvious from the start that while a mere mail replacement is certainly of interest as a basic service, the survey showed participants' great interest in teleradiology scenarios to either share one's workload or provide reporting capacities. Due to high demand, the original number of pilot installations needed to be corrected from 20 to 35, which still left another 35 potential interested parties that are waiting to be connected with the start of the regular operation phase.

Regarding the number of transmissions before and after that point, it became obvious that this was the "critical mass" for a healthy network. Suddenly, the mark for gigabytes being sent was pushed from around 10GB to 60GB per month. Due to its great success, the number of pilot participants was also extended to 35 gateways and 11 DICOM Mail Clients. Reaching an install base of about 20 gateways, the manual management of all the gateway connections became a demanding job, as with the installation of each new gateway all the already installed gateways needed to be updated with the communication data of the new gateway. This clearly shows the importance of having a directory service to manage these configurations.

Directory Service an Important Asset

The development of the directory service has made good progress and the first tests are promising for a start with the beginning of the normal operation phase intended during 2012. In order to provide the services vendor-independently, the DICOM Email recommendation is currently being set up to receive an update so that the directory service can be reached using DICOM Email only. The update can be expected for mid-2012.

Figure 2 outlines the data-flow between an image provider (hospital) and an image consumer (healthcare centre). The hospital sends its images directly from its PACS using the

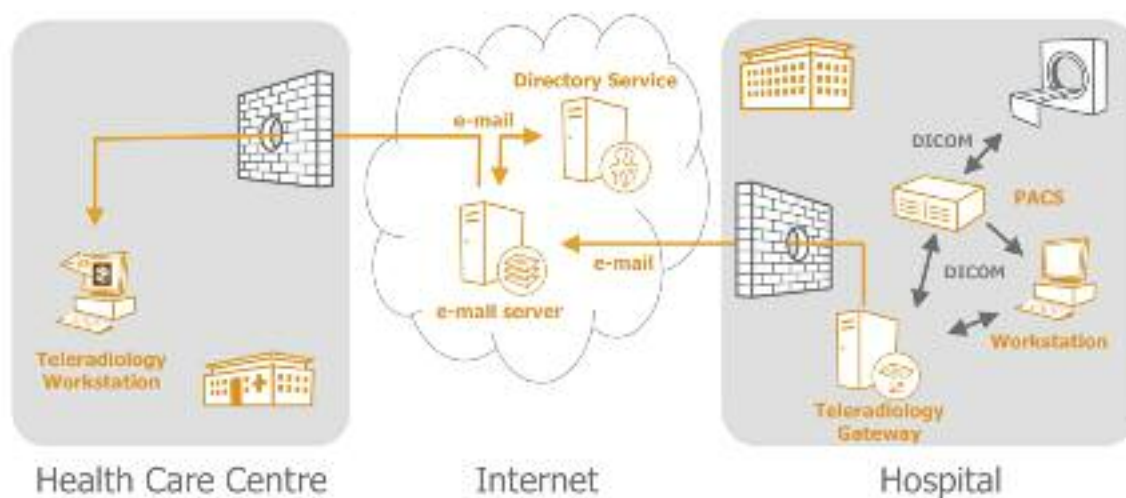


Figure 2

Example of a Set-Up Using DICOM Email

teleradiology gateway as a communication server, which transforms the DICOM images into DICOM Emails. These emails are being sent to the email server of the network. On the other side the teleradiology workstation downloads these emails and converts them into DICOM images, which can be displayed with the viewer of that workstation. This scenario shows a very effective and reliable setup for exchanging images electronically without the need for a big PACS infrastructure on either side.

Next Phase in the Works

With the beginning of normal operations, it's also planned to initiate the next development phase for enhancing the services of the platform for the support of Stroke Units, the treatment of heart patients as well as supporting research and education.

In conclusion, setting up a new network platform based on DICOM email has successfully been proven. It is neces-

sary to reach a critical mass of users before a network has the potential to be of use in the future. To reach that "mass" it is of help to have some financial support for the starting phase but it is essential that the structure is able to be financially independent by the time it reaches its routine operation.

The technique of using email for exchanging medical data contributes to the success of network construction, as it limits the technical challenges to an absolute minimum. Using a dedicated email server with a configuration for high throughput doesn't seem to cause greater problems in regards to stability and transmission speed. Problems only occur if the sender has a substantially greater bandwidth than the receiver, leaving him no chance to draw all the emails from his account.

Entering routine operation is only the first step for the platform. The potential lies in the upcoming services, which will be provided over the next years with an application spectrum from simple mail replacement to real-time collaboration and a service spectrum from unattended to a 24/7 support. ■

FURTHER RESOURCES

1. DICOM, <http://www.dclunie.com/dicom-status/status.html#AcrNemaI985>
2. DICOM, <http://en.wikipedia.org/wiki/DICOM>
3. IHE, http://wiki.ihe.net/index.php?title=PCC_TF-1/History
4. XDS, http://ihewiki.wustl.edu/wiki/index.php/XDS_Main_Page
5. DICOM Email standard recommendation, <http://www.tele-x-standard.de>
6. Multipurpose Internet Mail Extensions (MIME), <http://en.wikipedia.org/wiki/MIME>
7. DICOM E-Mail, ftp://medical.nema.org/medical/dicom/final/sup54_ft.pdf
8. Public Key Cryptography, http://en.wikipedia.org/wiki/Public-key_cryptography
9. Teleradiology Network Baden-Württemberg, <http://www.teleradiologie-rnd.de/>
10. Teleradiology Network Ruhr; <http://www.teleradiologienetzwerkruhr.de/>

MULTIMODAL IMAGING

The Imaging Technology of the Future

Insight by:
Frost and Sullivan

Multimodality imaging is widely considered to involve the incorporation of two or more imaging modalities, usually within the setting of a single examination using, for example, dual- or triple-labelled optical or nuclear medicine “reporter” agents or by performing ultrasound or optical studies within the MR, single-photon emission computed tomography (SPECT), or x-ray computed tomography (CT) environment.

Rapid Evolution a Hallmark

Clinically, the best example of multimodality imaging is now being seen in the rapid evolution of PET-SPECT and PET-CT scanner hybrids. The PET modality has developed into perhaps the most used multimodal imaging method. The incorporation of PET into single, hybrid, and multimodality units to provide functional (typically from injected F-18DG studies) and anatomic information is becoming extremely popular, so much so that, for example, PET/CT hybrids can be found in outpatient screening centres located in shopping malls.

“MR-PET (or MRI/PET) is the future of multimodality medical imaging. Several prototypes are undergoing research and one institution – the Brookhaven National Laboratory – has announced licensing opportunities for a prototype device that it has developed”

The role of any multimodal imaging approach should ideally provide the exact localisation, extent, and metabolic activity of the target tissue, yield the tissue flow and function or functional changes within the surrounding tissues, and in the process of imaging or screening, highlight any pathogenic changes leading to eventual disease. Multimodal clinical NM, PET, and MRI techniques have, to date, fallen into the growing fields of molecular and functional imaging for primary-to-metastatic cancer screening of the body, neuro-assessment of gliomas, integrated stroke imaging exams, and functional neuroimaging exams

In current medical imaging practice, image fusion has substantially expanded the scope of non-invasive exploration of

the human body. Image fusion/co-registration can be performed intra-patient or extra-patient. Intra-patient image fusion is the true form of image co-registration and requires specially designed equipment that has dedicated instrumentation for each modality. The latter involves fusion of images with the help of mathematical algorithms and computational power. Such software-based fusion techniques are performed by identifying and aligning landmarks or fiducials. Image fusion extends exploration by combining details of anatomy with function captured using various cross-sectional modalities. Only instrumentation-based image fusion innovations are described here.

PET/CT and SPECT/CT

This multimodal imaging technique involving the combination of nuclear imaging and x-ray scanning is a fusion of anatomic and functional imaging. Pioneered at the University of San Francisco by Hasegawa et al., the first commercial designs were the Hawkeye SPECT/CT from GE in 1999. PET/CT hybrid scanners arrived on the market within the next three years, pioneered by researchers at the University of Pittsburgh. Co-registration of PET with CT enables anatomic localisation of F-18-FDG accumulation, thus improving specificity of lesion detection.

Further, the combination bypasses the need for photon attenuation correction owing to the differences in the energy spectra of X-rays and 511 keV gamma rays. Attenuation correction is performed through the formation of an attenuation map using the CT part of the instrument. In regular PET scans, attenuation correction is performed through a blank scan of the transmission source and the patient before administration of the radionuclide. Most marketed SPECT/CT scanners incorporate a dual head gamma camera coupled to two 64-slice CT equipment. PET/CT scanners have full ring PET modules and have up to 64 slice CT capacity. Sattler et al. (2010) estimated that PET/CT scanners have replaced 75 percent of all stand-alone PET systems installed in Europe.

MR-PET

MR-PET (or MRI/PET) is the future of multimodality medical imaging. Several prototypes are undergoing research and one institution – the Brookhaven National Laboratory – has announced licensing opportunities for a prototype device that it has developed. As discussed earlier, the PET

detectors will have to be devoid of PMTs and will have to incorporate alternatives such as solid state technology. Incorporating PET cameras and MRI coils into the same gantry is the most prominent concern in developing a combined instrument. The prototype developed by Brookhaven National Laboratory involves a PET detector assembly concentric to MRI coils. The PET detector used is basically an LSO scintillator coupled with a Hamamatsu S8550 APD.

The design owes to the institution's RatCAP small animal scanner that is completely 3D and is used to image live rat brains. The RatCAP scanner also has an improved readout circuit (front end ASIC, preamplifier, and signal system) that produces less noise. Among the manufacturers of PET and MRI who have ventured into development of MR-PET machines are Siemens and Philips. Each of them has developed separate perspectives about the positioning of the PET camera module in relation to the MR coils. Siemens has developed a prototype in collaboration with researchers from the University of Tübingen and the University of Tennessee, which is undergoing trials in Germany. The prototype is very similar to the model available for licensing from Brookhaven National Laboratory. It uses APD as the workhorse and is being evaluated as a tool for

brain imaging. Attenuation correction is performed on the basis of the MR image by identifying landmark regions.

Concluding Remarks

During the last decade, considerable progress has been made in the development of anatomical and functional imaging modalities and supportive software, leading to rapid and accurate data acquisition and analysis. This has enabled imaging to be used more broadly to aid diagnosis, identify disease stages and support treatment and patient monitoring. In many cases the price has decreased and accessibility has increased, facilitating the use of medical imaging as an integral tool in the physician's armory to detect and treat disease. In return technological breakthroughs have allowed surgeons to migrate towards less invasive medical procedures and early treatment intervention as multimodal systems and novel imaging agents enhance their ability to stratify patients through accurate and educated treatment decisions. New contrast agents, detectors and computer aided programs will guarantee this innovative market continues to meet the demands of the consumer helping to ensure the right treatment for the right patient. ■

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Pisa, Italy

Targeted Training Efforts Succeed in Bridging Knowledge Gap

Please tell us how you became interested in the study and promotion of radiation safety.

I am a cardiologist and a Senior Medical Researcher for the Italian National Research Council at the Institute of Clinical Physiology in Pisa. I am a clinical cardiologist with experience in the Intensive Care Unit (ICU), database and epidemiological studies. In the last ten years our institute and its present director, Dr. Eugenio Picano became pioneers in the development of new practice models to improve the economic, social and biological sustainability of medical imaging. These underlying principles were the basis for my interest in the field.

“Cardiologists prescribe and/or directly perform >50 percent of all imaging examinations, accounting for about two thirds of the total effective dose to patients”

What is your opinion on the debate over who is responsible for errors in radiation safety; the department chair, policy-makers, or the individual technologist?

In my opinion the responsibility for errors in radiation safety lies at each level within an organisation. Policy makers have the power to influence or determine policies and practices and should take into account the problem of radiation safety. Doctors should know the level of radiation that their patients are exposed to during radiological investigations and should avoid inappropriate radiological prescriptions and should correctly inform patients about the procedure. Technologists should be aware of the mechanisms to evaluate appropriate dose level and to use the “as low as rea-

sonably achievable” dose (the ALARA principle). Patients should be required to sign an explicit and transparent informed consent form for each radiological examination. This will make doctors and patients more likely to consider the risks as well as the benefits as well as helping to reduce pressure from patients for redundant examinations.

You have investigated the low awareness of radiation safety issues amongst cardiologists. Why are cardiologists an interesting target group for increased awareness in this particular area?

Cardiologists prescribe and/or directly perform >50 percent of all imaging examinations, accounting for about two thirds of the total effective dose to patients. Three types of procedures were responsible for about 86 percent of the total collective effective dose: arteriography and interventional catheterisations, nuclear cardiac procedures and CT. Moreover, as interventional cardiologists, they are the most at risk amongst exposed professionals (their professional exposure being three times higher than radiologists). Their knowledge of the doses and risks of ionising testing is low and this lack of awareness is true for all classes of doctors. These are the main reasons for the growing interest of the cardiology community towards the radiation issue.

Can you tell us about your work to improve this knowledge amongst cardiologists?

The study’s hypothesis is that radioprotection unawareness can be modified with a brief, targeted teaching effort. The aim of the study was to assess radioprotection awareness of physicians (mainly cardiologists, but also general practitioners) before and after a one-day intensive radioprotection primer course, which consisted of six classroom lessons. Each attendee was asked to answer a multiple-choice test at entry and again at the end of the class. In each of the 403 attendees who completed the study, their radiological awareness score improved.

What were the conclusions of this research?

Awareness of radiological doses and risks, albeit essential for risk–benefit assessment of radiological testing, is limited among physicians. However, it can dramatically improve by means of a limited teaching effort through targeted training.

What should cardiologists do to protect their patients when prescribing imaging tests?

Cardiologists, as with any class of doctors, should prescribe only appropriate procedures following guideline indications. Moreover, when it is possible, I would suggest choosing a radiation free procedure (echography or magnetic resonance versus myocardial scintigraphy and CT) to minimise the radiation injury hazard to their patients.

“I would suggest choosing a radiation free procedure (echography or magnetic resonance versus myocardial scintigraphy and CT) to minimise the radiation injury hazard”

Can you tell us about the SUI-Heart (Stop Useless Imaging Testing in Heart disease) Project of the Tuscany region?

The SUI-Heart (Stop Useless Imaging Testing in Heart disease) project was funded by a grant of the Istituto Toscana Tumori (Tuscany Institute for Cancer), and co-funded by an unrestricted scientific grant of Banca Popolare del Cassinate for the economic sustainability of medical testing. The SUI-HEART project started to reshape current clinical cardiological practice, with a paradigm shift based on expanding physician knowledge. The project is organised into six main thematic sub-projects targeting different objectives; these are in the clinical, radiological-radioprotection, economic, informatics, patients’ rights and oncology areas. The result is expected to improve the quality of medical care, lower healthcare costs, and move a substantial step towards more sustainable application of medical imaging in contemporary medicine. The project was financed by the Regional Institute of Cancer. We believe that patients, doctors and our society will benefit from the project.

Can you tell us about Radio-Risk software, developed by yourself and colleagues with the aim of providing more user-friendly risk evaluation?

The purpose of this work was to develop user-friendly software for simpler estimation and communication of radiological risk to patients and doctors. The software programme allows estimation of cumulative radiation dose starting from a predetermined menu of variables relating to natural (e.g., airplane flights and geo-tracked background exposure), professional (e.g., cath lab workers) and medical (e.g., CT, cardiac scintigraphy, coronary stenting) sources.

What parameters does the software use in its evaluation of long-term cumulative risk in patients?

For each reference effective dose, cancer age- and gender-weighted risks were derived from the BEIR VII Committee report of 2006.

What does current knowledge tell us about the percentage of patients who develop negative side effects from an excess of radiation from x-rays taken over a lifespan?

The risk estimates are based on studies from populations exposed to a range of doses, such as the Japanese atomic bomb survivors. The risk from diagnostic x-rays is invisible, long-term and cumulative. It is significantly modulated by polymorphisms of genes involved in DNA damage and repair such as the BRCA1/BRCA2 mutation. The target molecule is DNA, and target cells are actively dividing somatic cells for cancer effects, embryo cells for teratogenic effects and germ cells for adverse hereditary effects.

The updated risk estimates were released in the Seventh Report of the authoritative Committee to Assess Health Risks from Exposure to Low Levels of Ionising Radiation (BEIR VII report), which provides a framework for estimating the lifetime attributable risk of cancer incidence from radiation exposure using the most current data on the health effects of radiation. A 64-slice CT coronary angiography without tube current modulation is associated with a cancer risk ranging from one in 143 for a 20-year-old woman to one in 5,017 in an 80-year-old man for a scan performed with tube current modulation. Females are at higher risk than males and children at higher risk than adults. According to these estimates it is predicted that for an adult, an effective dose of 100 mSv results in a risk of cancer of approximately of 1 out of 100 exposed patients. About 42 additional people in the same group would be expected to develop solid cancer or leukemia

from other causes. Current risk estimates suffer from some degree of approximation and uncertainties – it can be two or three times higher, or lower, than current estimates.

In what ways did you make the Radio-Risk software solution accessible and user friendly?

The programme is fully downloadable at <http://suit-heart.ifc.cnr.it>. The software uses simple graphic display (for cumulative temporal trends of exposure, cancer cases out of 100 exposed persons and risk equivalent).

Finally, what are your key pieces of advice to those prescribing and performing radiation involved exams?

Common sense, deontological code, patients' rights, medical imaging guidelines and Euratom law all recommend the justified, optimised, responsible and informed use of testing with ionising radiation. Many imaging technologies offer diagnostic benefits and should be prescribed if appropriate following the principle that each patient should get the right imaging exam, at the right time, with the right radiation dose. ■

A NOVEL TOOL FOR USER-FRIENDLY ESTIMATION OF NATURAL, DIAGNOSTIC AND PROFESSIONAL RADIATION RISK: RADIO-RISK SOFTWARE.

In 2010 the International Atomic Energy Agency launched the "3 A's campaign": Audit, Appropriateness and Awareness for radiological justification, which is an effective tool for cancer prevention. Cardiologists prescribe the majority of radiological testing, but their awareness of doses and risks of ionizing cardiac imaging test is low. To assess radioprotection awareness of prescribing and practicing physicians (mainly cardiologists) before and after a radioprotection course, organisers held a one-day six hour primer of radioprotection for a limited number (20 - 35) of physicians. Awareness of radiological doses and risks, albeit essential for risk-benefit assessment of radiological testing, is suboptimal among cardiologists, but can dramatically improve with a limited teaching effort through targeted training.

BACKGROUND:

Awareness of radiological risk is low among doctors and patients. An educational/decision tool that considers each patient's cumulative lifetime radiation exposure would facilitate provider-patient communication.

AIM:

The purpose of this work was to develop user-friendly software for simple estimation and communication of radiological risk to patients and doctors as a part of the SUIT-Heart (Stop Useless Imaging Testing in Heart disease) Project of the Tuscany Region.

METHODS:

The researchers developed a novel software programme (PC-platform, Windows OS fully downloadable at <http://suit-heart.ifc.cnr.it>) considering reference dose estimates from American Heart Association Radiological Imaging 2009 guidelines and UK Royal College of Radiology 2007 guidelines. Cancer age and gender-weighted risk were derived from Biological Effects of Ionising Radiation VII Committee, 2006.

RESULTS:

With simple input functions (demographics, age, gender) the user selects from a predetermined menu variables relating to natural (e.g., airplane flights and geo-tracked background exposure), professional (e.g., cath lab workers) and medical (e.g., CT, cardiac scintigraphy, coronary stenting) sources. The programme provides a simple numeric (cumulative effective dose in milliSievert, mSv, and equivalent number of chest X-rays) and graphic (cumulative temporal trends of exposure, cancer cases out of 100 exposed persons) display.

CONCLUSIONS:

A simple software programme allows straightforward estimation of cumulative dose (in multiples of chest x-rays) and risk (in extra percentage of lifetime cancer risk), with simple numbers quantifying lifetime extra cancer risk. Pictorial display of radiation risk may be valuable for increasing radiological awareness in cardiologists.



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PROS AND PITFALLS OF PAEDIATRIC CONTRAST-ENHANCED ULTRASOUND

Work Underway to Assess its Utility in Common Practice

Despite the widespread use and proven efficacy of ultrasound (US) contrast media in the adult population, as showed in Table 1 (see pg. 39), contrast-enhanced US (CEUS) has not achieved the same level of diffusion in the paediatric population. The rare reports in the scientific literature denote their sporadic and experimental use, most likely in off-label use. Only Levovist® (Bayer-Schering Pharma AG, Germany) is approved for use in children and adolescents and only for the indication of vesico-ureteral reflux study. At the same time production of Levovist® has ceased and it is no longer available. SonoVue® (Bracco Spa, Italy), performs equally well for this particular indication, and for others but it has to be used off-label.

CEUS in Children: Looking Ahead

The current use of CEUS in paediatric work-up in Europe is a sensitive topic. CEUS in paediatric applications remains of critical importance, because of its obvious benefits compared to alternative imaging modalities, which in most cases necessitate exposure to ionising radiation and the use of potentially harmful contrast agents. The benefit of avoiding ionising radiation is clearly far more important in children and adolescents than in adult patients. However the effectiveness and safety of contrast media use in patients <18 years has not been evaluated and their use in these patients is not advisable. There are probably various reasons why US contrast media use in children has not been validated. These include the lower incidence of focal lesions, particularly hepatic lesions in children, and technical reasons: indeed, by using higher frequency transducers, improved sensitivity to vascular flow can be achieved. Then, of course, there are the potential medico-legal consequences in the case of adverse events.

Experimentation with medications in children has always been limited, for two main reasons:

Economic: lack of interest on the part of companies to invest in the paediatric population, which is relatively healthy, with specific studies on efficacy, safety and toxicity.

Ethical: difficulties encountered in subjecting children to the risks involved in experimentation.

Further problems encountered in drug trials in paediatric populations include the tendency to exclude children from phase I trials, with a consequent slowing down of the process as well as:

- The presence of stricter legislation;
- Use of a small patient population;
- Difficulty enrolling children and obtaining an adequate

supply of biological samples and,

- The possibility of adverse events that may only become apparent in the long term and therefore go unnoticed unless long-term studies are undertaken.

Currently, the rare reports in the literature concerning such use in children indicate only sporadic and experimental use as shown in Table 2 (see pg. 39). For these reasons US contrast media is currently used in children for off label only, i.e. the use of approved medications for non-approved indications (dose, age, administration route, indications and contraindications) for which the scientific evidence suggests their rational use even in clinical situations not approved by regulations. Moreover there are no specific guidelines available for the off-label use of medications.

The therapeutic activity of the physician is instead currently reputed to be fully legitimate only when the medication has

“We are proposing an international working group to bring together the different experiences that can help to draft new guidelines on the use of CEUS in children with the aim to obtain regular use in daily medical practice”

been previously approved by the regulatory body for the same route of administration, dosage or therapeutic indication for which it is effectively prescribed to the patient. In individual cases the physician may, under his [or her] own liability (extended to the head physician when the off-label prescription

▶ Cardiological examination	Analysis of abdominal trauma
▶ Vascular examination	Evaluation of scrotum: torsion of the spermatic cord, segmental infarction, trauma, inflammation, tumors
▶ Characterisation of focal liver lesions and hepatocellular carcinoma	Evaluation of renal function, renal ischaemia, renal artery stenosis, renal focal lesions, renal infections
▶ Characterisation of pancreatic masses and pancreatitis	Evaluation of bladder emptying and vesico-teretic reflux
▶ Splenic tumor detection	Contrast Enhanced Endoscopic US (CE-EUS)
▶ Evaluation of inflammatory bowel disease	Intraoperative Contrast Enhanced Ultrasonography
▶ Searching for primary or metastatic tumors	Evaluation of lung and pleural lesion
▶ Inflammatory joint disease	Lymph Nodes
▶ Prostate cancer	Evaluation of patency of Fallopian tubes

Table 1

Some applications of Contrast Enhanced Ultrasonography

takes place within a hospital or in the university setting) and after having informed the patient and acquired the patient's consent, use an industrially produced medication for an indication, route of administration, manner of administration or non-approved use. Although it should be noted the formalisation of consent can in no way whatsoever involve mitigation of the level of qualified liability required by the physician, or the acceptance of inadequate treatment or treatment lacking therapeutic justification. There is an apparent need to define requirements, obligations and liability of the physician prescribing off-label medications, in accordance with the laws in force.

The desirable use of contrast media, as in CEUS, even in children, does not imply a decision based on therapeutic need, as the examination is diagnostic in nature and preferable to others that, despite being effective are biologically invasive (the use of ionising radiation, the need for narcosis, etc.). Rather, the diagnostic efficacy of the product and, above all, the scarcity of its side effects provide substantial reasons for supporting the use of this kind of diagnostic instrument both in children and in adults. In this sense, the clear provisions of the Regulation of the European Community No. 1901/2006 dd. 12 December 2006 regarding medications for paediatric use should be followed. With the aim to "facilitate the development and accessibility of medicinal products for use in the paediatric population", the regulation provides for:

- Ongoing improvement of the information available on the use of medications in different paediatric populations;
- Constant updating of analyses on the use of medications in paediatrics, including all forms of off-label use;

- Careful analysis of the existing paediatric medicinal products in order to ascertain the consistency with the favourable scientific evidence in terms of the paediatric risk-benefit profile;
- Standardising, in the setting of a paediatric study framework, indications, dosage, contraindications and precautions for paediatric use of products that contain the same active ingredient.

This regulation undoubtedly indicates a way ahead for safe and certain experimentation that could approve the use of CEUS in paediatric populations and therefore enable the US radiologist to break free from the use of contrast media in an off-label framework.

Conclusions

There is a need to draft new guidelines on the use of CEUS in children to overcome the dichotomy between a strict regulation for an official registration of medical drugs and the absence of specific guidelines available for its off-label use. For these reasons, the physician is on his (or her) own in terms of liability when faced with the decision to use CEUS in children. We are working to assess the efficacy of CEUS in two strands of applicability: trauma and cancer according to the law in force to extend its possible and often decisive use to this category of patients. We are proposing an international working group to bring together the different experiences that can help to draft new guidelines on the use of CEUS in children with the aim to obtain regular use in daily medical practice. ■

▶ Historic (or Classic) Applications	Evaluation of vesicoureteral reflux: urosonography Evaluation of traumatic injury (liver, spleen, pancreas) Evaluation of gastro-oesophageal reflux
▶ Atypical (or Border) Applications	Diagnosis of Meckel diverticulum Evaluation of epiploic appendicitis Evaluation of revascularisation flow in Perthes' disease Diagnosis of acute appendicitis
▶ Future Applications	Evaluation of vascular disease (Angioma, Arterio-Venous Malformations) Advice in pediatric oncology for solid tumors (for example, Osteosarcoma, Neuroblastoma, etc.) Increase in diagnostic confidence for doubtful twisting of testicles, above all in infant and toddler

Further Reading:

- [1] Piscaglia F. et al. (2011) "The EFSUMB Guidelines and Recommendations on the Clinical Practice of Contrast Enhanced Ultrasound (CEUS): Update 2011 on non-hepatic applications" *Ultraschall in Med DOI* <http://dx.doi.org/10.1055/s-0031-1281676>
- [2] Drug Package Insert *SonoVue® (2008) Bracco Imaging S.p.A.*
- [3] Esposito F. et al. (2011) "Ultrasound contrast media in paediatric patients: is it an off-label use? Regulatory requirements and radiologist's liability" *Radiol med* 116:000-000 DOI 10.1007/s11547-011-0718-1

Table 2

Possible application of CEUS in the paediatric age



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THE ECONOMICS OF INTERVENTIONAL RADIOLOGY

Is IR Cost-Effective?

Healthcare teams naturally strive to provide patients with the most effective treatments, resulting in the best possible clinical outcomes. There are however, inevitable budgetary limits to which treatments and procedures can be made available. The economic impact of clinical decisions should therefore always be considered, especially as new technologies become available and costs rise. This is as true for interventional radiology (IR) as it is for any other specialty, especially given that IR is a technology-centred branch of medicine and is often perceived as expensive.

Maximum Health at a Reasonable Cost

Whereas healthcare professionals may treat patients without full consideration of costs or affordability, hospital managers are often perceived as being in opposition and might focus primarily on budget containment. Budget management is, of course, necessary but it is important not to forget the end objective of healthcare, which is to produce health, and not just save money for its own sake. Many IR techniques have revolutionised the clinical management of certain diseases and so they deserve to be considered and should not be rejected outright due to an assumption of high cost.

As budgets are not infinite, the reality of modern health-

“Only radiologists themselves are in a position to influence funding decisions around IR, as managers may be too focused on the up-front costs”

care is that decision-makers and payers consider economic as well as clinical data when making difficult funding allocation decisions. The costs of a treatment are weighed up against the benefits it provides, the legitimate aim being the production of maximum health at the most reasonable cost. In other words, the goal is to obtain value for money, which is often measured in terms of cost per quality-adjusted life-year (QALY).

In the UK, for example, the cost-effectiveness of a new treatment is conventionally assessed as an incremental cost-effectiveness ratio (ICER), which is derived from a comparison of the new treatment's cost-benefit ratio to that of the conventional treatment. In the UK healthcare system, such assessment is based on decision making at the National Institute for Health and Clinical Excellence (NICE) and to be

deemed cost-effective a treatment usually requires an ICER below UK£20,000 - £30,000.

Understanding Economics to Defend IR

As well as being aware of the economic landscape of healthcare as a whole, it is useful for radiologists to know some detail about the methods involved in the economic evaluation of treatments and procedures. This will enable them to engage effectively with managers, who might seek to veto a valuable therapy for reasons of cost.

Decision-makers want to be sure that the outcomes of an expensive procedure justify the high purchase cost, so if the long-term benefits of an expensive intervention can be demonstrated then the intervention is more likely to be approved. An IR treatment option that is expensive at face value can often turn out to be the most prudent choice if it saves costs in the long run and is appropriate for the patient group in question. Interventions that offer the best ratio of costs and effects are the ones that should be prioritised and preferred. After asking if a new therapy works, the next natural question should address the cost for society and ask whether the therapy represents value for money.

Is IR Worth the Investment?

Being minimally invasive also means that in many circumstances, IR procedures are an improvement upon the conventional treatment in that they are more effective and less costly. Using imaging to guide biopsy is an example of this, as the alternative (e.g. an open surgical biopsy) is likely to have higher risks and be more expensive. On the other hand, some of the devices that interventional radiologists use do entail comparatively high spending in terms of the initial cost of the device, but this is usually offset by savings in other areas. Although hard to quantify, it is also notewor-

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thy that patients tend to prefer IR treatments due to their being minimally invasive.

Being minimally invasive also means that IR patients may not need to spend time in high dependency care (ITU/HDU) and have reduced hospital stays generally, which produces significant cost savings. This is one of the reasons that interventional radiological techniques have often replaced invasive surgery such as in the common use of vena cava filters to prevent pulmonary embolisation; no-one would now consider performing the surgical alternative of open IVC ligation.

Often the value of IR lies in it being lower risk compared to the alternative surgical procedure. Aortic stent grafting to treat traumatic aortic transection is an example of this. Traditionally, major cardiothoracic surgery is performed to repair the damaged thoracic aorta. For a seriously injured patient, after a road traffic accident for example, this has a very high morbidity and mortality rate. In avoiding major surgery, the use of stent grafts reduces this risk as they can be placed from an artery in the groin to cover and seal the damaged aorta.

Long-term outcomes are also important when considering the economic value of a procedure. An expensive intervention may prove its worth if it prevents a disability that would result in more costly long-term care, or loss of quality of life for the patient. The International Subarachnoid Aneurysm Trial (ISAT) showed that endovascular coiling of intracranial aneurysms, though the procedure itself was more costly, resulted in better outcomes for patients compared to surgical clipping, and the long-term costs saved in preventing disability mean that the IR method is not only more effective clinically but is also cost effective.

Increasing Use Lowers Costs

Initially, many new IR procedures are comparatively expensive, but this is partially related to their small market base at the time of introduction. When a new technology with a limited market is developed, prices must understandably be set at a level that covers development costs and prevents the seller making a loss. As acceptance and clinical evidence accumulates, usage increases and the cost may be reduced. For example, there is now an evidence base stating that coronary stents and stents used for treating certain lesions of the superficial femoral artery (particularly drug eluting stents) are more effective compared to angioplasty alone. In terms of cost-effectiveness, however, the details surrounding these devices are still not clear. Nevertheless, with increasing use of stent technology due to proven clinical efficacy, prices have come down and the respective side of the cost-benefit equation is improved.

Building a Case for IR

Only radiologists themselves are in a position to influence funding decisions around IR, as managers may be too focused on the up-front costs. By being involved in developing business cases for new procedures, comprehensively presenting the costs and benefits to payers, interventional radiologists can ensure that the best and most appropriate treatments are funded and made available to patients.

IR has many new and rapidly evolving technologies, a phenomenon that has made cost assessment difficult and has resulted in a lack of cost-effectiveness data. The collection of quality data is expensive, time consuming and would ideally be performed as part of a large-scale clinical trial. However, this is often beyond the scope of the assessment of a new technique or device. Such trials need to be powered correctly and may not be logistically possible. As a result of these obstacles, smaller scale evidence such as case series are critical in showing the cost-effectiveness of new interventions. Any quality data on the cost-effectiveness of a treatment should then be included alongside clinical efficacy in treatment guidelines, strengthening the message of support for the treatment in question.

As well as collecting and reporting data, interventional radiologists should be at the forefront of the tendering and purchasing of devices for their department and should be up to date with evidence on costs and effectiveness of new technologies. Manufacturers are sometimes reluctant to present cost-effectiveness data, fearing that their product might not be shown in the best light. However, as economic evaluation of health technologies becomes standard practice, working with manufacturers to present the relevant data might help this technology's adoption and survival in a competitive marketplace.

Collaboration a Profitable Approach

Cooperation with manufacturers can also allow selected departments to act as a repository for more expensive devices, which may also be consignment stock to help control inventory costs. For example, when a stent graft is required in an emergency it can be made available to other centres through a coordinated network. This system enables more centres to provide an IR service at a reasonable price.

By offering high-quality and wide-ranging IR procedures a centre increases the likelihood that it will receive case referrals. An institution's profit depends on the reimbursement scheme of the particular healthcare system in which it is situated. Nevertheless, as long as the reimbursement for both elective and emergency IR procedures is adequate, then performing more IR is not only beneficial to patients but is also likely to make financial sense for the individual institution. ■

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HOT TOPICS FOR MEDICAL IMAGING IN SWEDEN

Patient Safety: Contrast Media in the Spotlight



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Reported by
Dervla Gleeson

Managing Editor

This edition's **Hot Topics** series looks to Sweden to find out what is going on in the field of research into the justification of contrast media in high-risk patients. Having studied with the inventor of non-ionic contrast media, Prof. Torsten Almén, who later collaborated with GE Healthcare, as well as Profs. Sundgren and Leander are carrying on this work by focusing on patient safety. Here they tell us why they were inspired to work in this field, and discuss the fall out from the highly publicised discovery of the potential toxicity of contrast media in certain groups of high risk patients.

Can you tell us a little bit about how you were first drawn to research in contrast media, and what the environment was like for you when you were in training?

Sundgren: Both Associate Prof. Leander and I were trained in the department at Malmö in Sweden, where there is a long tradition of contrast media research. Its former professor, Torsten Almén was our leading star. As the inventor of non-ionic radiographic contrast media and a part of a profound research collaboration with the, at that time Norwegian company Nycomed, which later became part of GE Healthcare, he supervised many PhD students in this area. After writing my PhD thesis in dysphagia I started to work with Prof. Almén and performed animal and clinical studies on new contrast media and neurotoxicity. The past 10 years I have focused on neuroradiology, but maintained my interest in contrast media and published papers on the use of MR contrast media in paediatrics as well as lecturing at ISMRM on the topic of MR contrast media in pregnant woman. After nine years in the U.S. at the University of Michigan, I am back in Sweden as Professor of Diagnostic Radiology at the department of radiology at Lund University.

Leander: I also studied at the abovementioned department in Malmö, where my PhD subject explored liver-specific contrast media for both radiography and MRI. I have maintained my interest in contrast media work and am a member of a Swedish network for MRI contrast media that is also responsible for issuing national guidelines.

What prompted you to get involved in research in the field of imaging and the administration of contrast media?

Sundgren: Both of us were trainees in a particularly inspiring environment, at the Department in Malmö, which fostered our early interest.

What are the current known risks of gadolinium based contrast media, to high-risk patients such as children?

Sundgren: It is always difficult to carry out research on the administration of gadolinium-based contrast media in children. However I have previously looked into some retrospective studies on the use of gadolinium based contrast media in children and written a few papers describing the overuse of contrast media and suggested guidelines for those cases when contrast media would be beneficial in the diagnosis of certain conditions and situations when no need for contrast enhancement exists.

Leander: However, there were no specific studies performed in our department concerning children.

“It was a shock for the radiological world. MRI contrast media was considered as safe and had, at the time the first NSF cases arose, been used for almost 20 years in millions of patients.”

What was your opinion on the handling of the diagnosis of nephrogenic systemic fibrosis (NSF) as a result of contrast media administration in high-risk patients, several years ago, and are safety guidelines in this area now sufficient?

Leander: It was a shock for the radiological world. MRI contrast media was considered as a safe diagnostic tool and had, at the time the first NSF cases arose, been in use for almost 20 years, in millions of patients. Its safety had been rigorously examined. For example, in the early era of gadolinium-based contrast media usage there were concerns about chelate-stability. For example, there were studies performed on the product Om-

niscan® by its inventors, Salutar. These studies of its stability were initiated, as there was a concern about the trans-metallation of zinc and the symptoms associated with this. This was shown not to be problematic and these studies were not referred to for almost two decades. As we were aware of the situation with NSF in Sweden and the Skåne Region, we immediately issued guidelines that advocated practitioners not to administer gadolinium contrast media in patients with severely impaired renal function. At that time, in the Skåne Region one of the cyclic chelates was a first choice gadolinium contrast medium. In addition, a search was initiated for cases of NSF in Sweden and none have been found so far. A particular search that was carried out in the hospital in Malmö resulted in a publication.

What sort of safety guidelines are implemented for high risk patients in Sweden for administration of gadolinium contrast media, and are they in concurrence with the European ones at large?

Leander: The Swedish Society of Radiology publishes guidelines on both radiographic and MRI contrast media. It is our impression that departments in Sweden are well aware of these guidelines for the safe administration of contrast media and methods to avoid adverse events. These national guidelines are in concurrence with the European ones at large. There are also Swedish radiologists participating in the development of European guidelines under the auspices of the European Society of Uroradiology (ESUR / www.esur.org).

What role does the Swedish Society of Radiology play in the education of its members on these important safety issues?

Sundgren: The annual meeting of the Swedish Society of Radiology (dubbed “Roentgen-week”) arranges regular symposia on the topic of contrast media. Its homepage also publicises these guidelines and updates members and non-members alike on developments in the safety and administration of contrast media.

Is the government in Sweden actively liaising with leaders in medical imaging to discuss patient safety issues? Is this a topic that is discussed at a national level?

Sundgren: I cannot say that contrast media are, in particular, often on the national agenda.

Leander: I agree. However, when the European Medicines Agency (EMA) published new directives concerning gadolinium contrast media and NSF, the Swedish Medical Product Agency (MPA) provided that information to the profession-

al community, so activities in this area are taking place at an international level.

What advice would you give to other radiologists in guiding the safe administration of contrast media?

Sundgren: We would urge our colleagues to read the European guidelines published by ESUR and to follow them.

What other imaging exams could potentially be prescribed instead of contrast media involved exams, that might adequately illuminate a diagnosis without adding a high risk for the patient’s health? Is contrast media too often or unnecessarily used?

Sundgren: It is important to understand that under normal conditions in a healthy patient, contrast media do not add a higher risk for the patient. The problem arises when you have a patient with reduced kidney function. Routine guidelines are followed in those cases. Alternatively, MR without contrast administration can be used and is satisfactory in some cases. For lesions in the brain, ultrasound is not an option as it might be in certain circumstances in, for example, the abdomen.

Leander: This is hard to answer. Many times MRI without contrast medium is satisfactory. Other choices may be ultrasound in some parts of the body. ■

FURTHER READING

- Petrou M, Jennings J, Eldevik P, Ksar J, Smythe J, Maly P, Sundgren PC. Added utility of gadolinium administration for brain MRI examinations in children under the age of two. ESNR 2004 Neuroradiology 46 Supl 1 p 70, Sept 2004
- Foerster B, Jennings J, Petrou M, Eldevik P, Maly P, Sundgren PC. Limited added utility of gadolinium in diagnosing cause of radiologically proven cerebral hemorrhages in children under two years of age. ESNR 2004 Neuroradiology 46 Supl 1, p 129, Sept 2004.
- Petrou M, Sundgren PC, Maly P, Eldevik P. Incidence, clinical presentation, MR imaging and histological findings of intracranial neoplasms in children under the age of two and added utility of gadolinium in their initial diagnosis ECR '05 Proceedings C 0916 p 534
- Foerster B, Ksar J, Petrou M, Eldevik P, Maly P, Sundgren PC. Value of gadolinium administration in brain MRI examinations for developmental delay in children less than two years of age. ECR'05 Proceedings B 645 p 279.

KEY CONFERENCES & EVENTS

JANUARY 2012

- 12 – 14 **MIR Winter Course**
Schladming, Austria
www.mir-online.org
- 16 – 18 **Bristol MRI 2012**
Bristol, UK
www.jcaseminars.com
- 18 – 19 **IT @ Networking 2012**
Brussels, Belgium
www.itandnetworking.org

MARCH 2012

- 01 – 05 **European Congress of Radiology (ECR) Annual Meeting**
Vienna, Austria
www.myesr.org
- 25 – 30 **Abdominal Radiology Course / Society of Gastrointestinal Radiologists & Society of Uroradiology**
Arizona, U.S.
www.sgr.org
- 25 – 30 **44th International Diagnostic Course Davos (IDKD)**
Davos, Switzerland
www.idkd.org

APRIL 2012

- 14 – 17 **34th Charing Cross International Symposium**
London, UK
www.cxsymposium.org
- 15 – 18 **The Breast Course 2012**
Lisbon, Portugal
www.thebreastpractices.com

20 – 21 **ESIR 2012 Embolisation Course**
Amsterdam, The Netherlands
www.esir.org

25 – 28 **2nd European Congress on Interventional Oncology (ECIO)**
Florence, Italy
www.ecio2012.org

JUNE 2012

12 – 15 **ESGAR 2012**
Edinburgh, UK
www.esgar.org

27 – 30 **CARS 26th International Congress and Exhibition Joint Congress of CAR / ISCAS / CAD / CMI / EuroPACS**
Pisa, Italy
<http://www.cars-int.org>

SEPTEMBER 2012

15 – 19 **CIRSE**
Lisbon, Portugal
www.cirse.org

OCTOBER 2012

11 – 12 **Management in Radiology (MIR) Annual Scientific Congress & Meeting**
Milan, Italy
www.mir-online.org

19 – 23 **Journées Françaises de Radiologie 2012 (JFR)**
Paris, France
www.sfrnet.org

27 – 31 **EANM Congress**
Milan, Italy
eanm12.eanm.org

IMAGING Management

is published by MindBYTE Communications Ltd
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Subscription Rates (5 Issues/Year)

One year: Europe 85 euros
Overseas 105 euros

Two years: Europe 150 euros
Overseas 180 euros

Production & Printing

Print Run: 12,000
ISSN = 1377-7629a

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