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OBESITY

The epidemic of obesity is now recognised as one of the most important public health problems facing the world today. The causes of obesity are complex and differ from individual to individual. There are a multitude of 'obesogenic' factors contributing to the increased energy consumption and decreased energy expenditure that are responsible for obesity, including: declining levels of physical labour; higher levels of food consumption or a decrease in energy density; social, economic, educational and cultural factors. At the World Obesity Federation our mission is to lead and drive global efforts to prevent, reduce and treat obesity.

We often assume that education on obesity needs to be directed towards patients. But research is increasingly finding that educating health professionals may be even more important. In an October 2013 article in the New England Journal of Medicine, researchers James Colbert and Sughrut Jangi found that while obesity is becoming increasingly prominent "physicians-in-training frequently fail to recognise obesity, are unfamiliar with treatment options, and spend relatively little clinic time treating obesity" (Colbert and Jangi 2013).

Too often obesity treatment is reduced to advising an obese patient to "eat less and move more". If diet and exercise suit a particular patient then strategies need to be put into place to motivate that patient. What if they have a physical disability that prevents them from exercising? What if they work and live in a sedentary environment or "food desert" that doesn't facilitate exercise or a nutritious diet? Is counselling needed to overcome mental health causes of their excess weight? Better education is needed to help patients overcome the barriers to weight loss.

In some severe cases, lifestyle interventions are not the solution. When do you refer a patient for bariatric surgery? Is pharmacotherapy an option? How do we address childhood obesity or obesity in pregnancy? Again, better education is needed to address the complex multi-faceted nature of this chronic illness.

With only 10-15 minutes to discuss their patients' excess weight, health professionals need evidence-based strategies to help them address not just the symptoms but the root cause of their patients' obesity. This requires a multidisciplinary approach so health professionals can tailor their treatment to address the unique causes and severity of their patients' obesity.

More often than not patients leave a consultation ill equipped to manage their obesity. Even worse, many come away misunderstood and even discriminated against by their clinician. A 2002 survey of 2,449 overweight and obese women in the United States of America found that 69% reported bias from their doctor, 46% from nurses and 37% from dieticians (Puhl and Brownell 2006). With sobering statistics like these it is no wonder that patients turn to a multi-billion dollar weight loss industry for solutions, falling into the trap of 'yo-yo dieting'.

Effective obesity management begins with well-trained health professionals. That is why the World Obesity Federation developed SCOPE - an online obesity education programme that equips health professionals with a solid evidence-based education in all aspects of obesity management. The aim of SCOPE is to bring together health professionals from a variety of disciplines, and train them on how to manage the growing global obesity epidemic. After completion of the programme they receive an internationally recognised certificate that confirms that they have improved their training in obesity management through the guidance of leading obesity experts.

Since releasing SCOPE online 2 years ago, World Obesity have registered over 8,000 health professionals from around the world, certified 50 health professionals and recognised over 150 SCOPE Fellows. Our programme has been endorsed by over 50 national and regional obesity associations and institutions such as the National Health Service in the United Kingdom. Soon we will bring our resources to social media to provide a forum for health professionals to share best practices in obesity management.

Obesity is now reaching pandemic proportions across much of the world, and its consequences are set to impose unprecedented health, financial and social burdens on global society, unless effective actions are taken to reverse the trend. Here at World Obesity, we feel that health professionals are key to the reversal of the trend along with further research into obesity, policy of governments and businesses at global, regional and national levels, practical training, publications, conferences and accreditation.

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Note: *The World Obesity Federation is a registered charity.*

References and Further Reading

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HealthManagement is a new cross-departmental journal, combining the Editorial Boards of IMAGING Management, Healthcare IT Management and Cardiology Management.

EUSOBI ANNUAL SCIENTIFIC MEETING

Breast radiologists from Europe and beyond meet in Amsterdam from 26-27 September for the EUSOBI Annual Scientific Meeting to learn about the latest in breast imaging, discuss such contentious topics as whether to screen women under 50 or over 70, if mammography will still be the gold standard...and more

Highlights

Friday 26 September

- 09.00-10.30
  Radiologic-pathologic correlation in the era of molecular pathology
- 11.30-12.00
  EUSOBI meets...India
- 12:00-13:00
  Preoperative MRI: an open discussion
- 13:00-13:50
  Will mammography stay the gold standard for breast screening in future?
- 14:40-15:50
  Do we need high/ultrahigh field for breast MRI?
- 16:20-17:30
  Breast cancer screening under 50

Saturday 27 September

- 08:20-09:30
  Breast cancer over 70
- 10:00-10:30
  From the US Society of Breast Imaging (SBI): Background enhancement on breast MRI: Clinics and research - Elizabeth Morris, Vice President, Society of Breast Imaging

- 11:00-11:30
  Keynote lecture - Breast imaging with PET: From diagnosis to treatment monitoring - Johannes Czernin, Los Angeles, USA

- 14:00-15:30
  Updates on breast imaging – including tomosynthesis, contrast and more, ultrasound, image-guided interventions and MR-guided focused ultrasound for breast cancer treatment
- 15:30-16:40
  Interval cancers and reading errors in screening mammography

In this issue: We interview Prof. Francesco Sardanelli, President of the European Society of Breast Imaging EUSOBI, and Dr. Smiti Hari and Dr. C.S. Pant write about the current status of breast imaging in India.

THE EUROPEAN SOCIETY OF BREAST IMAGING

INCREASING PARTICIPATION FROM EUROPE AND BEYOND

Prof. Sardanelli, why did you choose to specialise in breast imaging?
To be honest, it was the result of a series of events, not of my special preference. At the beginning of the 1980s, I was a staff radiologist, mainly dedicated to MRI and CT, at the Radiology Department of the University of Genoa, Italy. A joint initiative between the Hospital and the National Cancer Institute had created a Senology Centre with much activity dedicated to breast imaging (i.e., mammography, sonography and needle biopsy). My mentor and boss, Prof. Giorgio Cittadini, asked me to take responsibility for diagnostic imaging at this centre while also keeping responsibility for MRI activity. I accepted this nomination enthusiastically. The combination explains my interest in breast MRI.

It seems that not a month goes by without discussion on the effectiveness of mammographic screening, and in Switzerland they are recommending that mass screening stops. Do you see a continuing role for mammographic screening?
The latest evidence, published in the BMJ on June 17, 2014 by Weedon-Fekjaer et al. from Norway is that "Invitation to modern mammography

Interviewee

Prof. Francesco Sardanelli

University of Milan,
IRCCS Policlinico San Donato,
Milan, Italy

President, European Society of Breast Imaging

Director, European Network for the Assessment of Imaging in Medicine

Interviewed by

Claire Pillar

Managing Editor, HealthManagement

screening may reduce deaths from breast cancer by about 28%". However, if we consider the impact on women who really get mammograms every two years, there is evidence that mortality reduction is over 40%. Mammographic screening, allowing for an earlier diagnosis of breast cancer, strongly contributed to the reduction of mortality from breast cancer, together with better and better therapies including surgery, radiation, chemo-, and hormonal therapy. The current discussion on screening limitations should be focused on methods to obtain better results from it, not on stopping it. Key points are the following: extension from 40 to 75 years of age; special programmes using MRI for high-risk women; reducing recall rate; reducing interval cancer rate (i.e., underdiagnosis).

The very good news is that the evolution from film-screen to digital mammography not only reduced the x-ray dose delivered to women, but also opened the way to a dramatic technological advancement: digital breast tomosynthesis (DBT). DBT is now at the take-off point. A relevant increase in cancer detection rate and a strong reduction in recall rate have already been shown using DBT in the screening setting. A reduction in interval cancer rate is expected. It will be the mammography of the near future. Any evaluation of the results of screening mammography will not have real sense if not considering DBT as the 'modern' mammography.

In your opinion, is overdiagnosis an issue in mammographic screening? If so, how can radiologists help to reduce overdiagnosis and overtreatment resulting from mammographic screening?

Overdiagnosis, i.e. the diagnosis of a disease, which would never become clinically significant during the patient's lifetime, is an issue. Notably it is an issue not only for screening mammography, but also for the day-by-day detection of incidental findings at cross-sectional imaging in radiology practice.

Probably the more appropriate term 'overdetection' should be used, especially in the screening setting. 'Diagnosis' and 'overdiagnosis' are the conclusive steps of a pathway in which other members of the breast care team are involved, especially pathologists (what about the blurred pathological border between atypical ductal hyperplasia, non-malignant, and ductal carcinoma in situ, malignant?). Notably, overdetection is an unavoidable trade-off we should pay when we want to get an early diagnosis of whatever disease, i.e. before the onset of symptoms or signs.

Due to biological variability and to competing causes of death, a fraction of early diagnosed cases will be, by default, overdetected. The problem is how much overdetection we have and what overtreatment is caused by the overdetection. Unfortunately, estimates of overdetection by screening mammography may vary hugely, depending on type of studies considered, statistical methods and statistical assumptions. In the EUSOBI recommendations for women's information, we cautiously said that 5% to 20% of breast cancers could be overdetected by screening (Sardanelli and Helbich 2012). To be short, according to a very recent estimation, for every 1,000 women screened biennially from ages 50-51 to 68-69 years and followed up until age 79 years, 7-9 breast cancer deaths are avoided, 4 cancers are overdiagnosed, 170 women have at least one recall followed by non-invasive assessment with a negative result, and 30 women have at least one recall followed by invasive procedures yielding a negative result. The chance of a death being avoided by mammography screening is more than that of overdiagnosis (Paci et al. 2014). We must communicate these outcomes to women offered service screening in Europe.

Finally, we should note that while much attention is paid to overdiagnosis, overtreatment is not equally considered. More efforts should be dedicated to reduce overtreatment, for example to avoid surgical excision of high-risk (B3) lesions using contrast-enhanced MRI as gatekeeper to surgery (Londero et al. 2012).

"the current discussion on screening limitations should be focused on methods to obtain better results from it, not on stopping it"

You are well-known for your interest in evidence-based radiology. How can radiologists ensure that what they are doing is based on the best possible evidence, particularly in breast imaging?

Education, education and education. The breast radiologist of the future will have to be not only a radiologist dedicated to breast, but also an epidemiologist and an expert in breast cancer therapy. Changes are faster and faster, the evidence is modified every year, perhaps every month. Look at DBT: the discussion on the x-ray dose is now closed by the possibility to obtain virtual 2D images from the 3D dataset. Thus, the ability to read and understand scientific papers is more and more a must for each of us. As a consequence, knowing the methodology of radiological research is important as is being able to read mammograms or to perform needle biopsies. The rapidity of changes implies that recommendations of medical bodies may be not always useful. Moreover, according to evidence-based medicine principles, we have to always consider choices and preferences of the individual patient. Thus, the breast radiologist

should always consider "the evidence", but also use medical common sense. To give two different examples: 1) today DBT can be firstly used as a substitute for dedicated views and/or ultrasound when an abnormality is detected on a 2D mammogram; 2) breast MRI is currently used in the case of suspicious nipple discharge after mammography and ultrasound and ductogalactography is more and more rarely performed.

Can you tell us about the multicentre study on preoperative breast MRI in clinical practice, which you are leading?

The "Preoperative Breast MRI in Clinical Practice: Multicenter International Prospective Meta-Analysis (MIPA) of Individual Woman Data" study is ongoing (http://www.eusobi.org/html/img/pool/MIPA_Outline.pdf). More than 1,000 patients were enrolled by about 20 centres active in Europe, the U.S. and Australia. It's already a very good result. We have to thank Bayer for supporting this great observational study. I hope to close the enrolment within less than 2 years. We will have a huge amount of data to study and to publish.

What is the role of breast MRI when mammographic or ultrasound findings are inconclusive?

MRI should be used in cases where you don't know where to put a needle for biopsy or, for different reasons, when you cannot perform an image-based needle biopsy.

What are the most promising recent technologies for breast imaging?

- *Digital breast tomosynthesis for screening women at average risk of breast cancer.*
- *Breast MRI for defined indications (Sardanelli et al. 2010).*

What role do you see for molecular breast imaging?

Apart from proton and phosphorus MR spectroscopy, which remains a research tool, breast molecular imaging is nuclide-based imaging, which implies a non-negligible ionising radiation exposure. Thus, even if research in this field is welcome (we opened to nuclear physicians the awarded sessions at the EUSOBI Amsterdam meeting), the potential expansion for its clinical use is – in my view – relatively limited.

The EUSOBI Annual Scientific Meeting in Amsterdam in September will include two discussions – on the role of preoperative MRI and breast cancer screening for women over 70? What are you expecting from these discussions?

For the first topic, a frank and honest debate comparing different views on preoperative MRI, showing that nobody possesses the truth and that research is still needed. For the second one, I hope that speakers will show that the longer and longer women's lifetime reduces the competing causes of death, allowing early diagnosis to save lives.

What are you most looking forward to at the EUSOBI Annual Scientific Meeting?

On one side, the larger and larger participation from European countries. On the other side, the increasing participation from non-European countries. This year, we will have the session "EUSOBI meets India"... EUSOBI is more and more becoming a reference point for breast radiologists all over the world.

Digital Breast Tomosynthesis

Carestream Vue Mammo Workstation and Vue Pacs Solution

If Digital Breast Tomosynthesis is on offer at your imaging centre, Carestream offers a DBT module for its Vue Mammo Workstation and PACS to optimize reading, workflow, archiving and storage. Not only does the module benefit the radiologist, but the use of DBT has been shown to reduce the patient recall rate. Furthermore, if synthetic 2D views are generated from the DBT acquisition, the patient is exposed to less radiation.

The CARESTREAM Vue Mammo Workstation and PACS is a single desktop multi-modality reading solution that can store and display any vendor DICOM compliant DBT, mammography and general radiology exams, in addition to non-DICOM data associated with the patient.

Key Advantages

Time Saving

By reading all procedures from a single workstation or desktop the radiologist saves a significant amount of time by not having to move between different viewers, log in multiple times, or become familiar with multiple user interfaces. All patient data is available from a single desktop. Pre-fetching means that priors are immediately available while reading the current case, and this helps maintain efficient workflow.

Scalable

The various configurations available assure users that the solution is architected to their environment and needs, while providing a scalable solution for future growth.

Workflow

The Vue Connect architecture lets healthcare providers manage patient information across multi-site facilities regardless of location by synchronizing data and providing a global worklist. This allows the workload to be balanced between facilities or where physicians are available to read. The data is provided to the physician, rather than the physician needing to move to where the data is. The Worklist Indicator allows quick identification of exams with DBT images

2D View Synthesis

Synthesising the 2D view from the 3D views benefits patients as it reduces their radiation exposure. Carestream supports the display of both conventional and synthetic 2D mammography views.

Key Features

The solution provides an industry-leading tool set for both workflow efficiency and diagnostic confidence.

An extensive set of tools eliminates the need for physicians to manually manipulate the images, optimizes their workflow, and reduces fatigue. For example, images are automatically positioned and scaled to the display, eliminating the need to manually pan and zoom them. Hanging protocols can be configured to the individual user so that the sequence of images match their reading style. A desktop keypad is provided that allows the user to quickly

access their most commonly used operations with a single button press. Additionally, many of the tools further improve diagnostic confidence and improve patient care by either helping them locate lesions or provide a clear indication that all images were viewed.

The key to achieving maximum efficiency is to minimize any manual manipulations, provide the quickest access possible to the tools, and provide the most efficient means of navigating through the views and DBT slices. The features that target these efficiencies include:

- **Automatic positioning and sizing of the images** to eliminate manual manipulations. This includes the display of images at the same physical size when different vendors are being compared, for ease of comparing a change in pathology.
- **Automatic skin line detection for positioning**. This also allows for only inversion or window/level of the tissue area.
- **Intelli zoom**, which displays segments of the image at original resolution, and at the same size if desired.
- **Drag and Drop images** as you read with automatic resizing and positioning.
- **Hanging protocols** that can be customized and configured at the user, group, or system level. Protocols can be designed to support just 2D views, 2D and DBT, or other combinations.
- **Cross Reference Lines**, a digital triangulation tool. This allows the user to quickly assess the location of a lesion or area of interest across views.
- **Image map**, a graphical orthogonal view of the breast with a reference line to indicate where the currently displayed slice is. As the DBT slices are scrolled through, the reference reflects the new position in the breast. This provides the user with an intuitive graphical view of the breast so they are always sure what they are looking at.
- **Concurrent Magnifying Glasses** provide a close-up comparison of pathology across multiple views and procedures.
- **Scrolling tools** to quickly scroll through the DBT data. These range from manual scrolling using the graphical user interface or a scroll wheel to a configurable cine mode.
- **Annotation and mark-up tools** to save and catalogue key images.
- **Sticky Notes** that can be used for communication between users outside of the report .
- **Key Images and Significant Series**. The Key Images feature allows the user to identify a specific image for viewing later (by the Referring Physician, Technologist, or Radiographer). The Significant Series allows the user to identify a series of consecutive images for viewing later.
- **Teaching Files** that de-identify and mark specific studies for later review (e.g. for a tumour board, teaching, etc.)
- **My Tab** that allows a user to customize the tools available in the toolbar to just the ones they use. There is a configurable right-click menu to customize the tools available in it.
- **Backlit desktop keypad** for single click navigation for users preferring to navigate using a keypad.

Network Infrastructure

The solution is offered in standalone, enterprise, and multi-site configurations. IHE compliance and integration through industry standard protocols allows for integration with existing equipment or the addition of other vendor equipment.

From a storage perspective, Carestream software utilizes a 64-bit architecture so that large data sets, such as DBT, are handled well. This architecture allows for improved display performance as the available memory can be better utilized. Additionally, Carestream recommends the configuration of pre-fetching rules so that prior exams can be moved to the online storage and allow for immediate display when needed.

Once centres decide to implement DBT, they need to upgrade their network, as both modality and PACS vendors recommend a 1gigabit network. It is recommended that lossless compression be used on both the sending and receiving ends of the data to ensure fast movement of data.

What Customers Say

Ron Muscosky, Worldwide Product Line Manager Healthcare Information Solutions at Carestream says that feedback from radiologists has been very positive.

"Carestream has embraced DBT since it was first being introduced, so we are much further ahead of most other competitors. Customers comment most on the multi-modality support, flexibility of hanging protocols, extensive tool set, and ease of use. They believe these items make a significant difference in their workflow efficiency and reduction of fatigue, especially with how much more data DBT provides them to read."

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

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Carestream

THRIVING IN THE FAST LANE

Interviewee

Prof. Panos Vardas

Outgoing President of ESC

EUROPEAN SOCIETY OF CARDIOLOGY®

Interviewed by

Christian Marolt

HealthManagement

Prof. Vardas, looking back on the past two years, how would you sum up your presidency?

It was a very easy, productive and creative period; it was a great period, just as I was expecting it to be. During the last two years I had the opportunity to work with many specialists and colleagues from different cardiac societies, and in many countries, the opportunity to communicate with leaders of some important institutions outside of the regular ESC circles. More importantly, I had the opportunity, through our institutional decisions, to develop some vital and strategic projects. These are, in my view, of great importance for our society.

You have introduced the permanent ESC delegation in Brussels. How has this benefited the society?

I am very proud of this decision to expand ESC in Brussels. Indeed, I believe this to be one of the most strategic developments in the history of ESC for a number of reasons. One being location. Due to being based in Nice, the society is to some degree isolated. Nice is of course a very attractive and touristic area, but not easily reachable. A very big society, such as the European Society of Cardiology, needs to be in a big city, and Brussels is the political capital of Europe. However, apart from establishing the routine use of these offices in Brussels, we have now developed a whole new project under the name "European Heart Agency" there, aiming to accommodate very novel ideas and projects. This agency is rated in three different divisions:

The first concerns European affairs, dealing with regulations, issues and cardio-political EU matters.

The second is named "The European Heart Health Institute", targeted towards new initiatives to organise studies and activities related to health policies and health economics, healthcare management and statistics, biostatistics and everything related indeed to the matrix and economics in our field. It includes innovation and implementation, nanotechnologies, e-health and other evolving areas.

The third unit, "The European Heart Academy" concerns clinical trials.

What will the academy do?

The European Society of Cardiology is a CME (continued medical education) provider, and these activities have always been developed in Nice and will continue to be. "The European Heart Academy" has another role, aiming to open special 1 or 2 year-courses leading to a certain kind of title, in collaboration with selected universities who are official CME providers. We are very proud that just some weeks ago, we had the first official press release on behalf of the London School of Economics (LSE), announcing our joint project for a Master course related to policies, economics and health management in cardiovascular medicine. We are also working with the Zurich University for a two years' course, and now we are going to start a new collaboration with Maastricht University for a two years' course in arrhythmias.

Do you believe that in the long run, it will be imperative to move the entire ESC operation to Brussels?

I often get asked this question. The answer here is: reasonably, yes, practically, however, it is very difficult, because we currently have 160 employees in Nice and we have to take into account local reality. We cannot ignore all these employees. Europe is much more emotional towards employees' rights than other continents of the world and I think in the future, this total relocation is very difficult or near impossible.

What did you enjoy most about your term?

I have enjoyed everything. Of course, as a leader you enjoy leadership, and the privilege of this leadership is the opportunity to make decisions, deal with charismatic characters, materialise ideas, or to share your views and your ideas with other peers. It was not only one moment or project that gave me satisfaction; it was a mixture of everything over the last two years, the contacts, communication and decisions. Of course, a leader also has to deal with crisis, which is the other part of leadership not always the happiest or pleasurable. But unavoidably, if you are leading a large society such as the ESC, you also have deal with crisis. The last two years were not boring at all.

The society's mission is to reduce the burden of cardiovascular disease in Europe. Will this ever truly be accomplished in the face of the mounting challenge represented by obesity?

This is the mission of the European Society of Cardiology, however, this definition is outdated now. As I had the opportunity to say at the opening ceremony last year at the ESC congress, and will have opportunity to repeat this at the opening ceremony again this year, the mission of the European Society of Cardiology could be expanded: to reduce the burden of cardiovascular disease in Europe and even beyond, and to tackle and eliminate inequalities in healthcare and cardiological medicine. We could even add here: to promote humanism.

Obesity, diabetes and other similar situations and conditions are of course on our agenda. We try to educate the different ESC countries' population directly and indirectly on how to be healthier, and obesity is one of the challenges we have to deal with. The consumption of salt is another big issue, and how to deal with arterial hypertension as a consequence is a huge subject that has been neglected to some degree in the last few years.

In a 2013 ESC TV interview you stated

that cardiology has achieved the prolongation of a human being's life by an average of 10 years. Do you see this increasing further in the future?

I have repeated this message for many reasons over the years. Cardiovascular medicine, because of the developments, the investments and because of our efforts, has indeed managed to prolong the life of human beings by 10 years in average, and this life is of good quality. In comparison, despite the huge investments, oncology has managed to prolong life only by a few months. I do not know if the war against cancer is lost, but the war against cardiovascular death is still very important. Cardiac death is being significantly well handled, because we have such good devices to deal with any episode of lethal arrhythmia. Coronary artery disease is being managed properly and so are heart failure and defibrillation, to name but a few heart conditions.

At the moment, I am afraid cardiovascular medicine is a victim of its own success. The industry has progressively lost the momentum for new ideas and innovations because of all these achievements and progress in effective treatments. The European healthcare systems are very happy to deal with lower prices, using generics, cheaper stents, cheaper pacemakers and devices, and this is indeed the risk if in our magnificent specialty: when the profitability of the industry is very low, then there is less incentive for research and investments. I am afraid we are entering an area of turbulence, low profitability of industry, low investments in research, few new products. I hope I am wrong, but there is no comparison between the investments and expenses offered for cancer or other diseases, and those offered in cardiovascular medicine. What is very good for the healthcare systems, low prices, is disadvantageous for the industry. To help the industry we also have to take into account its needs, because without the industry, novel ideas and novel technologies cannot be promoted.

Going back to the new ESC Academy: when the ESC is pushing certain areas it is not looking into profitability, but more into necessity. Are you hoping the Brussels institute will in part fill the gap where the industry does not deliver?

No doubt it will. In Brussels, one of our priorities is to promote the official rules and regulations, and the communication with the industry. There we have the opportunity to meet with other important players, not only from the European Union, but also from the industry. Of course, we have official contacts with EUCOMED and EFPIA. We believe that through transparent collaboration we will enjoy fruitful outcomes.

Management and cross-departmental collaboration are increasingly at the forefront of today's healthcare environment. Why is that development so important for cardiology and for the society?

In the last 3-4 years, and I have to confess that especially in my specialty, health economics and management, we have identified the need to come closer to these topics and issues. About 5-10 years ago, nothing was said about health economics and healthcare management in the European Society of Cardiology. All the main leaders and pioneers were talking about was certification. It is true that we have been influenced by examples of other societies and one of them, the European Society of Radiology, is very well organised. They hold an annual meeting related to management in radiology. We are discussing the organisation of similar meetings for management in cardiovascular medicine. Great ideas from other areas are important for ESC. The ESC itself has acknowledged the significance of healthcare management issues, because over the last 10 years, matters related to health economics and quality have become progressively more important for the communities of patients and the communities of physicians.

Healthcare management and healthcare specialists have increasingly entered our area, whereas 15 to 20 years ago, physicians were the central players in the daily life of hospitals. Now physicians have been pushed to a corner to a significant degree, and the main players are health managers and health economists. Physicians should not tolerate this situation; physicians should develop their own skills and techniques. They should be more familiar with, and more educated on the issue of health economics and healthcare management. They should speak the same jargon as health economists; otherwise physicians will be marginalised in the near future.

What about the patients in your view? Somebody told me once that an informed patient is the archenemy of the doctor's convenience

I believe that one the strongest drivers of the future is the informed patient. This is a one-way road. Nowadays, Google offers a huge opportunity to patients, and even to physicians, to be quickly and well informed. Because of this fact many of us are now working for the power of patients. Personally, I am involved with a new site that will come online a few months from now, entitled cardiopublic.com, dealing entirely with the empowerment of cardiovascular patients. I think we should work together, we should not be afraid of more informed patients.

You will soon be handing over the ESC presidency to Prof. Fausto Pinto, what advice would you give him?

I wish him all the best. Good luck, well balanced decisions, great vision and the full support of ESC. One of the main and very important priorities for him should be to continue thriving of the ESC's successful projects, such as the congress, journals, guidelines and registries. These are our main priorities and these should be the main priorities of the new president, how to maintain the success of existing projects under difficult economic conditions. Secondly, I would suggest to my good friend Fausto to focus on how to keep the unity between cardiovascular specialists in our different European countries. And of

course, his difficult job is to find a way to work together with the past president and the president elect as we always do, as it is up to the presidential trio to preserve the continuity of the society and promote the novel values of our society internationally.

You have previously mentioned the radiologists. They have created a European Diploma of Radiology, an accreditation and ultimately the entrance ticket to any radiology job anywhere in Europe. Do you think that Prof. Pinto should create something similar?

I would like to remind you that the European Society of Cardiology created this idea, the European Diploma of Cardiology, 20 years ago, however the project collapsed for different reasons. We are now following a different route to the European radiologists and are closely collaborating with the European Union of Medical Specialists (UEMS). One of the first priorities of the UEMS cardiology section is a new start for this diploma. We are discussing it, however the ESC presidency is not so enthusiastic. We currently have many reasons to be sceptical or even be concerned about the value of this diploma. Probably in the future though, it will be necessary.

As past president you will still dedicate a lot of your time to ESC. Where do you see your next career challenge?

Firstly, I have more time to spend in Crete and will be dedicating more time to the University of Crete. I would like to thank the University authorities because they were so tolerant with me during the last few years. My second priority is the promotion of the European Heart Agency. One year ago, when we started this new project in Brussels, we made a very important decision to organise the managerial team for each of the three sections. For the next 4-6 years, I will be the Executive Chairman of the European Heart Agency and its managerial team. Therefore, I will spend a lot of time promoting the agency's values.

On a personal note, when you end your presidency what are you most looking forward to?

To enjoy life more and I hope to have good health for my family and myself. There are so many things in life one can do. In the last 20 years I have spent much of my time on cardiology and had no time to read the classics, Dostoyevsky, Tolstoy or ancient greek philosophers, and many other authors. I would like to visit other countries not all the time as an ESC ambassador, but as a human being. I will have more time to look at the past and also into the future.

ESC PREVIEW

With a record submission of over 11,000 abstracts from 100 countries, this year's congress places the spotlight on innovations in scientific discoveries, technology, clinical practice and education, as well as on applications to clinical care. Between August 30 and September 3, the Fira de Barcelona Gran Via will welcome close to 30,000 attendants interested in learning about the latest developments across the spectrum of cardiovascular disease.

Mobile App

New for 2014, the ESC Congress App will facilitate direct interaction and voting during specifically designed sessions. These include: Guidelines in Daily Practice, Cases in Crossfire, Global Focus and Meet the Experts.

The app will be active for the duration of these sessions with two features:

'Ask a Question': Allows a session-related question to be sent to the chairperson directly, with a selection of questions answered during the session.

'Voting': Allows for answers to be displayed on the app screen, relevant to the speaker's question slide, where users can vote for their personal choice of answer.

To download the congress app, please scan the QR code on the left.

Meet the Legends

Clinical practice sessions, experts sessions, abstract sessions, traditional sessions, joint sessions, clinical & basic latest science, as well as the general cardiology track will offer a wide array of learning opportunities.

Of particular interest will be Sunday afternoon's 'Meet the Legends' segment, aimed to provide attendants with a unique chance to interact with legendary individuals, who have changed the landscape of modern cardiology: Eugene Braunwald, Alain Carpentier, Sir Rory Collins and Petr Widimsky will conclude their sessions with an open forum.

Cardiologists of Tomorrow

A dynamic, specific educational track that runs throughout the duration of the congress, allowing young cardiologists to follow case-based learning in 'The Hub" at the Central Village. Six sessions will discuss cases that have been submitted under the main topics Cardiomyopathies, Endocarditis, Acute Cardiac Care and Spotlight of the Congress: Innovation and the Heart.

The "Challenging Case Reports" segment will award prizes to the best case presentations based on originality, scientific content, presentation and answers to questions.

Scientists of Tomorrow

This is a new group of young, pro-active basic and clinical researchers, working closely with the Council on Basic Cardiovascular Science to fulfil its mission in promoting and supporting basic science among young ESC members.

DAS EREIGNIS IM SEPTEMBER:
Informieren Sie sich! Diskutieren Sie mit!

Über diese und weitere Themen:

- → Die neuesten Forschungsergebnisse zum 6. Kondratieff
- → Wie weiter Krankenhäuser?
- → Der Vergleich – was bringt der OECD-Benchmark?
- → Ethik und Ökonomie – der „gefühlte" Konflikt?
- → Personal – Lösungen für einen offenen Gesundheitsmarkt

Als Top-Redner mit dabei:

Hermann Gröhe, Leo Nefiodow, Prof. Charles Normand, Prof. Dr. Dr. Daniel Strech, Dr. Josef Düllings und viele weitere namhafte Referenten aus ganz Europa

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Kongressgebühr	€ 655,00
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Die Teilnahmegebühr beinhaltet:

- → Teilnahme am wissenschaftlichen Programm
- → Besuch der Fachausstellung
- → Mittagsversorgung und Kaffeepausen im bcc Berlin
- → Teilnahme am Rahmenprogramm

Alle weiteren Informationen finden Sie auf der Kongress-Webseite **www.eahm-berlin2014.de**.

World-Health Economic-Forum

25. EVKD Kongress
25th EAHM Congress
25e Congrès AEDH

UPDATE

10–13 September 2014, Berlin
bcc Berliner Congress Center

Gesundheitswirtschaft:
unsere Verantwortung für die Menschen

Health sector:
our responsibility for the people

Économie de la santé:
notre rôle et responsabilité

Verband der Krankenhausdirektoren Deutschlands eV

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At this year's congress, the Cardiovascular Scientists of Tomorrow will have their own dedicated track for the first time. Sessions cover a variety of topics and include key tips on the first successful grant application, the first paper published and opportunities to develop the next career step.

Industry Programme

At the heart of the venue, the exhibition hall will provide the backdrop to scientific discussion and exchange during the congress. Industry partners have scheduled satellite symposia, 'Experts on the Spot' sessions, hands-on tutorials as well as EBAC accredited educational programmes to provide attendants with the latest technical innovations, data and products available to improve patient outcomes.

CPR and AED Workshops

With the collaboration of the European Resuscitation Council, the ESC will be providing free CPR workshops for congress delegates once more in 2014. From Sunday through Tuesday, one morning and one afternoon session are on the schedule, followed by a 'Meet the ERC Instructor and ask your questions' time slot.

The full final programme of the ESC Congress 2014 is available here: *http://content.zone-secure.net/esc_barcelona_2014/*

SHAPING THE FUTURE OF IR AT CIRSE 2014

As always, this year's Annual Meeting in Glasgow offers a first-rate, comprehensive scientific and educational programme covering all aspects of interventional radiology. An exceptional group of specialists will deliver lectures, lead workshops, teach courses and participate in debates on a broad range of topics in this ever-evolving sub-specialty.

Author

Uta Melzer

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Vienna, Austria

Improved Structure

The Annual Meeting's programme has traditionally been split into six tracks that each focus on core themes in IR: vascular interventions, interventional oncology, transcatheter embolisation, non-vascular interventions, neurointerventions, and IR management. CIRSE 2014 will again adhere to this structure, only with a minor but important improvement: sessions will now run parallel, making it easier for delegates to seamlessly follow the clinical tracks.

Vascular IR

The Vascular Track will again be a major focus, encompassing a wide range of pathologies. The event will offer more than 50 hours of vascular education in various formats, including 15 Special Sessions, 12 Workshops, 4 Fundamental Courses and more than 10 Hands-on Workshops.

This year's Evidence Fora promise to be particularly intriguing. These sessions provide an opportunity for experts to present the most up-to-date research on a particular treatment option, using trials and evidence to support their case. The topics addressed this year include abdominal and thoracic aortic treatments, discussing whether practitioners have sufficiently scrutinised the drawbacks and benefits of recent breakthroughs in the field.

The Controversies Sessions, which provide a forum for spirited discussions on controversial issues that divide the IR community, have also been consistently popular. Featuring three sets of cutting-edge debates each, these sessions encourage practitioners to re-think their presumptions by confronting them with the best arguments both for and against particular aspects of the chosen topics. This year's discussions will focus on superficial femoral artery revascularisation and below-the-knee interventions.

Interventional Oncology

Minimally invasive procedures are playing an increasingly important and multi-faceted role in the fight against cancer, and this year's programme reflects that reality. The interventional oncology track will explore various new clinical applications, such as neuroendocrine tumours, and will offer a range of case-based Workshops and Hands-on Workshops on the basic skills needed to treat liver, kidney or bone tumours.

One of the Hot Topic Symposia will also be of particular interest to participants interested in oncology, tackling the topic of high-intensity focused ultrasound (HIFU), with presenters addressing whether this promising treatment option may offer benefits beyond those provided by more established ablation modalities.

Transcatheter Embolisation

Transcatheter embolisation is another area in which interventional radiologists have become more active in recent years. Embolotherapy will be comprehensively discussed in a number of key sessions and workshops, including the Controversies in transcatheter embolisation debate and an Interactive Case Session on iatrogenic bleeding.

Neurointerventions

The programme will also offer up-to-date information on image-guided stroke therapies, with studies and trials a crucial

component. A Special Session entitled Interventional acute stroke treatment: trials update and outlook will be dedicated to evaluating both completed and ongoing trials, including a close examination of patient selection. Other focus sessions include a Special Session on Chronic ischaemia of the brain: revascularisation, and an Interactive Case Session on Revascularisation in acute stroke: technical problems and solutions.

Non-Vascular Interventions

This year's Non-Vascular Track will address a variety of important nonvascular interventions that remain an important part of every IR's repertoire. Offered sessions include five workshops and two hands-on workshops, which will provide participants the opportunity to practice vertebroplasty and kyphoplasty techniques. In addition, four Special Sessions will address the essential skills needed for enteral and parenteral nutrition, biliary interventions and pancreatitis treatment, as well as the field of spine interventions.

IR Management

The IR Management Track will centre on safety and education. Sessions will address optimal care, how hospitals and health boards can assess patient safety, and what role regulatory agencies and professional bodies can play. IR education and training will be addressed in workshops exploring IR training and accreditation and providing information on Taking the EBIR.

Finally, tying in with CIRSE's Radiation Protection Campaign, a session on minimising radiation hazards (Practical issues in dose management) will nicely complement an exciting new feature of CIRSE's Radiation Protection Campaign – the Radiation Protection Pavilion, which will make its debut in Glasgow.

As always, the programme will include honorary lectures by individuals who have consistently distinguished themselves in the field of IR. This year's Josef Roesch Lecture will be delivered by Dr. Francisco Carnevale, who will present a speech entitled, "Prostatic artery embolisation: familiar concept, new indication and state-of-the-art methods". Prof. Philippe L. Pereira will deliver the Andreas Gruentzig Lecture, addressing "Standard clinical guidelines for interventional oncology: where are we at present?"

We are delighted to be returning to the UK for this year's Annual Meeting, and are convinced that CIRSE 2014 will once again be an event that showcases the very best of interventional radiology.

LEADING HEALTHCARE IN TAXING TIMES: IS THERE ANOTHER WAY?

Introduction

The future of healthcare brings challenges to hospital managers, clinicians and the patients they serve. The growing expense within an era of austerity implies that we need to re-examine the way care is delivered. Change is difficult, as we are inexplicitly bound to a thought process dictated to us by the medical, biomedical and pharmaceutical fraternity. The public is now demanding safe and effective services, and expects us to provide these within the constraints of available funds. In turn we have built up expectations for the clinicians, with new technology and bigger and larger hospital facilities, each burdened by the immense cost of construction and the ongoing cost of maintenance and operations. It is time to step back and reflect on what we are actually trying to do.

I propose six steps to address this problem, based on current best practice. What is really needed is profound and radical change that redirects healthcare in a new direction and takes it to an entirely different level of working and effectiveness.

Key issues to address

1. Understanding the change in the needs of the population, now and in the future.
2. Addressing rising cost, as we are spending in the wrong place.
3. Designing services for flow, in order to eliminate artificial variation.
4. Considering the value of care delivered to patients.
5. Changing our leadership style so that it is inclusive and distributive.
6. Developing a compact with clinicians to develop joint solutions to the problems.

1. Understanding the Change in the Needs of the Population, Now and in the Future

Life expectancy at birth reaches 80 years across OECD countries, a gain of more than 10 years since 1960 (OECD 2013). Women live almost six years longer than men, averaging 83 years versus 77 years for men. Children who could have died are now teenagers with long-term conditions. People do not have single organ illnesses, and now many have long-term conditions. This implies added complexity, each with the potential of increased cost. At the same time, we have not developed person-centred care, with a move towards health management, as opposed to disease management. Maureen Bisognano (2013) has called for us to "flip health care, moving from a system

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that does things TO patients to one that works WITH patients to achieve the best results." This in turn is a fundamental shift from asking "what is the matter?" – i.e. a disease oriented approach – to "what matters to you?", a person-centred approach. When we manage hospitals in the current environment this is a challenge, as we often deal with patients who would be better managed in more cost-effective and person-friendly environments. In order to move to the new paradigm we need to rethink how we will plan services, not around the disease, but around the person, who is likely to have more than one chronic problem. This means we need to understand the changing epidemiology of disease, and accept that the models of care based on the diseases of the 20th century simply will not work in the 21st.

> ***"We cannot solve operating problems by using the same kind of thinking we used when we created them."***
>
> **Attributed to Albert Einstein**

Christensen and colleagues (2009) call for a change in the way we deliver care, based on the theory of continual disruption in delivery. Previously, Christensen et al (2000) wrote, "The health care industry today is trying to preserve outmoded institutions. Yet the history of disruptive innovations tells us that those institutions will be replaced, soon enough, with new institutions whose business models are appropriate to the new technologies". This is a call for us to rethink the way we organise healthcare, and to move from the current model to one that is flexible and meets the needs of patients. This does not mean that we do not need hospitals; rather that we must rethink the way we use them. This includes ensuring that we build for the future with paperless systems and the latest IT as standard in all future design.

2. Addressing Rising Cost, as We Are Spending in the Wrong Place

Cost cannot go on rising, so we need to spend wisely. We need to design to decrease cost, and at the same time increasing quality - often referred to as the Triple Aim – how to develop high quality and great patient experience at low cost (Berwick et al, 2008). Emmanuel (2013) suggests that one needs to reinvent healthcare delivery to focus on delivering care to patients with chronic illness. This in turn means avoiding hospitalisation, with more outpatient monitoring and intervention at home. The expressed aim is to decrease emergency department visits. To achieve this one could consider the key elements of the Chronic Care Model (Wagner et al, 2001) that includes decision support and community based activated patients and care teams. The foundation is team-based care coordination between office, hospital, pharmacy and home, with reduction in the use of inappropriate interventions that do not add benefit to the patient.

Reduction of cost can occur if we change priorities as above and stop serving the current paradigm. (Weinstein and Skinner, 2010). The technology that we use needs to be directed at decreasing complexity and cost, rather than adding layers to it. Technology improvements require a change in the way we think, as well as the way we work.

3. Design Services for Flow in Order to Eliminate Artificial Variation

The traditional approach to sorting out the logjams in hospitals has been to try to improve flow through the emergency services, which constantly bump the scheduled patients. Paradoxically, this approach is not the way to go. The most predictable flows of patients in a hospital are the unscheduled patients – they are natural variations and one can predict their flow, unless there is a special cause - such as an epidemic or an accident, etc. The scheduled flow, that the clinicians plan, is the more unpredictable and constitutes the artificial variability of hospital flow. These patients are subject to peaks and troughs, as well as different demands. Though superficially it may seem to be planned, the reality is that most hospital managers have no idea of who will be in the hospital for scheduled care at any one time, nor of the resulting demands on in-hospital services such as radiology, pathology and ICU. The theory of managing operations (IHO, 2014) offers an alternative approach and consists of the following elements:

- One needs to end the competition between scheduled or elective care and acute or unscheduled patient flows. This is achieved by separation of the flow streams.
- The way we organise care consists of artificially created variation in scheduling, with peaks and troughs in the artificial demand that results. Smoothing of the flow in order to eliminate the artificial variation is key to the solution.
- To achieve the best and most cost-effective flow one needs to assign separate resources for scheduled and unscheduled patients.
- The patients who are acute need to be seen as per clinical need and in the acute settings. Once the artificial variability has been removed, one can use queuing theory to develop the flow solution.
- Resources for scheduled elective patients are then decided on the concept of maximising patient throughput and minimising unnecessary waits.

Accelero - a subsidiary of Zimmer - Identifies Opportunities for European Hospital to Improve Perioperative Efficiency

Standardised perioperative process to improve orthopedic surgical throughput

AT A GLANCE

- Large, academic hospital in Northern Europe
- Over 6,000 orthopedic surgeries annually
- Nearly 1,000 hip fractures per year

ISSUES

- First case starts often delayed
- Low perioperative throughput due to fixed schedules
- Poorly coordinated room turnover procedures

RESULTS

Accelero assessed the orthopedic perioperative process and provided a solution to improve first case on-time starts, reduce room turnover and add one additional joint arthroplasty per OR per surgical day.

Introduction

Accelero Health Partners was hired to evaluate the orthopedic perioperative process for a hospital in a major European city. The hospital is one of the large academic hospitals in Northern Europe with an equally large emergency department. The orthopedic group performs approximately 6,000 surgeries per year, both scheduled and unscheduled, with nearly 1,000 resulting from accidental hip fractures.

The hospital is experiencing a decrease in the average reimbursement rate with a coinciding increase in the number of cases. To more effectively manage the growth, a new unit of OR suites was opened to accommodate the scheduled cases. However, current processes were limiting throughput to three joint arthroplasties per OR per day. Furthermore, staffing guidelines required all procedures to be completed by 4:00 pm.

Accelero was asked to provide insights and recommendations that would enable the hospital to increase orthopedic perioperative throughput and accomodate the budgeted case volume. Accelero team members went onsite to identify inefficiencies via benchmarking, observation of operating room procedures, patient flow review and interviews with key stakeholders.

Findings

The hospital had established a goal of four joint arthroplasties per OR per surgical day. The timing of first case starts and a longer than normal room turnover were seen as the primary reasons the hospital was not meeting this goal. FIGURE 1 shows the first case on-time starts of the hospital versus benchmarking data obtained from Accelero's proprietary database for joint arthroplasty cases.

First case on-time starts were well below the industry calculated based on the Accelero database due to variations in patient arrival times, poor communication, insufficient organization of materials and supplies and unclear expectations.

Inefficient processes that varied by staff members and a lack of clear expectations contributed to average room turnover times of 41 minutes between joint arthroplasty procedures, significantly higher than the average for hospitals in the Accelero database (FIGURE 2).

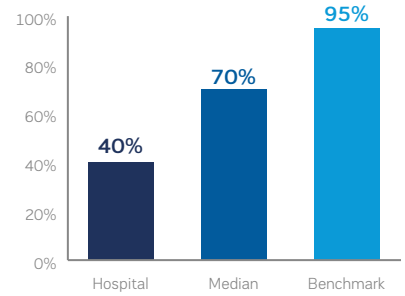

FIGURE 1. First case on-time starts for the hospital v. the Accelero database.

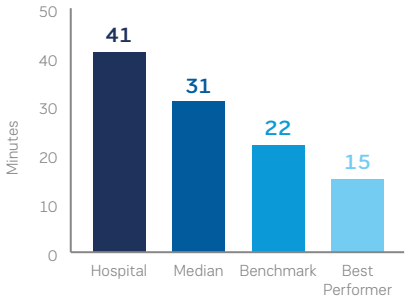

FIGURE 2. Room turnover times for the hospital v. the Accelero database.

Recommendations

At the request of the hospital, Accelero presented a plan to meet current demand and case volume by improving first case on-time starts and room turnover.

First Case On-Time Start

Accelero's solution to meet or exceed the benchmark for on-time starts consisted of:

- Clearly define and communicate the time patients need to arrive in both the pre-op area and the OR
- Develop a process flow document with responsibilities and timing of events for all staff members so they have clear expectations for daily arrival and tasks
- Create protocols to ensure all anesthesia and instrument case carts are fully stocked in advance
- Implement tracking methodology with an action plan for unprepared carts

Room Turnover

The proprietary Accelero hospital database was used to establish a room turnover goal of 22 minutes. The steps required to meet this goal consisted of:

- Clearly define and communicate goals
- Establish a multidisciplinary team of OR staff, management, housekeeping and anesthesia to focus specifically on room turnover process improvement
- Utilize lean methodologies to create standard work and eliminate wasteful efforts for all stakeholders
- Create control documents for monitoring progress with action plans for slow room turnover

Summary

Accelero confirmed that a low percentage of the daily first cases were starting on time. In addition, long room turnover time was identified as a limiting factor in meeting the hospital's joint arthroplasty volume goals. After a thorough analysis, Accelero provided a plan to add one more joint arthroplasty per OR per surgical day during normal operating room hours.

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This approach turns healthcare into an efficient cost-effective process, which is safer, with patients being in the right bed under the right clinical teams. It does require leadership and constancy of purpose, as it totally changes the current paradigm

4. Considering the Value of the Care Delivered to Patients

The concept of value in healthcare is now centre stage, particularly since the budget for healthcare has become finite. We need to ask whether the care we provide actually does add value. In a review of what type of leadership is required, Swensen et al. (2103) call for a move from a volume-driven approach to one that is more value-driven. With this approach patients are persons who are partners, there is continual focus on waste reduction in service provision, quality is everyone's responsibility, not only that of the quality department, and we move from high cost complex large hospitals to lower cost focused care delivery units. Porter and Lee (2013) have described this value as matching quality with cost, and have recommended integrated care that takes into account the entire patient journey and not parts of it. Both these approaches would change the way we currently run hospitals, managing segments of the patients often in disease-oriented rather than patient-focused delivery units.

5. Changing our Leadership Style to be Inclusive and Distributive

Best and colleagues (2012) studied transformation change, and have suggested that in order to make change meaningful, we need to distribute leadership to the front line. This is what happens in the most successful organisations outside healthcare, and if one looks at the systems that perform well, e.g. Virginia Mason Institute in Seattle (2014), there is an alignment of vision and goals at all levels, and the front line is involved in ensuring safe and effective care takes place. The key elements are:

- Effective distributive leadership, where members of staff in the front line are encouraged to continually improve;
- Data feedback on improvement and performance is given in real time;
- The work of the front line is respected and honoured as they continually improve;
- Engagement of physicians as partners for change is a key component;
- Patients and families are involved from the start, and not as tokens but as real partners.

6. Developing a Compact with Clinicians to Develop Joint Solutions

The final challenge is the need to consider how we will deliver change in the future. Hospital managers are an important part of the process, but they need to work with clinician leaders and clinicians themselves in order to deliver the change. This will require the development of a compact with clinicians and sharing the ownership of the change that is needed (Taitz et al, 2013). This is probably the most difficult of the steps to take, as professional autonomy is a deep-seated cultural facet of the life of a clinician. Yet we need to move to a middle ground where there is joint working towards continual improvement of care from both the clinical and the patients' point of view.

The new environment is possible and we need to work together to redesign the services we provide, rather than to continue working at the solution using old techniques. Hospitals have an important role to play in the future, but we need to continually question how we deliver services so that we get the right care to the patient the first time every time. ■

Key Points

- *The economic challenge of providing reliable care to patients requires a radical rethink of what we perceive of healthcare*
- *The aim should be to move to effective management of disease and the development of a new operating system that allows this move*
- *This paper examines six key steps to take to ensure that we can restructure healthcare*

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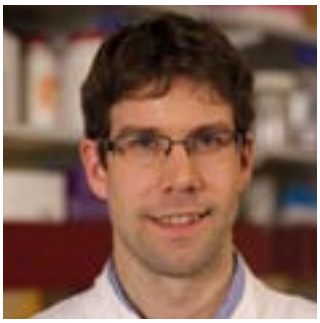
OBESITY

CAUSES, CONSEQUENCES AND PATIENT-CENTRED THERAPEUTIC APPROACHES



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Obesity is one of the greatest 21st century public health challenges. However, government strategies aimed at reducing the unprecedented levels of obesity have been largely unsuccessful to date (Institute of Medicine 2013). Only in 2013 the American Medical Association (AMA) identified the necessity for prevention and medical interventions in the obesity field, suggesting that clinicians are also lagging behind in the fight to halt the obesity epidemic (American Medical Association 2013). Excess weight is the fifth leading risk factor for global deaths. At least 2.8 million adults die each year as a result of being overweight or obese. In addition, approximately 44% of the type 2 diabetes (T2D) burden, 23% of the ischaemic heart disease burden and between 7% and 41% of certain cancer burdens are attributable to overweight and obesity. Obesity is also a major risk factor for numerous other health problems, including hypertension, respiratory and musculoskeletal problems. Mortality also increases above the overweight threshold in direct proportion to increasing body mass index (BMI) (Whitlock et al. 2009). In this article, we will briefly summarise the epidemiologic and economic burdens of obesity. We will also discuss the role of biological factors, with a focus on the gastrointestinal (GI) tract, the pathophysiology of obesity and how understanding the biology may hold the key to novel therapeutic approaches.

Obesity Trends

It has been estimated that obesity has nearly doubled worldwide since 1980. In Europe its prevalence has tripled in many European Union (EU) countries since the 1980s. In 2008 more than 1.4 billion adults, aged 20 and older, were overweight (defined as BMI 25.0 – 29.9 kg/m^2) and over 500 million were obese (defined as BMI >30.0 kg/m^2) (WHO Regional Office for Europe 2013). These trends are dramatic also in the paediatric setting, with more than 40 million overweight children in 2011. Based on the latest available data, more than half (52%) of the adult population in the EU are overweight or obese. The prevalence of overweight and obesity among adults exceeds 50% in no less than 18 of 27 EU member states. Obesity varies threefold among countries, from a low of around 8% in Romania (and Switzerland) to over 25% in Hungary and the UK. Across EU member states 17% of the adult population is obese on average. There is little difference in the average obesity rate between men and women. However, there is some variation among individual countries, with more men than women being obese in Malta, Iceland and Norway, whereas a higher proportion of women are obese in Latvia, Turkey and Hungary. The largest disparities were in Latvia, whereas there was little, if any difference in male and female obesity rates in the Czech Republic, Greece and the UK. The rate of obesity has doubled over the past 20 years in many European countries, regardless of previous levels. For example, in both France and the UK, the prevalence of obesity in 2010 is close to twice that of 1990, even though the rate in France is currently half that of the UK (WHO Regional Office for Europe 2013).

Costs of Obesity

There are innumerable costs associated with obesity and its comorbidities in the health economic setting, fitting into two broad categories: 1) direct costs, which are the result of outpatient and inpatient health services (laboratory and radiological investigations, medications and bariatric surgery) and 2) indirect costs, which are the lost resources as a result of a health condition, for example days missed from work, insurance or wages. Obesity is associated with very high, preventable costs, and it has been estimated that it is already responsible for 2-8% of health costs (Organisation for Economic Co-operation and Development 2012). Although this cost quantification is complex, the overall cost of obesity in Europe in 2010 has been estimated at about 460 billion Euros per annum. The enormity of this obesity-related economic burden is beginning to raise global political awareness that individuals, communities, states, nations and international organisations must do more to face the rising tide of obesity (Organisation for Economic Co-operation and Development 2012).

Evolutionary Context

The widely expounded, but somewhat simplistic, understanding of why individuals develop obesity is based on the premise that a chronic state of energy intake exceeding energy expenditure results in excess calories being stored as body fat. However, this simplistic view does not take into account the multitude of factors that affect what we eat, how physically active we are and how our bodies process energy and adapt to changes in energy availability or expenditure. In this regard, we must consider the evolutionary context of how procurement of food is critical for survival. Drive for food is one of the most powerful human and animal behaviours, and it is fundamental for preservation of the species. There are several systems controlling food intake and body weight (Berthoud 2011; Coll et al. 2007). These biological drivers have adapted during

the evolution of the human body over the millennia. One hypothesis that has been put forward is that 'thrifty' genotypes have been positively selected because of the survival and fecundity advantages conferred by a better use of scarce energy resources (Neel 1962). In modern society, such genotypes may be counterproductive, because they promote fat deposition in preparation for a famine that never comes, and the result is widespread obesity. However, the high prevalence of normal bodyweight in the face of an obesogenic environment suggests that other hypotheses such as the 'drifty gene' hypothesis may better explain our genetic propensity to obesity (Speakman 2008). This hypothesis points to the gradual advent of a reduced risk of predation as an important event in our evolutionary history, which in turn led to progressively less negative selection for factors predisposing to excess weight. Thus, this reduced risk of predation was subsequently followed by random genetic mutations, affecting energy balance control systems, which over time became more numerous and prevalent, i.e. an upward 'drift' in the genetic susceptibility to obesity. Undoubtedly, it has been the recent dramatic changes in our environment, including the increasingly wide availability of food and sedentary lifestyle, that have rapidly unveiled this slow burning underlying genetic susceptibility to obesity (Speakman et al. 2011).

Gastrointestinal Tract

In recent years the role of the GI tract as the body's largest endocrine organ has emerged. Cells in the GI tract called enteroendocrine cells produce hormones that play an important role in regulating bodyweight. These hormones act through a complex neuroendocrine system, including the hypothalamus and brain reward centres, to regulate energy homeostasis. In obesity there is increasing evidence that this gut-brain homeostatic balance is disrupted, either through alterations in circulating hormone levels or through altered responsivity in key brain homeostatic or hedonic centres (Hussain and Bloom 2013).

Peptide YY (PYY) is a 36-amino-acid peptide hormone that is co-secreted from enteroendocrine L-cells with the incretin hormone glucagon-like peptide-1 (GLP-1). PYY3-36, the major circulating form, is produced upon N-terminal cleavage of PYY1-36 by the enzyme dipeptidyl peptidase-4 (DPP-4). PYY3-36, is the anorectic form of PYY, and its role as a regulator of energy homeostasis was first highlighted only in 2002 (Batterham et al. 2002). This role was firmly established through multiple human and animal studies revealing that physiological levels of circulating PYY3-36, achieved by exogenous administration, reduce food intake by a central action (Batterham et al. 2003) Moreover, circulating PYY3-36 levels are reduced in obese individuals, but the anorectic effect of PYY remains intact, raising high expectations for a new therapy for obesity (Batterham et al. 2006). Studies using functional neuroimaging indicate that PYY3-36 mediates its anorectic effects predominantly by acting upon central appetite-regulating circuits, within key brain regions involved in eating control and food reward (Batterham et al. 2007).

GLP-1 is a gut hormone secreted in response to nutrient ingestion, and it is a key gut hormone responsible for enhancing the insulin response to nutrient ingestion, a phenomenon known as the 'incretin effect' (Drucker 2007). For this reason GLP-1-based pharmacotherapies are already a mainstay of treatment for T2D. Nevertheless, there is strong evidence that supraphysiological circulating GLP-1 levels also have appetite-suppressing effects through direct activation of energy homeostatic centres in the brain (De Silva et al. 2011). These observations have led to the development of a GLP-1 receptor agonist, used for treatment of T2D, as an anti-obesity agent, and its licence may soon be extended to this indication also (Manning et al. 2014).

Ghrelin is a peptide produced by cells located in the stomach, and it is the only known circulating orexigenic (appetite-stimulating) factor. The pattern of circulating ghrelin levels is opposite to that of PYY3-36, being higher after a fast and falling after food intake. Ghrelin increases hunger and the amount of food eaten, acting upon key brain regions that control eating and reward (Cummings et al. 2002; Malik et al. 2008). Due to its orexigenic and metabolic effects, it could have potential benefits in antagonising weight loss in catabolic conditions. Theoretically, antagonism of the ghrelin receptor or the more specific approach of blocking ghrelin O-acyltransferase (GOAT), the enzyme responsible for generating active ghrelin, could be employed as anti-obesity therapeutic approaches (Kirchner et al. 2012).

Treatment

Dietary modifications, such as caloric restriction, have long been the first-line obesity treatments. Lifestyle intervention programmes, which may include dietetic, exercise or psychological aspects, are effective in reducing

weight in the short to medium term, as are more intensive meal replacements or very low energy diets for patients with severe obesity. However, in the long term, most will regain much of their lost weight (Manning et al. 2014). Currently, the role of anti-obesity drugs in Europe is limited, after many were withdrawn due to their association with severe psychiatric and/or cardiovascular side effects. At present, the only EU licensed drug for weight management is orlistat, which is an inhibitor of gastric and pancreatic lipases that block fat absorption from the gut, resulting in an average weight loss of about 3 kgs. In the US two novel agents have been approved; lorcaserin (Belviq, a selective serotonin type 2C receptor agonist) and a combination of low-dose phentermine/topiramate (Qsymia, non-selective stimulator of synaptic noradrenaline, dopamine and serotonin release + weight loss-inducing anticonvulsant) are centrally acting agents that can induce an average percentage of weight loss of about 3.5 and 9% respectively (Manning et al. 2014).

Surgery

Bariatric/metabolic surgery is an efficacious treatment modality for obesity, producing durable weight loss, amelioration of obesity-associated co-morbidities and reduced mortality (Sjöström et al. 2007). To date bariatric/metabolic surgery is the only effective way for patients with obesity to achieve a meaningful and sustainable weight loss in the long term (Sjöström et al. 2007). Consequently, the number of bariatric procedures undertaken within Europe has doubled in the last five years with 112,000 procedures undertaken in 2011 (Buchwald and Oien 2013). Metabolic surgery is considered for the treatment of patients with severe obesity (BMI ≥ 40.0 kg/m^2) or with BMI ≥ 35.0 kg/m^2 plus co-morbid conditions that will be improved by weight loss. The three most performed procedures worldwide are Roux-en-Y gastric bypass (RYGBP), sleeve gastrectomy (SG) and adjustable gastric band (AGB). In contrast to AGB, both RYGBP and SG alter the anatomy of the normal gastrointestinal tract resulting in an accelerated passage of food through the gut, and also produce more weight loss and comorbidity improvements than AGB (Franco et al. 2011).

Central to the increasing popularity of metabolic surgery are the marked beneficial effects of metabolic surgery on obesity-related comorbidities such as T2D, hypertension, dyslipidaemia, cardiovascular disease, obstructive sleep apnoea, subfertility, non-alcoholic fatty liver disease all together with a reduced mortality rate (Sjöström et al. 2007). Perhaps the most striking effects of RYGBP and SG are the rapid beneficial changes in glucose homeostasis and insulin secretion, which occur within days of the operation, before any significant weight change, and are sustained in the long term, proving these procedures to be the most effective therapy for T2D. In 2009 a systematic review reported that T2D was resolved or improved in 87% of patients following metabolic surgery (Buchwald et al. 2009).

According to a report from the UK Office of Health Economics in September 2010, if 5% of the 1.1 million patients eligible for metabolic surgery, according to the National Institute for Health and Care Excellence (NICE) guidelines, underwent metabolic surgery the economy would gain £382m within 3 years (reduced NHS burden, reduced benefits and income tax generated by those back in work), and if 25% underwent metabolic surgery, a saving of £1.3bn would be realised within three years, even taking into account the cost of the surgery itself (Office of Health Economics 2010).

In recent years evidence has emerged that surgically-induced alterations in circulating gut hormones mediate the weight-loss and metabolic beneficial effects of bariatric surgery (Scott and Batterham 2011). In contrast, sustained counter-regulatory mechanisms during dieting are thought to provide a strong physiological basis for the high failure rate of non-surgical approaches to weight loss (Larder and O-Rahilly 2012). During a diet PYY and GLP-1 decrease (Sumithran et al. 2011), while RYGBP and SG result in weight loss independent of enhanced PYY and GLP-1 responses after a meal. While diet-mediated weight loss results in increased circulating ghrelin concentrations, in contrast, several studies report low circulating ghrelin concentrations after SG, potentially leading to a stable reduction of hunger and food intake (Cummings et al. 2002). As a consequence of these hormonal changes the final effect of a diet is increased hunger and less satiety, leading to increased food intake and ultimately diet failure. Conversely, surgery-induced hormonal changes result in reduced hunger and more satiety leading to sustained weight loss. Moreover, there is a decrease in metabolic rate/energy expenditure during a diet, and a formerly obese person requires about 15-20% fewer calories to maintain a 'normal' weight than someone who has not been obese (Major et al. 2007). The body defends against weight loss presumably to ensure that reproductive capacity

"to date bariatric/metabolic surgery is the only effective way for patients with obesity to achieve a meaningful and sustainable weight loss in the long term"

and/or survival will not be compromised.

Understanding the mechanisms underlying the metabolic benefits of bariatric surgery is the basis for a burgeoning field of metabolic research. Metabolic surgery is an intriguing model to understand the roles of potential biological drivers such as alterations in gut hormones, gut microbiota, bile acids, neural activity, adipokines and other factors with the aim of elucidating novel therapeutic strategies or achieving a 'medical' or 'knifeless' metabolic surgery.

Conclusion

In summary, given the vast extent of the obesity epidemic, prevention of obesity is central to public health strategy. Ideally, preventative efforts must encourage a healthier environment, promote education, and identify people with a higher risk who could benefit from more intensive interventions. Active treatment of obesity must also be addressed at a population level. However, in the context of the complexity of energy balance, we envisage that development of novel medical approaches for treating obesity is likely to require a better understanding of the biology of genetic risk as well as gaining insights into the successes of bariatric surgery. ■

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Available on the website or on request

IMPACT OF OBESITY ON MEDICAL IMAGING

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Obesity impacts medical imaging. The increases of weight and girth of the patient population are testing the current limits of imaging equipment. With the increasing prevalence of overweight and obese population, more patients are encountering difficulties in obtaining diagnostic quality images.

The purpose of this article is to define the challenges in imaging obese patients and describe current solutions to address these challenges.

Challenges in Imaging Obese Patients

Medical imaging, now used to diagnose and treat a majority of medical conditions, including cardiovascular disease, cancer and trauma, was designed to accommodate patients with defined maximum dimensions. Patients who exceed these defined dimensions of medical imaging equipment pose challenges to acquiring diagnostic medical images (Uppot et al. 2006; Uppot et al. 2007; Uppot 2007; Ginde et al. 2008; Campbell et al. 2009; Buckley et al. 2009; Reynolds 2011; Carucci 2013).

The impact of obesity on medical imaging can simply be defined as a twofold problem:

1. Can the patient fit on medical imaging equipment? 2. Can we get diagnostic quality images?

Inability to fit patients on imaging equipment has both a psychological impact on patient and doctor and an economic impact. Patients and their families are devastated when they are told that they cannot fit on imaging equipment to make a diagnosis. Doctors and healthcare workers feel helpless and anxious as to next diagnostic and therapeutic steps. Inability to obtain a scan also results in an economic impact with the potential need for hospitalisation, further observation, additional laboratory work, and possible exploratory surgery for diagnosis.

Can the Patient Fit?

For all medical imaging equipment (except ultrasound) there are industry standard design limitations to accommodate patients (see Table 1).

The first limitation is the table weight. Although CT and MRI tables can physically accommodate patients up to 1500lbs [680lg], the actual table weight limits are lower, owing to limits in the ability of the table motor to move the table into the gantry at an accurate rate. Industry standard table weight limits are 450lbs [204kg] for CT, 350lbs [158kg] for MRI, and 350lbs [158kg] for fluoroscopy.

The second limitation is the aperture diameter. Although a patient may meet table weight limits, the patient's girth may exceed the aperture diameter. Industry standard limits in aperture opening include 70cm diameter for CT, 60cm diameter for MRI, and 45cm for fluoroscopy.

In the past several years. owing to the increasing need to accommodate larger patients, manufacturers have built larger "bariatric" scanners. There are now tables that can accommodate patients up to 680lbs [308kg] for CT and 550lbs [249kg] for MRI. Manufacturers have also addressed the aperture diameter. There are now bariatric CT scanners that have a gantry opening of 90cm, MRI scanners that have a bore diameter of 70cm, and fluoroscopic equipment with 112cm aperture openings (see Figure 1).

Can We Get Diagnostic

Table 1.
Industry Standard Weight Limits And Aperture Diameters For Imaging Equipment Compared To Available "Bariatic" Imaging Equipment

	Industry Standard			Available Bariatric Equipment		
	Maximum Weight	Maximum Aperture Diameter	Field of View	Maximum Weight	Maximum Aperture Diameter	Field of View
MRI	350 lb [158kg]	60 cm	45-50 cm	550 lb [249kg] 499 lb.	70 cm	
Fluoroscopy	350 lb [158kg]	45 cm		[226kg] 680 lb.	112 cm	
CT	425-450 lb [192-204kg]	70 cm	50 cm	[308kg]	90 cm	70 cm
Nuclear Medicine	400 lb [181kg]					
Radiography		N/A				
Prone	480 lb [217kg]		14 x 17 in. [35.5-43.1cm]			
Standing	None		14 x 17 in.			
Ultrasound	None	N/A	N/A			

Modified from MGH Radiology Rounds Imaging Obese Patients August 2011 Volume 9, Issue 8. Kg conversions by HealthManagement are approximate.

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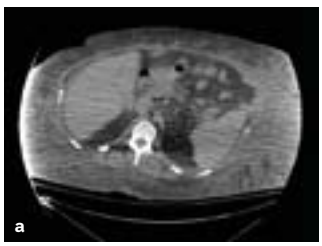
Figure 1.
Images Comparing Fluoroscopy Equipment
Figure 1a - Industry standard fluoroscopic machine has a table weight limit of 350 lbs [158kg] and 18" [45.7cm] aperture (white arrow). **Figure 1b** - Bariatric fluoroscopic equipment has a table weight limit of 500 lbs [226kg] and aperture opening of 44" [111.7 cm] (white arrow).



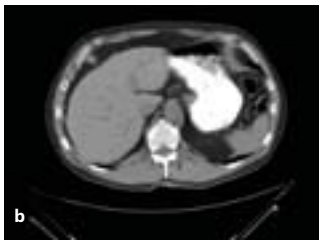


Figure 2.
Axial CT Image of an Obese Patient
Figure 2a showing a poor quality noisy image and beam hardening artifact (arrows) compared to **Figure 2b** - a similar non-contrast axial CT in a non-obese patient

Quality Images?

Although patients may fit onto imaging equipment, the next challenge is: can they get diagnostic quality images? Image quality is directly related to the depth of soft tissue penetration. For x-ray beams, which includes CT, plain radiographs and fluoroscopy, the greater thickness of tissue to penetrate through means more image noise and increased motion artifact, all of which reduces image quality and increases radiation dose to the patient. For ultrasound beams there is a direct relationship between depth of tissue and decline in ultrasound energy resulting in a poor quality image. A study reviewing ten years of dictated radiology reports between 1991 -2001 found the modality most affected by obesity was ultrasound with approximately 1.5% of ultrasound reports dictated containing a disclaimer as to the accuracy of the interpretation of the study due to the poor image quality as a result of obesity (Uppot et al. 2006). The second modality most affected by obesity was plain radiographs.

Over the past 10 years, radiologists and technologists have tweaked imaging protocols to optimise image quality in obese patients. These challenges and solutions are specific for each imaging modality.

> ***"CT is the best modality for obese patients as it has the largest table weight limits and aperture openings"***

CT

CT is the workhorse of medical imaging, and is widely prevalent in the United States. Its widespread availability, fast imaging times and excellent resolution make it a near ideal imaging tool for most patients. In addition, of all the imaging equipment available, it is the best imaging modality to accommodate obese populations. CT scanners tend to have the largest weight limits and aperture diameters as described above. Therefore, the main challenge in CT imaging of obese patients is optimising the CT settings to improve image quality in the obese population. If an obese patient can fit onto a CT scanner and CT scanner settings can be optimised, a diagnostic quality image can typically be obtained. Factors to address in CT for obese patients include kilovoltage peak (kvP), miliiamperes per second (mAS) and field of view (FOV).

kvP and mAS represent the energy and number of x-ray beam as it penetrates through a patient. In larger patients with increased soft tissue, these x-ray beams are hindered from reaching the detector, resulting in a poor quality, noisy image (see Figure 2). Standard CT protocols for normal size patients typically are set at 80-120kVP and "fixed" mAS. In order to accommodate larger patients, increasing the kVP to 140 increases the energy of the x-ray beam to help penetrate through the greater thickness of tissue. Making this adjustment decreases image noise. Changing the mAS setting to "automatic" also allos the CT machine to deliver as many numbers of x-ray photons as needed to improve image quality and decrease noise. The change in these settings, however, has a tradeoff of decreased image contrast with increase in kVP and increased radiation dose delivered to the patient. However, with newer iterative reconstructions offered by all CT manufacturers these increases in radiation dose can be minimised while maintaining image quality (Desai et al. 2012). In addition, newer dual source CT can potentially deliver greater energy and improve image quality in obese patients.

All CT scanners have a defined field of view usually smaller than the gantry diameter. Typically for most CT scanners this field of view is 50cm. Obese patients who can fit onto CT scanners, but exceed the 50cm field of view will have a bright truncation artifact (beam hardening artifact) along the edges of their CT image (see Figure 2), which may limit image interpretation of organs adjacent to the artifact. One solution to address this issue includes positioning the patient so that the area of interest lies within the field of view while sacrificing other parts of the body. The second solution is to invest in a larger bariatric scanner that typically also comes with larger field of views up to 65cm.

Fluoroscopy

Fluoroscopy is used to obtain real time 2D views of the body. It is a vitally important imaging modality for obese patients as it is commonly used to image post gastric bypass patients. Patients who undergo laparascopic gastric bypass surgery or lap band surgery always require post surgical gastrograffin swallow. Although most of these studies can be obtained in a standing position obviating table weight limits, the large girth of the patient can be an issue. Two solutions to address this issue include:

1. Doing a limited study by getting serial plain abdominal radiographs. This eliminates the need for using fluoroscopy and the images obtained allow for a 6 feet space between x-ray generator and patient. The limitation of this method is that the images are not real time and may potentially miss a small anastomotic leak.
2. Buying a bariatric fluoroscopy machine. These "bariatric" machines invert the image intensifier and x-ray generator, and allow for a larger opening for the patient. The tradeoff in these machines is that there is more scattered radiation in the room and therefore radiologists typically manage the fluoroscopic machine controls from behind a leaded glass, as opposed to standing next to the patient.

Ultrasound

Of all the imaging modalities, ultrasound is most limited by obesity. There is a direct decrease of ultrasound energy

as it penetrates through thickness of tissue and results in poor image quality. However, this does not mean that all obese patients will have poor image quality with ultrasound (see Figure 3). The distribution of fat is critically important for image quality. Obese patients with predominately subcutaneous fat as compared to preponderance of intra-peritoneal fat tend to have poorer image quality, as the ultrasound beam has to penetrate through the thickness of the subcutaneous tissue before it reaches the internal organs. Patients with preponderance of intra-peritoneal and very little subcutaneous fat can have high quality image as the depth from probe to internal organs is small and ultrasound beam energy is not attenuated by the fat.

Solutions to improve standard ultrasound imaging in obese patients include:

1. Using the lowest frequency transducer typically decreasing from 4 to 2 mHz transducer. The lower the frequency of the transducer, the greater the energy of the ultrasound beam and the greater the penetration.
2. Position probe closest to the organ of interest and apply pressure to displace the subcutaneous tissues and decrease depth of penetration.
3. Use acoustical windows.

MRI

As with CT, if patients can fit on MRI machines, imaging protocols can be adjusted to optimise the image quality. The limitations unique to MRI include long bore length, which can make obese patients, who are squeezed into MRI machines, claustrophobic. In addition, obese patients can get minor skin burns if their skin is pushed up against the inner lining of the MR bore and RF energy deposited at the skin results in heating. From an image quality standpoint the biggest issue is adjusting the field of view settings. Patients who exceed the field of view will have a "wrap around artifact" that will limit the quality of the image (see Figure 4).

Interventional Radiology

Interventional radiology has its own unique sets of challenges in obese patients. In addition to the limitations of image quality for ultrasound, fluoroscopy and CT guided procedures, obese patients pose special challenges such as: 1. Are instrument lengths long enough? Can the patient and instruments fit into the CT gantry for CT-guided procedures? 2. Will medications given for sedation be adequate to sedate, and does the patient have obstructive sleep apnoea making conscious sedation challenging? 3. Are obese patients at risk for poor wound healing/infections?

Are Instruments Long Enough?

All interventional equipment, including needles, probes, catheters have set maximum lengths. Typically needles and probes are 25cm in maximum length. Until manufacturers develop longer instruments, solutions to address this issue include meticulous pre-procedural planning to identify the shortest distance to the target via alternative entrance sites, and minimising depth to target by pushing the needle hub into soft tissues to displace the subcutaneous fat. The other issue is whether the patient with needles or probes fits into the limited diameter CT gantry. Solutions to address this include using larger gantry diameter bariatric CT scanners for interventional procedures. In addition, some equipment manufacturers have developed flexible instruments that can bend when the patient is moved into the gantry.

Will Medications Given For Sedation Be Adequate?

Although many medications used for conscious sedation are weight-based, sometimes even very large doses do not adequately control pain in obese patients. In addition, obese patients are at risk for having sleep apnoea and airway compromise. Solutions to address these issues include using more than 2 or 3 medications to help with sedation (ie adding demerol to midazolam hydrochloride and sublimaze fentanyl regimens), or, if this is inadequate and the patient is at risk for respiratory compromise, consulting the anaesthesia department for possible general anaesthesia for the procedure.

Infection/Wound Healing

As with risks for surgical procedures, obese patients who are at risk for diabetes are at risk for poor wound healing after interventional procedures. Meticulous attention to interventional techniques, administering pre-procedure antibiotics and close post procedure monitoring can minimise infections.

Conclusion

Obesity not only poses health risks, but also poses challenges in the delivery of healthcare. Imaging protocols can be adjusted to accommodate larger patients. Of all imaging modalities available CT is the best modality for obese patients as it has the largest table weight limits and aperture openings. There are now bariatric scanners with larger weight limits and gantry diameters to address the growing obesity epidemic. ■

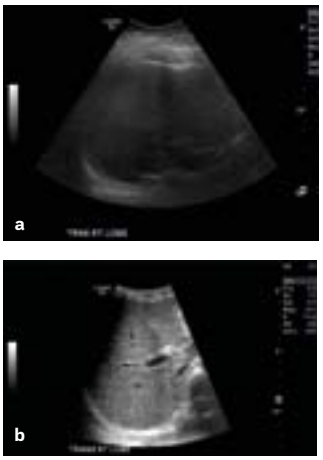


Figure 3.
Compare limited quality right upper quadrant ultrasound in an obese patient **Figure 3a** with right upper quadrant ultrasound in non-obese patient **Figure 3b**

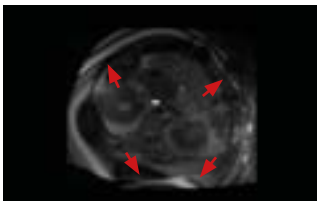


Figure 4.
Image of MRI showing wrap around artifact (arrows) due to patient size exceeding MRI field of view.

Key Points

1. *Obesity is impacting the ability to acquire diagnostic quality images.*
2. *Obese patients may not be able to fit on imaging equipment.*
3. *Standard imaging protocols may not be suitable for obese patients.*
4. *Newer bariatric scanners and adjustments to imaging protocols can improve image quality in obese patients.*

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BARIATRIC SURGERY

CHALLENGES AND SUCCESSES

Interviewee

Dr. Matthias Lannoo

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Interviewed by

Claire Pillar

Managing Editor, HealthManagement

Dr. Matthias Lannoo is an abdominal surgeon at UZ Leuven, Belgium, specialising in bariatric surgery. He is currently researching the effects of bariatric surgery on the glucose metabolism and type 2 diabetes for a PhD. Abdominal surgery appealed to him, he says, for its variety and available specialisms. He started his career researching islet transplantation for type 1 diabetes, before moving to bariatric surgery in 2005, relishing the challenge of laparascopic surgery and gastric bypass as it was starting up, and researching the effects on glucose metabolism. At UZ Leuven he says he has the best of both worlds: challenging surgery and very interesting research in the field of diabetes. He became President of the Belgian Section for Obesity and Metabolic Surgery in 2014, and his term runs until 2016.

What bariatric surgeries are provided at your institution?

At UZ Leuven we mostly perform gastric bypass, which is the gold standard. Gastric bypasses are 70% of the caseload, with gastric sleeves the remainder. Gastric sleeves can be indicated, for example, in patients who have a transplanted organ and immunosuppression, type 1 diabetes or Crohn's disease. As Leuven is a university hospital we see a wide variety of patients. We have approximately 400 cases a year.

What are the main challenges of bariatric surgery?

Firstly, the lack of follow-up. Surgery is only a little tool that you implant into the patient so that they can stick to the life-long therapy of eating less and eating healthier than their body and mind is indicating. Even after you have operated, obesity being a chronic disease needs intensive management. In the past, if the surgery went well, wounds were healed, the patient had lost sufficient weight, follow-up was often ceased. So for long term complications like protein malnutrition, vitamin deficiencies, hypoglycaemic episodes... there was no early detection. GPs did not have sufficient training and support to follow them up. Now we see patients who are not doing well, who are regaining weight, at least partially due to lack of sufficient follow-up. A number of patients experience so-called refractory dumping mainly due to the lack of adequate dietary coaching.

Here in Belgium only the surgery is reimbursed; follow-up by a psychologist or a dietician is not. In this way the problem of insufficient follow-up increases. Bariatric surgery is not a cure for obesity and its comorbidities but a highly necessary therapeutic module in the multimodal treatment of this disease. Now it starts happening, and in our institution we have worked hard in the last few years to manage all our patients (surgical and non-surgical) in the same multidisciplinary programme. It's working. Results are much better. The most important issue is to make the surgery even more effective in the long term and safer by following up patients, anticipating complications and treating them early before they get all kinds of therapy-related side effects.

The programme at UZ Leuven implemented life-long follow-up for bariatric patients. Despite these efforts we have only data on 30% of the patients at time points longer than 3 years. The rate in the USA is often lower, only 9-10%. So patients need more imperative motivators to become compliant to follow-up and additional therapies. When we want to know the full effect of surgery honestly in the long term we need to put patients in a obligatory programme as for diabetes, where they have to go to a doctor at least 3 times a year, and have these kind of conventions so they get support from a dietician, a psychologist, physical therapist etc. That will be the biggest challenge. The short-term problem is the cost, because there are so many of these patients at this moment. In the long term it will be beneficial as the incidence of expensive obesity-related comorbidities will decrease.

Second is the challenge of getting the surgery in the right place in the clinical management of obese patients. Timing of surgery will become very important in the future. Now, timing of the surgery is when the patient thinks of it, when they are sick of being obese and experiencing the multiple treatment failures, and want the surgery. Surgery is probably most effective, for example, just before or when diabetes starts. However, we have to investigate this to make surgery more effective with good timing and with good follow-up of the patients.

Third is the challenge of new techniques. Surgeons like to invent operations that carry their name! You have the gastric sleeve and approximately 15 other operations that you can see in the literature. Surgeons are trying to do something different, based on some possible insight into the effects of the surgery. To prove safety and effectiveness of a new procedure it requires thousands of patients and 15 years of follow-up. For the moment I think we should optimise our time and resources by sticking to four standard procedures and learning how they work and what their effects are.

Fourthly, on the research side the problem is that we do not know what is causing the overconsumption and

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underuse of calories, resulting in obesity. Obesity was only classed as a disease two years ago. As most of the disease is mainly genetically determined with a cocktail of immune and environmental mediated disturbances started with some trigger such as smoking cessation, pharmacological agents, depression... In obesity we do not know fully which metabolic processes are affected and how they interact in a healthy subject. In surgery we were extremely lucky – we did not know the disease, we performed procedures and are now curing 80% of patients. We are also trying to get insights into knowing the comorbidities of the disease – obesity, type 2 diabetes, non-alcoholic steatohepatitis (NASH) and all the things that are correlated. We need to know how surgery is influencing these effects. Increasing our knowledge on this disease or possibly many different diseases with obesity as the common symptom, will be the most important issue. In the case that there are several mechanisms of disease and their combinations, surgery can only be tailored when knowledge of both disease and therapy is more complete. In addition we will learn why 20 per cent of patients escape from the therapeutic effect of surgery in the long term or others experience invalidating side effects e.g. hypoglycaemia. The ultimate goal of research is to make the therapy less invasive and safer.

Bariatric surgery sometimes gets a bad name. Some of the public but also medical professionals think that the problem is not a disease, but laziness of obese patients, and categorise bariatric surgery in the group of aesthetic procedures. That obesity was not classed as a disease until recently indicates the dimension of this wrong way of thinking. It's not an aesthetic operation; it's purely a medical therapy. The problem is that a lot of people deserve this therapy, but are considered as aesthetic cases rather than medical when potential reimbursement is evaluated.

> ***"bariatric surgery is not a cure for obesity and its comorbidities but a highly necessary therapeutic module in the multimodal treatment of this disease"***

What have been the major advances in bariatric surgery?

The introduction of laparoscopy. With open surgery you have to make an incision just below the sternal notch, and obese patients had the most problems with breathing, wound infections and eventually large incisional hernias. Now you can do the operation minimally invasive with less postoperative pain and fast mobilisation resulting in fewer possibly lethal complications. Patients can be home after two days. Stapling devices have also evolved. Anaesthesia has improved a lot with a lower use of opioids, the use of agents that are not absorbed by the large fat mass and less opioid use in postoperative pain regimens. All enhance postoperative recovery and early mobilisation. These have made bariatric surgery safer in the short term.

What are the pros and cons of invasive as against minimally invasive bariatric surgery?

Minimally invasive is the gold standard in bariatric surgery. Even if there are complications after an operation, such as sepsis or shock due to an early fistula these patients are re-operated laparoscopically. It is more difficult, but recovery is so much faster and there are fewer complications. In the case of upper abdomen surgery in morbidly obese patients exposure is also so much easier with laparoscopic surgery, making surgery more accurate and safer.

How important is multidisciplinary management of obesity?

Multidisciplinary management is mandatory for the long term. Although the effect of surgery is tremendous, when you take the other disciplines away, surgery only is 50% effective. Once patients lose weight, more weight than they have ever lost, it seems easy when it stays off when they start eating. The patients think they do not need follow-up, only surgery. However, in the long term if you do not follow them up, and give them support from dieticians and psychologists you see a lot of side effects that can be avoided. If a patient has gained a lot of weight you cannot re-operate, and it is as difficult as before to get the weight off. We need to see them early to prevent weight regain.

What are the side effects and complications of bariatric surgery?

The side effects include vitamin deficiency, dysphagia, small bowel obstruction and inadequate dumping syndrome. Vitamin and mineral deficiencies are frequent (up to 40% of the patients). Even in the case of preventive administration of a multivitamin, control of the blood levels is imperative at least once a year. The most common deficiencies are iron, vitamin B12, vitamin D and folic acid.

Normally, patients with a Roux-en-Y gastric bypass (RYGB) or a sleeve gastrectomy (SG) do not vomit. If this is the case a stenosis of the gastroenterostomy, mostly due to a marginal ulcer or a small bowel obstruction is present. Small bowel obstruction is always a surgical urgency, due to a high incidence of subsequent ischaemia of

the complete small bowel either to an acute dilatation of the native stomach with a high chance of cardiac arrest. The most frequent cause is an internal herniation of small bowel into the mesodefect at the enteroenterostomy or between the mesenterium of the alimentary limb and the tranverse colon. A CT scan is negative in almost half the cases of small bowel obstruction. So a high index of suspicion and a very low threshold for urgent exploratory laparoscopy is advised.

Dumping may occur after surgery to the stomach more particularly after ingestion of mainly simple carbohydrates. To a lesser extent it may also occur after fatty food and low calorie food with a beverage, or with a beverage less than half an hour apart from the meal. Early dumping occurs immediately after a meal, and symptoms are dizziness, nausea, diarrhoea, abdominal cramping pain and angina-like pain. Late dumping occurs two hours after a meal causing hypoglyacemia with neuroglycopenia symptoms. These symptoms are induced by osmotic large-fluid shift to the small intestine with consequent vasomotor reactions and by an excessive incretin response with disproportional insulin secretion, respectively. Dumping can be avoided if the patient adheres to a sugar-free and fat-free diet. Moreover, a very regular eating pattern and avoidance of alcohol are mandatory to avoid hypoglycaemic events. If patients do not adhere to this advice the hypoglycaemic episodes will induce more craving for sugar. It is a vicious circle, resulting in alternating hyper- and hypoglycaemic episodes with subsequent tiredness and headaches. This can be identified quickly in follow-up. If not, patients will come back eventually with weight regain.

Another complication is marginal ulcers at the gastroenetrostomy. If patients are smoking, drinking diet coke or taking non-steroidal anti-inflammatory drugs they are prone to get an ulcer. Most common complications of a marginal ulcer are stenosis, bleeding or perforation. Therefore patients are on proton pump inhibitors (PPI) the first 1 to 3 months after surgery and around 50% stay on PPIs lifelong. Reflux disease can be a long-term complication in patients with a sleeve gastrectomy. PPI use is even higher in these patients

What role does imaging play in planning and follow-up of surgery?

It is very important. Patients complaining of dysphagia, weight regain or symptoms of small bowel obstruction will always be investigated with a barium swallow upper GI series and/ or a CT scan of the abdomen. The volume of the pouch, the diameter of the gastroentrostomy, the presence of a gastrogastric fistula, whirl sign of the superior mesenteric artery, dilation of small bowel is appreciated. A lot of patients already have a gastric band, and in case of a planned secondary gastric bypass or just in case of troubles, they also get an a barium swallow upper GI series to see where the band is located, or if there is slippage. Nowadays most of the band fillings are also performed under radioscopy with a barium swallow to check the stoma diameter.

Is bariatric surgery a long-term cure?

Only if there is multidisciplinary management of the patient. Bariatric surgery is an essential tool to enable morbidly obese patients to adhere to the lifelong therapy of eating less, eating healthily and doing exercise. Our surgery is mandatory to make the obesity treatment successful, otherwise patients will lose the courage to stick to the therapies. When you have to do surgery, and what surgery to do in what patients will be the question for coming years.

At this moment, the right indications for surgery for patients with a BMI below 35 are unknown. Once it will be possible to identify the patients in this population that surely will develop a higher BMI and comorbidities later in life, surgery will possibly be indicated as an early intervention. Surgery earlier on may be even more effective in the long term. For now surgery in obese patients is only indicated in randomised clinical trials. First of all there is still a lot of work to make surgery, the only long term cure for morbid obesity, more accessible for all patients like in Belgium, Scandinavia and the Netherlands.

There have been controversies when patients have opted for bariatric surgery more for aesthetic reasons than health reasons, often by becoming medical tourists. Are national/ international guidelines strict enough? Would you like to comment on this issue.

You can make a thousand guidelines, but if patients come to a surgeon and are unhappy with their weight, there will always be surgeons who will do it irrespective of the guidelines. In these cases the surgeon lays responsibility with the patients by means of a tight informed consent analogous with aesthetic surgery. However, postoperative complications for aesthetic surgeries are not so bad as for bariatric surgery. Performing procedures in an abdomen is one bridge too far to do so only for aesthetic reasons. This is my personal opinion. Although legally it could be airtight when there is a clear contract between a surgeon and a patient. Anyway, a thousand guidelines cannot change this, and happily it is still an exception. ■

OBESITY POLICY

IS THERE A GAP IN PERCEPTION?

Author

Claire Pillar

Managing Editor, HealthManagement

A survey of policymakers has revealed gaps in perception of the causes and management of overweight and obesity, which could affect the way in which countries make and implement policies to prevent, manage and treat the obesity epidemic.

The multi-country survey was conducted by the European Association for the Study of Obesity in association with C3 Collaborating for Health. The report summaries obesity realities and policy in Brazil, Bulgaria, Canada, Denmark, England, France, Germany, Italy, Mexico, Spain and the United States. Three hundred and thirty-three policymakers were surveyed about their knowledge of and opinions on the extent of overweight and obesity, responsibility for obesity, drivers of obesity, prevention, treatment and management and obesity priorities now and in the future.

Findings

Only 1 in 5 of those surveyed knew that the standard for obesity is when body mass index (BMI) is 30kg/m^2. 66% did not have a clear idea of the prevalence of obesity while 84% did not know the extent of overweight. In addition, policymakers were not aware if there were national obesity targets in their country. The authors suggest, "Reporting against obesity targets would be helpful in raising awareness about progress among policymakers and the general public alike."

Almost all the policymakers saw the responsibility for reducing obesity as individual, with family and the food industry having a powerful influence (see Figure). The main drivers were perceived as physical activity and marketing of and access to unhealthy food. Healthcare professionals were seen as less responsible, although there were marked differences between countries. Respondents in Bulgaria, Canada, Denmark, England, Mexico and the United States saw health professionals as having the most responsibility, whereas in Brazil, France, Germany, Italy and Spain at least a fifth of the policymakers regard health professionals as having no responsibility at all. The authors say, "All these actors have a role to play in creating an environment in which it is easier to be healthy – something that Mexico's policymakers were the most likely to recognise. The lack of appreciation of, for example, the role of the government in Germany and the United States, healthcare professionals in Spain, or employers in France could be a barrier to progress."

As to what drives overweight and obesity, the policymakers surveyed agreed only on lack of motivation and lack of physical activity. The report authors note that poverty does play a role in limiting the choices available to people to live a healthy lifestyle, but that not all the policymakers were aware of this. "Issues around food marketing and access to unhealthy food were acknowledged as important drivers of the obesity epidemic, particularly by Mexico's policymakers." Interestingly, they also failed to recognise that people's perception is changing so that overweight is the "new normal." The report notes that "This failure by many policymakers to understand that people's perception of what is a 'healthy' weight is changing could reflect their relative lack of knowledge about 'overweight' – that the majority of people in many of the countries in the survey are now above a healthy weight." In addition, policymakers were asked if identification and diagnosis of people who are overweight or obese works well in their country. In England, Italy and Spain, most felt it was addressed well. However, in Bulgaria, Canada, France, Germany and the United States, more than a quarter felt this was not the case (almost 60% in the United States). The authors suggest, "This lack of faith in the ability of the health system to identify people with obesity reflects the reality in many countries – and improvements will be dependent on ensuring that health professionals play more of a role."

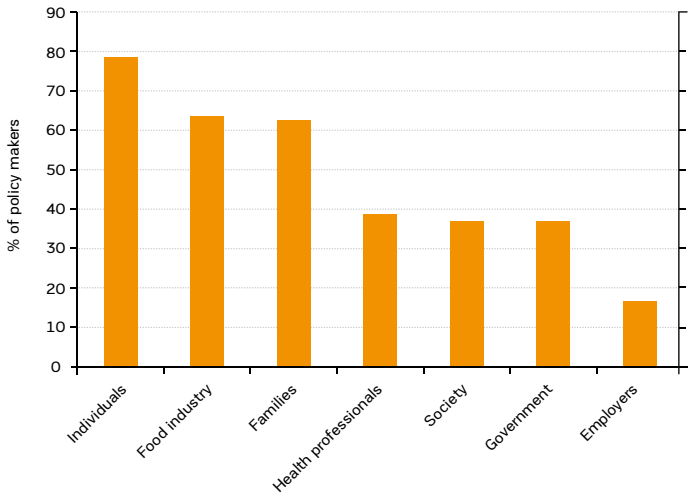
Conclusion

The report concludes, "There is clearly still more to be done to raise awareness among policymakers of the extent of obesity and overweight, the effectiveness and reach of different interventions, and the impact that obesity-prevention and management programmes are having (and could have) nationally. If policymakers have solid knowledge of the extent of the challenge posed by obesity, and the existing evidence for what can be done and who needs to be involved, national policies are more likely to be put in place that adequately address the reality of tackling obesity in the population." ■

Further reading

European Association for the Study of Obesity; C3 Collaborating for Health (2014) Obesity: perception and policy. Multi-country review and survey of policymakers 2014. London: EASO; C3. Available from: http://easo.org/wp-content/uploads/2014/05/C3_EASO_Survey_A4_Web-FINAL.pdf

Responsibility for obesity



WEIGHT BIAS

A HIDDEN STIGMA

Interviewee

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What Prompted Your Interest in Weight Bias, Stigma and Discrimination?

Early on in my training as a graduate student, I was offered an opportunity to do some research on weight stigma. This was an issue that I knew little about, but I became immersed in the topic as I learned how widespread weight bias is in our society, and that it was essentially unchallenged and ignored. At that time I was also providing psychological and behavioural weight loss treatment to patients with obesity. I was struck by how often patients talked about their experiences of weight bias, and how frequently these experiences caused emotional distress and created significant barriers in treatment. The more I learned about weight bias, the more I wanted to do research on this issue to try to help improve the quality of life of those who are affected.

Is Weight Bias a Problem In Healthcare?

Several decades of research show that weight bias exists in the healthcare setting. In fact, our research found that women with obesity report that doctors are one of the most common sources of weight bias in their lives – 69% of women reported these experiences with doctors. Negative weight-related attitudes and stereotypes toward patients with obesity have been documented among physicians, nurses, medical students, dietitians, psychologists, and even health professionals who specialise in obesity. Stereotypes include assumptions that patients with obesity are non-compliant with treatment, lazy, and lack willpower and motivation to improve their health. Recent studies have examined weight biases among large samples of medical students and physicians, and found that levels of weight bias in these groups were no different than the extent of weight bias present in the general population. Weight bias remains considerably common in our society, and health providers are not immune to adopting these biases.

What Effect Does it Have on Patients?

Weight biases by health providers can affect the quality and content of the care that they provide to patients. These biases are related to disparities in the quality of communication and decision-making by providers, how much time they spend with patients, the likelihood of discussing weight-related health, and can contribute to avoidance of healthcare and low ratings of care by patients. In addition, research shows that health providers have less respect for patients as their BMI increases, as well as more frustration, less patience, less rapport, and less desire to help patients with obesity compared to thinner patients.

> ***"women with obesity report that doctors are one of the most common sources of weight bias in their lives"***

What Should Healthcare Providers Do to Address Weight Bias?

Healthcare providers can implement a number of strategies in their clinical practice to reduce and avoid weight bias. As a first step, it is helpful to become aware of one's personal assumptions and attitudes about body weight, and to challenge weight-based stereotypes. In addition to increasing self-awareness, it is important to give careful consideration to the language you use to discuss body weight with patients and colleagues. Our research has found that when patients feel that a doctor has used stigmatising language to describe their excess body weight, many patients report feeling ashamed and intend to avoid future healthcare appointments. Using people-first language, motivational interviewing techniques, and language that avoids blaming or judging patients about their weight can help providers to more effectively support their patients with obesity. We often suggest that providers begin a conversation about weight with patients by asking patients how they feel about their current weight, and what preferred language or terminology to describe excess body weight patients would feel most comfortable with.

In addition to promoting positive and productive discussions about weight-related health, providers need to look carefully at the medical office setting to see where there might be unintentional messages or situations that promote weight bias. For example, the reading materials provided in the medical office waiting room offer an opportunity to provide patients with important health messages related to nutrition, eating and physical activity. But it's important to ensure that these reading materials or magazines have no stigmatising

SYMPOSIUM REPORT

Special K Weight Management

European Congress on Obesity, Sofia, Bulgaria, May 29th 2014

Kellogg's SpecialK has been exploring how digital tools can assist people lead healthier lives. In a recent symposium at the European Congress on Obesity in Sofia, speakers presented the findings of research in the efficacy of MySpecialK.co.uk, a free online weight loss website which provides users with calorie controlled meal plans, healthy lifestyle tips and simple weight loss tracking tools.

Dr David Johns (MRC Human Nutrition Research, Cambridge, UK) presented the National Institute for Health and Care Excellence (NICE) review of Behavioural Weight Loss Programmes (BWMP's) and subsequent recommendations for successful services. In the review, calorie counting, contact with a dietitian and use of behaviour change techniques that compare participants' behaviour with others were associated with greater weight loss. BWMPs using a combination of diet and exercise were more effective than diet only or exercise only.

Dr Margaret Ashwell (Ashwell Associates, Ashwell, UK)) then summarised a UK trial, funded by The Kellogg Company, which tested the hypothesis that promoting breakfast cereal consumption, as part of a web based programme, results in loss of body mass. This trial was set up because there was reasonable evidence from observational studies that adults (de la Hunty and Ashwell 2007) and children(de la Hunty, Gibson et al. 2013) who regularly eat ready to eat cereals (RTEC) are slimmer than those who don't.

Therefore, in a single centre, single blind, randomised parallel study, the test group followed a fully interactive website (B) with 'prescribed' breakfast cereals whereas the control group followed website (A) giving standard advice on weight loss. Study site visits were made at 0, 4, 12 and 24 weeks for measurements of height, weight, skinfolds, body fat, waist and hip circumference. 180 women were randomly allocated to two equal groups. Subjects were in good health, aged 19-50 years, with a BMI ranging from 25-40 kg/m2. At baseline there was no difference in mean age or BMI of the two groups. The programme provided customisable goals based on lifestyle choice linked to a designated and flexible meal plan with detailed recipes and full ingredient information. Next to this, healthy lifestyle tips were provided and progress could be tracked and if wanted shared with friends.

The results showed that the percentage change in body mass loss was greater when following website B (2.4% with SD 4.0%) than website A (1.1% with SD 3.4%). There were 90 in each group and ITT ANOVA repeated measures showed a significant difference (p=0.013). For completers (website A: n=62, website B: n=64), the percentage change in body mass loss was also greater for website B (3.1% with SD 4.5%) than website A (1.5% with SD 3.1%)(p=0.023). The difference in fat mass loss

in the Digital Age

was borderline significance between groups. However this still shows that the body mass loss was not just due to water loss. Dr Ashwell concluded that the advice and motivation offered by an interactive website, including provision and consumption of breakfast cereals, results in significantly greater loss of body mass compared to the use of a standard website.

Dr Francis Bornet (NEALTH, Toulouse, France) then described a similar web-based weight management programme trial, which had been conducted in France. Its purpose was to determine whether the effectiveness of the programme as found in the UK would also be found in a country with a different dietary culture.

Its objective was to assess the efficacy of the weight-loss and weight-loss maintenance website programme in young overweight women without co-morbidity. The French trial was designed to be a single arm study to recruit and examine the effect of a 6m website programme in seventy healthy overweight women. They were asked to follow the recommendations of the website programme that provided nutritionally balanced controlled meal plans to lose weight during the first three months and to maintain their weight loss during the subsequent 3 months. Assessments were at the outset, at three months (3m) and at six months (6m). Main outcome variables were changes in body weight, waist and hip circumferences and fat mass. The main characteristics of women at baseline with mean (SD) were as follows: age (y): 33.4 (8.6); weight (kg): 77.0 (6.9); BMI (kg/m2): 28.4 (0.9); waist and hip circumferences (cm): 92.6 (5.9) and 109.8 (5.9), respectively.

Dr Bornet presented the results, which showed that changes in body weight and body circumferences measured between baseline and 3m, and baseline and 6m for patients in intention-to-treat (ITT) (n = 70) and completer (n = 49) populations were significantly reduced. At 3m, the completer population showed a significant reduction of body weight compared to baseline (2.7 (2.3) kg; t = –7.96, P <0.0001). During the 3m weight maintenance period women maintained their weight, hip and waist circumferences so that 6m measures did not vary significantly from 3m measures.

Dr Bornet concluded that the moderate, but maintained, reduction of body weight and body circumferences suggests that a website programme proposing a nutritionally balanced controlled eating plan can be a good approach to help with weight management in overweight women without any co-morbidities (Bornet F.R.J., Curis E. et al. 2014).

The results of the UK study and the French study suggest that strong differences in dietary culture do not seem to have large impact on the effectiveness of the web-based programme.

After discussion of these two trials, Dr. Nicola Lasikiewicz (James Cook University Australia, Singapore) presented the results of a recent systematic review exploring the psychological benefits of weight loss following participation in behavioural or dietary based interventions with or without exercise (Lasikiewicz, Myrissa et al. 2014). The results of the review demonstrated that improvements in psychological wellbeing, specifically, self-esteem, depressive symptoms, body image and vitality are frequently observed. Of interest, was that improvements in self-esteem and depressive symptoms were not always tied to actual weight loss, meaning that a person may feel better following the intervention, despite losing little or no weight. Dr. Lasikiewicz summarised by saying that understanding the changes a person goes through, psychologically, may be key to understanding successful weight loss following implementation of a weight loss intervention, specifically one that is behavioural in nature. Essentially, if a person feels better about themselves and loses weight following an intervention, then this may promote future weight loss success or weight loss maintenance.

In conclusion, the digital age brings a suite of new tools for people managing their weight and the experts who advise them. Interactive websites, such as MySpecialK.co.uk, can offer the motivation, encouragement and tracking tools required for a success weight loss journey.

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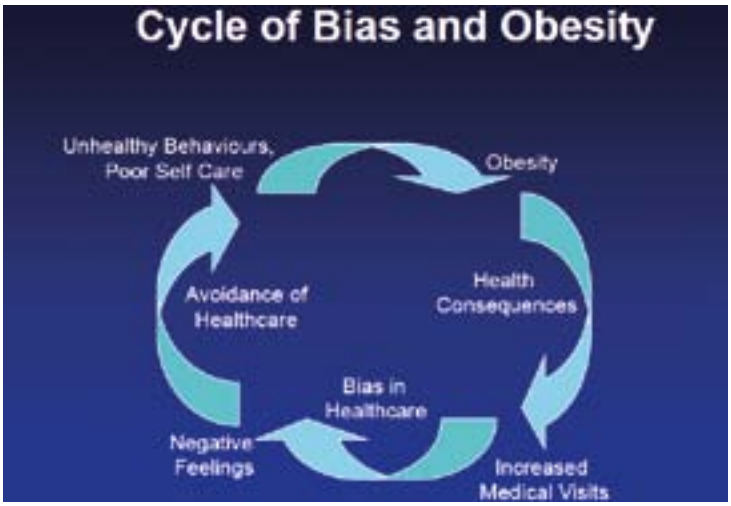
messages or emphasise the importance of weight loss for the purpose of physical appearance rather than improved health. Other aspects of the medical setting can also create experiences of shame or embarrassment for patients with larger bodies. To avoid this, be sure that medical equipment is large enough to accommodate patients with larger bodies, whether it be examination tables, blood pressure cuffs, scales, patient gowns, or waiting room chairs. Organisations like the U.S. National Institutes of Health have developed guidelines for strategies to promote a medical setting that accommodates patients of diverse body sizes.



Should Obesity be Viewed as a Disability with Attendant Legal and Civil Rights? There is a Test Case before the European Court of Human Rights on this Issue. What is the Position in the United States?

There are different views about whether or not obesity should be considered a disability. In our national polling studies, we have found that Americans express substantial support for legal measures to prohibit weight discrimination toward people with obesity (especially in the context of weight discrimination in employment), but less so for laws that would extend disability protections to persons with obesity. Still, in our most recent study which tracked public attitudes for laws that would extend disability benefits to individuals with obesity, we found increasingly favourable public attitudes between 2011-2013. The increased support for this type of law was primarily observed in 2013, and it's possible that this was partially attributed to the announcement by the American Medical Association (and resulting national media attention) classifying obesity as an official disease. This announcement and media coverage occurred shortly before our 2013 data collection.

At the same time, some people have argued that labelling obesity as a disability may instead promote additional societal stigma. There are many individuals with obesity who are not disabled by their weight, and who do not want to be perceived as having a disability. This is certainly a complex issue, and one that warrants additional discussion and research attention.

Do Women Who Are Overweight or Obese Experience More Discrimination Than Men? Does This Mean, For Example, That They Are Less Likely to Present for Mammographic Screening?

The research on this topic is somewhat mixed. Certainly both women and men are vulnerable to weight bias and discrimination. Some of our studies, using national samples, have found that women are more vulnerable to weight discrimination, and at lower levels of overweight, compared to men. For example, we have found that women with a BMI of 27 are already reporting considerable weight discrimination, but that comparable levels of weight discrimination among men don't seem to occur until higher levels of obesity. It appears that for women, if they deviate (even slightly) from expected societal ideals of thinness and physical attractiveness, they are at risk for experiencing weight bias.

We also see in studies that women with obesity are more likely to delay preventative health screenings, and that weight bias may be a contributor. In one study by Amy and colleagues, women with obesity attributed their decision to avoid and cancel medical appointments to the fact that they had experienced weight bias from providers in the past, felt ashamed and embarrassed of being weighed, and felt that the medical equipment was too small to be functional for their body size. The percentage of women who reported these barriers increased with their BMI. So there are certainly important implications of weight bias for utilisation of healthcare. ■

Further information

For additional resources and tools on strategies for medical providers to reduce weight bias, visit:
http://www.yaleruddcenter.org/what_we_do.aspx?id=196

For podcasts, visit:
http://www.yaleruddcenter.org/podcasts.aspx

Preventing weight bias: helping without harming in clinical practice. online toolkit for healthcare providers. Available from:
http://www.yaleruddcenter.org/resources/bias_toolkit/index.html

Medical care for obese patients:
http://win.niddk.nih.gov/publications/pdfs/medcareobesebw.pdf

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Sabin JA, Marini M, Nosek BA (2012) Implicit and explicit anti-fat bias among a large sample of medical doctors by BMI, race/ethnicity and gender. PLoS One, 7: e48448.

Suh Y, Puhl RM, Liu S, Milici FF (2014) Support for laws to prohibit weight discrimination in the United States: Public attitudes from 2011-2013. Obesity, DOI:10.1002/oby.20750

IQP - AN INTEGRAL QUALITY PLAN. WHAT IS IT?

EXPERIENCES AND ACTIONS SINCE IMPLEMENTATION

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Processes Consultant

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Introduction

This article discusses the 'Integral Quality Plan' (IQP) created and employed at IDI (Institut de Diagnòstic per la Imatge).

IDI is a public organisation and part of CatSalut, the Catalan regulatory body of the National Health System. IDI is responsible for the management, administration and performance of computed tomography (CT), magnetic resonance (MR), interventional radiology and nuclear medicine in the main teaching hospitals of the Catalan public health system, including Vall Hebron, Bellvitge, Germans Trias i Pujol in Barcelona and Dr Josep Trueta in Girona.

The main purpose of the IQP is to establish a systematic approach to quality within IDI, in order to maintain and improve the highest standards of patient care.

To implement the IQP, a Quality Commission (QC) has been created. The QC is moderated by the Medical Director and consists of three units: clinical governance, the processes consultant and the technical department.

This article details the roles and interaction between the relevant parties, and how this has positively impacted the day-to-day running of IDI and contributed to the ultimate goal of continuous professional development, optimal patient care and high standards of excellence in imaging.

Historical Context

Since its creation in 1991, the challenge of quality and clinical governance has been a top priority at IDI, and has an important role within the processes map (see Figure 1). In this processes map quality has a strategic place with a direct relationship to operative processes.

In the years prior to the IQP there were several significant developments aimed at improving quality at IDI. These included:

- A Quality Policy in the strategy plan was established in 2007. In this context IDI's mission, vision and the Quality Handbook were defined.
- In 2007 the Management Team set out its commitment to Quality in a policy document (QPD, see Figure 2) where objectives were defined. The QPD covers aspects relating to the working practices of all staff at IDI. All staff members adhere to this declaration.
- In 2007 five IDI units obtained the International Organization for Standardization (ISO) 9001: Quality Management Systems certification from AENOR (Asociación Española de Normalización y Certificación), followed by two additional IDI units in 2010.
- In 2012 the IQP was defined and the Quality Commission created.
- In 2012 a progressive integration process was started in the Radiology and Nuclear Medicine ICS (Institut Català de la Salut) departments as a strategic bilateral initiative. The aim was to obtain an integral and unique model of imaging.
- By 2013 twelve out of thirteen units had obtained or renewed certification (see Figure 3). IDI staff performed these certification procedures.

Reason for the IQP

ISO 9001 is an excellent tool to manage processes, working groups and the continuous professional development of professionals. However it is more appropriate for manufacturing purposes than clinical activities.

For this reason, the IQP was introduced in 2013 in order to create internal IDI standards and to adapt to the recommendations of world-renowned radiological and nuclear medicine societies.

The objectives of the IQP were to reduce errors and clinical variability in the different departments. In addition there is a focus on continuous professional development and processes improvement, with the final aim of improving patient care.

To implement the IQP, we have created a Quality Committee made up of a Management Team and a Quality Commission. The Quality Commission consists of: the medical director (MD), clinical governance, the processes consultant and the technical department. These meet monthly and produce feedback for the Quality Committee. The Quality Committee reviews this feedback in a Quarterly Meeting (see Figure 4).

Table 1 includes the task list of actions taken by the Quality Commission since its creation.

Role of the Medical Director

The Medical Director is a member of

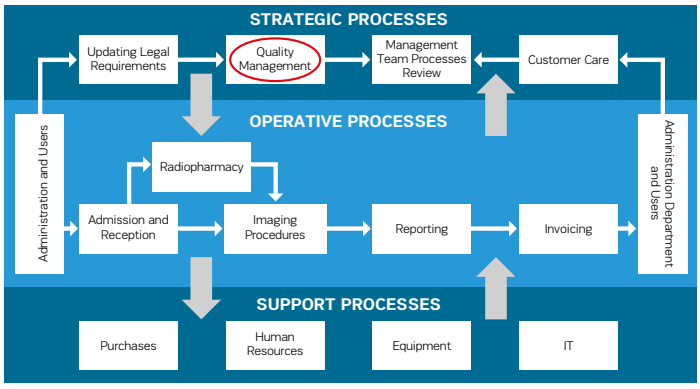
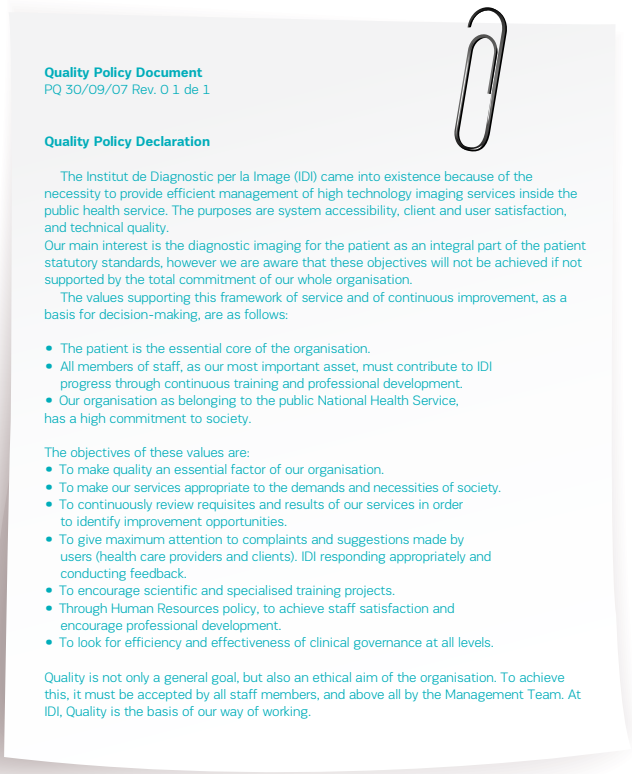


Figure 1.
IDI Processes Map



Quality Policy Document
PQ 30/09/07 Rev. 0 1 de 1

Quality Policy Declaration

The Institut de Diagnostic per la Image (IDI) came into existence because of the necessity to provide efficient management of high technology imaging services inside the public health service. The purposes are system accessibility, client and user satisfaction, and technical quality.
Our main interest is the diagnostic imaging for the patient as an integral part of the patient statutory standards, however we are aware that these objectives will not be achieved if not supported by the total commitment of our whole organisation.
The values supporting this framework of service and of continuous improvement, as a basis for decision-making, are as follows:

- The patient is the essential core of the organisation.
- All members of staff, as our most important asset, must contribute to IDI progress through continuous training and professional development.
- Our organisation as belonging to the public National Health Service, has a high commitment to society.

The objectives of these values are:
- To make quality an essential factor of our organisation.
- To make our services appropriate to the demands and necessities of society.
- To continuously review requisites and results of our services in order to identify improvement opportunities.
- To give maximum attention to complaints and suggestions made by users (health care providers and clients). IDI responding appropriately and conducting feedback.
- To encourage scientific and specialised training projects.
- Through Human Resources policy, to achieve staff satisfaction and encourage professional development.
- To look for efficiency and effectiveness of clinical governance at all levels.

Quality is not only a general goal, but also an ethical aim of the organisation. To achieve this, it must be accepted by all staff members, and above all by the Management Team. At IDI, Quality is the basis of our way of working.

Figure 2.
Quality Policy Document . The Quality Policy Document was created in the strategic plan in 2007.

IDI's management team and cooperates with the CEO in defining and executing the functional plans of the organisation. Medical Management also oversees and coordinates the operations and productivity of all IDI units. In addition, the Medical Director acts as the leader of the QC, establishing direction and priorities, moderating meetings and giving executive support to the remaining members.

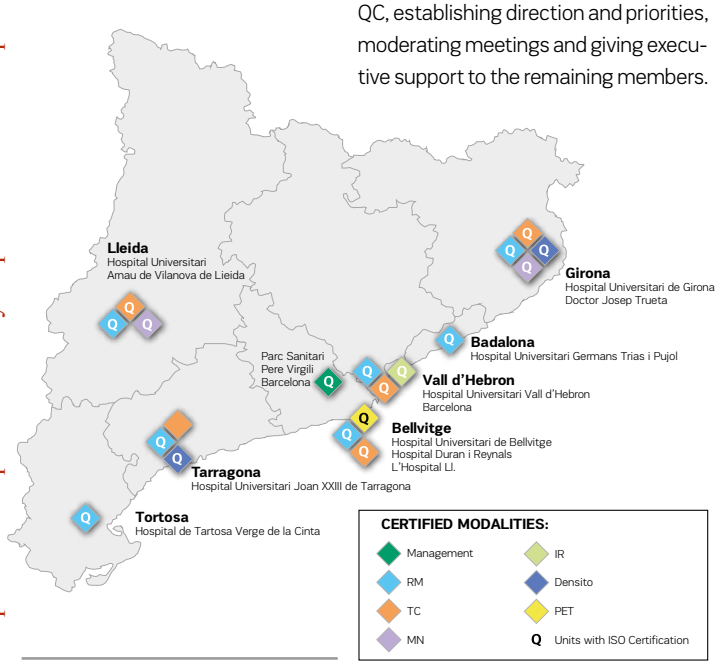


Figure 3.
Territory Map of IDI units in Catalonia. Q: Accredited unit.

In this way the Medical Director functions as a nexus between the QC and the Management Team. The Medical Director transmits the strategic vision, periodically informing the management team about progress, results and new upcoming projects.

The Medical Director acts as a moderator and leader to the QC and also directly participates in some of the working groups.

Role of Clinical Governance

Clinical Governance is led by a radiologist. Taking the ISO system as an initial reference, the aim of clinical governance is to introduce a dynamic of continuous professional development in order to detect clinical matters and to identify the people they concern.

Clinical Governance is responsible for the creation of several working teams across IDI. These working groups are continuous; when one group's function has ended a new working group is formed. These groups include medical and non-medical staff at every level, and they connect both face to face and in online environments. This collaboration allows for knowledge and experience to be shared, and establishes the quality standards for each department.

The communication between individual members of each working group is based on a progressive, non-critical approach. Our ethos is that collaboration is necessary to deal with all the issues that concern radiology and nuclear medicine in order to obtain the corresponding guidelines.

Clinical Governance Priority Actions:

- The IQP is communicated to all staff through presentations and also through notifications sent across the web.
- The dynamics of these actions are based on ISO 9001. In order to respond quickly to minor disconformities detected during the annual audits, we create working groups that work with the improvement actions.
- Through this dynamic network issues that are detected by one working group then become the focus for future working groups.

For Each Working Group:

- The group is formed by volunteer members.
- Time is scheduled for actions.
- Collaborative documents are shared online.
- The responsibilities for creating the meeting agenda, taking the meeting minutes and assigning tasks are shared amongst the group members.
- A consensus is achieved by collaboration with the sharing of experiences and knowledge within the group.

Role of the Technical Department

The Technical Department, which is led by a technical engineer, supervises and ensures that our facilities and equipment fulfil local regulations.

The Technical Department works closely with healthcare providers and qualified engineers so as to guarantee that the equipment has an up time of 95%.

Preventive maintenance protocols are scheduled periodically, following manufacturers' recommendations. Any technical or clinical-related issues or new applications are prioritised, and these are then solved in the shortest possible time.

Technical Department Priority Actions:

- All IDI units are maintained, correcting incidents detected during inspection in accordance with Spanish law.
- Resource optimisation and cost reduction opportunities are identified.
- New equipment is researched and acquired through public tender.
- Technical design, pre-installation and installation of equipment across IDI is performed.
- Quality control of equipment and appliances is executed to ISO system

standards in accordance with Spanish law and manufacturers' specifications.

Furthermore, a common online register for all IDI centres has been launched, where warnings, fault type and description, resolution, budgets, hour and shift work are recorded. This register enables quick and accurate data extraction, and with this in place any issues can be promptly resolved.

Role of the Processes Consultant

The processes consultant is also a technical engineer, who implements the management of the quality system and its procedures for ongoing improvement.

Responsibilities include maintaining and updating documentation, collecting client (both patients' and clinicians') satisfaction data, conducting internal audits and processes management.

Furthermore, the processes consultant supports the management team with data analysis and puts corrective and improvement measures into practice.

Quality Processes Priority Actions:

- Internal training is taken in ISO System requisites.
- Information is recorded and stored with respect to the Quality Management System.
- Support is made for each process including definition, follow-up and an indicators analysis.
- A continuous improvement system is implemented through disconformities and corrective action.
- Internal audits are coordinated.
- Client satisfaction feedback is monitored, analysed and reported.
- Support is given for defining strategic and operative processes as well as annual objectives.

Tools and Methods Employed in Managing the System:

- All actions at management and operational levels are filed in IDI's specific computerised recording system.
- The objectives of the organisation and monitoring of indicators are established and controlled by online applications.
- Management of nonconformities and corrective and preventive actions is computerised.
- Internal and external audits are conducted on a regular basis, both at operational and management levels (see Figure 1: Certificate AENOR ISO 9001:2008).

Conclusion

The creation and execution of the IQP has resulted in a dynamic network, which covers all parts of the organisation. This dynamic network has helped to improve many areas in the day-to-day running of IDI.

This arrangement has been instrumental in solving quality issues within the Radiology and Nuclear Medicine unit. Moreover, it has led to an increase in the safety of staff working in the unit along with a rise in the quality of patient care. Other effects of the IQP have been to improve the relationship with other clinicians and to clarify communications with service providers. It has enabled a systematic method of working with a daily checklist of technical issues that has helped to guarantee optimum performance of facilities and equipment. In addition, processes have been standardised and there is better control of the flow of information. Documentation support has been agreed upon, obtained and updated.

The Quality Commission helps to administer all activities, and at the core of these actions is the delegation of responsibilities, which are shared amongst staff from all departments.

Overall collaborative group work has made an invaluable contribution to our ultimate goals of continuous improvement, optimal patient care and high standards in imaging.

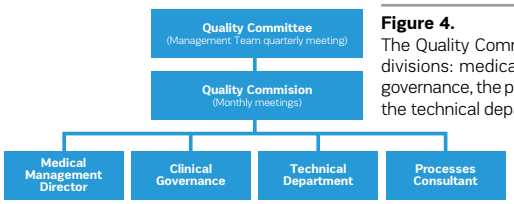


Figure 4.
The Quality Commission consists of four divisions: medical management, clinical governance, the processes consultant and the technical department.

TASK	RESPONSIBLE	TERM	STATUS
Communication of Important and Urgent Findings (CIF) Protocol Design	CG	31/12/2011	DONE
CIF presentation at SERAM 2012 congress	CG	25/05/2012	DONE
Updated CIF presentation at SENR 2012 congress	CG	18/10/2012	DONE
Updated CIF presentation at Health Plan Generalitat de Catalunya 2011-2015	CG	30/11/2012	DONE
Hanging Protocols Workshops for Radiological subspecialties	CG	31/12/2012	DONE
Updated CIF presentation at ESR 2013 congress	CG	07/03/2013	DONE
Final 2013 management review	PC	14/03/2013	DONE
Presentation IQP to the Heads of the IDI units	MD, CG, PC, TD	14/03/2013	DONE
Starting point Drugs Expire Date - ISO related Workshop	PC, CG	11/04/2013	DONE
Updated CIF presentation at Catalan Radiology 2013 congress	CG	09/05/2013	DONE
V4 Quality Handbook Updated	PC	31/05/2013	DONE
Starting point Informed Consent (IC) - ISO related Workshop	CG, PC	15/06/2013	DONE
Improving RIS Working Group	CG, IT - SAP - ICS	30/06/2013	DONE
Starting point CIF Workshop	CG - SAP - ICS	04/07/2013	DONE
Starting point satisfaction inquiry doctors	PC	05/07/2013	DONE
Starting point satisfaction inquiry patients	PC	05/07/2013	DONE
Presentation IQP to the Nursing and Radiographers heads	MD, CG, PC, TD	17/07/2013	DONE
General Procedure PG06.02 (8.- Registration) Logbook and Spread Sheet for daily registration	TD	Daily	DONE
Bureaucratic approvals regarding installations	TD	Daily	DONE
Daily inspections to fulfill current regulations procedures	TD	Daily	DONE
Daily follow-up of technical issues procedures	TD	Daily	DONE
Online Meeting and Internet Sharing folders Demo	IT	17/07/2013	DONE
Final guidelines concerning drugs contained in refrigeration	PC	22/07/2013	PENDING
Following protocols for InjPCtors preventative maintenance	TD	31/07/2013	PENDING
User complaints 2012/2013 analysis	PC	31/07/2013	PENDING
Poster MIR Congress BCN	CG	10/10/2013	DONE
Final point IC Workshop	ICS group	15/12/2013	IN PROCESS
CIF protocol IT application	CG - SAP - ICS	15/11/2013	IN PROCESS
Presentation IQP to the Radiology IDI and ICD staff of Hospital Joan XXIII - Tarragona	CG, TD	03/10/2013	IN PROCESS
Telediagnostic project initial working groups	MD, CG	15/01/2014	
Internal Audit design concerning correct indication of radiological tests	CG, PC	31/12/2013	DONE
Implementation of Internal Audit about indication of CT/MR - Neuroradiology	MD, CG, PC	31/01/2014	
Preparing abstracts for SERAM 2014 congress	CG, MD, PC, TD	31/12/2013	OPEN
Analysis of results Internal Audit about indication of CT/MR - Neuroradiology	MD, CG, PC	14/02/2014	
Injectors preventive maintenance	TD	14/02/2014	
Sending corrective actions to annual ISO-related audit	PC	30/05/2014	
Presenting report about results of Internal Audit Neuroradiology	PC	14/02/2014	
Presenting client satisfaction enquiries to IDI departments	PC	28/02/2014	
Conclusion Drugs Expire Date procedure	MD, CG, PC	30/04/2014	
Internal IDI course about ISO requirements and procedures	PC	30/04/2014	
Presenting SERAM oral communications	MD, CG, TD, PC	26/05/2014	
Implementation of Internal Audit about indication of TC/MR. Body and Musculoskeletal	MD, CG, PC	30/05/2014	
Presenting IQP and Telediagnositc projects to all staff in the IDI departments	MD, CG, TD, PC	10/06/2014	
Improving group for correct indication of radiological tests	MD, CG, PC	15/06/2014	
Guidelines for quality of radiological reports	CG	15/06/2014	
Internal Audit design for quality of radiological reports	CG, PC	30/06/2014	
Design of project about rescheduled patients	CG	01/09/2014	
Monitoring communication with clinicians design	CG, PC	30/09/2014	
New proposals projects	All staff members	open	

CG: Clinical Governance / PC: External Consultancy / TD: Technical Department / MD: Medical Management Director / IT: Information Tech
SAP: IT based System (HIS-RIS)
ICS: Institut Català de la Salut (National Health System)

Table 1.
Quality Commission Task List

Key Points

- *Healthcare policy*
- *Quality in imaging departments*
- *Team working*
- *Technological evaluation*
- *Standards and audits*
- *Continuous improvement*

References

Available on the website or on request

THE NATIONAL AUSTRIAN BREAST CANCER SCREENING PROGRAMME

THE FIRST SIX MONTHS

Interviewee

Oswald Graf, MD

Austria Roentgen Society
Breast Imaging Group

Interviewed by

Claire Pillar

Managing Editor, HealthManagement

Austria's formal breast screening programme started this year. Please explain the background.

Although there has not been organised mammography screening in Austria, breast cancer mortality has significantly decreased since the 1990s. With the exception of some local pilot projects, early breast cancer detection depended on unorganised opportunistic breast cancer screening in individual radiology practices.

In January 2014 organised mammography screening was introduced in Austria. One of the main goals was to utilise the existing robust infrastructure of local radiology practices. Performing screening exams in locations distributed all over the country should help to achieve high participation rates in the female population. Specific qualifications similar to screening programmes in other European countries are required for all institutions that want to participate in the screening programme.

Women aged 45 - 69 years are invited for screening. Women aged 40 – 44 years and 70 - 75 years may opt in for screening. Invitation to screening and evaluation of the entire programme is supported by central data management, which is provided by healthcare government authorities.

What features does the programme have?

The National Austrian Screening Programme has some specific features. Only digital mammography equipment is used, and, in addition to mammography, ultrasound is added as an adjunct test in women with dense breast tissue. This approach is supported by multiple studies, which showed that ultrasound is able to find a significant number of invasive cancers in dense breasts that will remain otherwise undetected at mammography.

In Austria ultrasound has been widely used in opportunistic breast cancer screening in the past, and radiologists are quite experienced using this technique. However, the impact of the use of supplemental ultrasound for early detection has not been systematically evaluated throughout the country. The practice of double reading of screening mammograms - intended to reduce the number of false negative results due to human error, and widely used in many other countries - has been applied only in some institutions in Austria.

In the first ever screening programme of its kind, the National Austrian Screening Programme combines mammography with ultrasound in women with dense breasts by the first line radiologist. Double reading of the mammograms is performed by a second radiologist. Regarding the limited value of mammography in dense breasts and the influence of human errors in reading screening mammograms, both steps should increase the overall sensitivity for early breast cancer detection.

This combined approach is a major logistic and scientific challenge. Most Austrian radiology practices in remote areas are run by single radiologists, with groups of radiologists found only in larger urban areas. Therefore, the process of double reading requires some logistic efforts. Teleradiology networking is used for the double reading process now in many institutions.

What has been the progress in the first few months?

The National Austrian Breast Cancer Screening Programme officially started on January 1st 2014 and invitations were rolled out. However, there were some setbacks in the last months.

In autumn 2013, physicians, predominantly gynaecologists and GPs were instructed by government authorities and officials in charge not to refer women to screening mammography anymore, as they used to do in the past.

From January 2014 referrals to mammography by physicians were restricted only to a dedicated list of specific indications, i.e. in the case of palpable abnormalities.

In the months from January to April 2014 experience in real life was rather disillusioning. Only 10% of women who were invited to screening actually scheduled an exam. This is a major setback, since approximately 50% of women used the access for mammography by referral in the past.

Furthermore, of all the women who showed up for screening, less than one percent never had a mammogram before or the last mammogram was performed more than three years ago. Thus, one of the main goals, to motivate new women for screening, was completely missed. Simultaneously, due to the limited access by referral the overall number of mammograms in Austria has dramatically decreased by 31%, in some regions up to 60%. The abrupt change of a system that has been prevalent for many years was not accepted by the majority of Austrian women and dissatisfaction rose, raising pressure on healthcare politicians.

In May 2014, this alarming development has led to an opinion change by politicians and officials in charge. Starting in July 2014, physicians will be allowed to send women for screening mammography again, following the age and screening interval guidelines of the programme. Furthermore, women over 45 years of age may come to a screening mammogram every other year without an invitation or a referral by a physician.

What data will be collected for the screening programme?

Data of all these examinations will be included in the evaluation of the programme, and these efforts will help to change continuously the uncontrolled opportunistic breast cancer screening into a controlled system. ■

THE AMERICAN SOCIETY OF EMERGENCY RADIOLOGY

GROWING RECOGNITION OF EMERGENCY IMAGING

Interviewee

Professor Susan John

President, American Society of Emergency Radiology

John S. Dunn Distinguished Chair in Diagnostic and Interventional Imaging
Professor of Diagnostic and Interventional Imaging and Pediatrics
Chief, Diagnostic and Interventional Imaging, Memorial Hermann Texas Medical Center (TMC)
Houston, Texas, USA

Interviewed by

Claire Pillar

Managing Editor, HealthManagement

The American Society of Emergency Radiology is 25 years old. What have been the major achievements of the Society in that time?

Twenty-five years ago emergency radiology was almost a non-existent subspecialty of radiology. A small group of radiologists who were actively practising emergency imaging, mostly working in trauma centres, recognised that this was going to be a growing and important sub-specialty, and that it involves special expertise. That's why the Society was founded. The past 25 years have largely been spent working towards gaining recognition for emergency radiology as a distinct discipline in radiology, advancing and promoting it as a subspecialty and helping to educate the radiology community as a whole in order to provide better emergency imaging care.

The Society now numbers close to 1000 members. In order to accomplish this, education needed to be improved for residents, and development of fellowship programmes had to occur in order to have radiologists who were trained in the intricacies of trauma imaging and emergent imaging. The Society developed an educational curriculum, and has a core curriculum project available on its website that provides teaching materials for residency programmes and for radiologists in general to learn more about trauma and emergency imaging.

The Society's Annual Meeting has developed into an outstanding educational course for emergency imaging in the United States. Our annual CME course, the Trauma Imaging Head to Toe course, has been extremely popular and well-received.

The Society has reached out to the international community, and we have a significant number of international members who have made major contributions to the Society. There is much work to be done internationally, because if emergency imaging is considered to be in its youth here in the United States, it is in its infancy in many parts of the world.

The Society has just begun to get involved in research and collaborative efforts to promote standards for imaging in emergency departments.

Another major accomplishment is our journal, Emergency Radiology, which goes to 8000 institutions. The quality of submissions and size of the journal has improved substantially over the past few years, under the editorship of Dr. Ronald Zagoria.

What do you see as the role of the Society in the future?

We will continue to focus on international outreach. In recent years, we have seen the development of emergency radiology societies, including the European Society of Emergency Radiology, the Asian Society of Trauma & Emergency Radiology, and also efforts in India, Scandinavia, Australia and the UK. The members of the international societies met at the 2013 meeting of RSNA, where we talked about the possibility of developing an international consortium to share ideas about standards and resources. A global project would really have value.

We want to continue to grow as a subspecialty in the United States. We have seen the emergence of new fellowship programmes, which is critical for the expansion of the discipline. Increased number of fellowship positions also gives a greater opportunity for international emergency radiologists to come to the U.S. to be trained.

We would like to gain formal recognition by the American Board of Radiology as a distinct subspecialty for the purposes of Board certification and maintenance of certification. The special knowledge and skills required to practise high quality emergency imaging should be reflected in our certification examinations. We are working with the American Board of Radiology to get more emergency radiology material included in the examination process, and we hope eventually to have separate emergency radiology testing modules..

What are the biggest challenges in emergency radiology currently?

First, a greater level of recognition as a sub-specialty. There are many radiology practices and departments that think of emergency radiologists as general radiologists that are willing to work at night. They do not really recognise the special expertise that is required. Academic departments exist that do not have a separate section of emergency radiology. We are promoting this concept with academic department chairs, in the hope that they will recognise that because Emergency Radiology is a critical area in which we need to train our residents, it is vital to have faculty with that subspecialty expertise to provide resident training and develop fellowship programmes. If we want to attract people to Emergency Radiology as a subspecialty, we need to instruct residents early on in their residency training. We need to include emergency imaging

as an important part of our residency training programmes.

To be recognised as a legitimate subspecialty, we need to define the role of emergency radiologists within the healthcare system and the radiology community. That has been difficult for emergency radiology, because radiologists who identify themselves as emergency radiologists practise in a wide variety of settings. Academicians often practise in Level I trauma centres in large urban centres, other emergency radiologists work in community hospitals with smaller emergency departments, and some provide teleradiology services that help to cover the night-time services for departments that don't have dedicated emergency radiologists on site. Military radiologists also align themselves with our subspecialty, because they often practise in a combat setting that creates special forms of major trauma. It is difficult to come up with one definition of what emergency radiology is and what precise knowledge a radiologist who practises emergency imaging should acquire. Development of a standardised Emergency Radiology curriculum is an ongoing challenge. We are currently polling our membership to get a sense of who we are, where we practise and what kind of specialty expertise is most needed for our members.

Another challenge is the growing need for 24-hour subspecialty and emergency radiology coverage. Our emergency medicine colleagues have developed effective models of practice that ensure an even standard of care for patients over the 24 hour day, and we are studying these models carefully. On-site availability of emergency radiologists is becoming more common in large emergency centres, but is still a challenge for smaller radiology groups. Teleradiology is a vital part of after-hours coverage for some practices, but we do not want to lose sight of the extra value of the on-site radiologist as a member of the emergency care team in hospitals and emergency centres.

What qualities does an emergency radiologist need?

In general, it is important for anyone who thinks they want to do emergency radiology to enjoy a fast-paced, interactive, multi-modality practice. They have to be able to deal with stressful situations. Activity in a trauma centre can get very intense with little notice, and the evening and night-time hours are often the busiest time..Emergency radiologists have to be able to make major life or death decisions about imaging studies quickly and confidently. They must have good communication skills. Emergency radiologists are most effective when they work as an integral part of the emergent care team. Frequently they physically are located in the patient care area, helping to make life-saving decisions about diagnosis and patient care.

Do you see a use for decision support in the emergency department?

I certainly think there is an important role for decision support. Many of the conditions that bring patients into the emergency department can look quite similar to one another clinically. There is potential for overuse of imaging without sound, evidence-based criteria to help decide when and what type of imaging should be used. There have been efforts to create decision rules for many different types of imaging. We have well-accepted decision rules for many clinical problems, such as extremity and cervical spine trauma. Decision rules are being developed for some of the more complex clinical questions, such as for abdominal pain or chest pain. A high percentage of chest CT scans for pulmonary embolism will be negative without good prediction rules. As a paediatric radiologist I am encouraged by the decision rules that are being developed for head CT and abdomen CT in children. Development and validation of clinical decision rules for imaging requires a collaborative effort. ASER looks forward to participating in a consensus conference organised by the Society for Academic Emergency Medicine in 2015, which will look at optimising the utilisation of diagnostic imaging in the emergency department.

"if we want to attract people to emergency radiology as a subspecialty, we need to instruct residents early on in their residency"

Could you comment on the perception that CT is over-used in emergency radiology?

There are areas where CT can be overused, especially when decision rules are in existence and are not being applied. In paediatrics, there are many efforts to streamline the use of CT and use alternative studies such as ultrasound or MRI as an initial study for children rather than CT. CT is vital for many trauma patients, but in some medical conditions there are opportunities to decrease CT use and make better choices. In general, I think the benefits of using CT out-weigh the risks of over-usage.

You have an interest in ultrasound in paediatric emergencies.

Could you tell us more about your research in this area?

It has long been recognised that ultrasound (US) is a very valuable tool in paediatrics. US is well suited for small patients with less body fat, allowing many parts of the anatomy to be very accessible with US. Much of my interest has been in US of the gastrointestinal tract. Evidence has shown that US is by far the best tool for diagnosing conditions like pyloric stenosis and intussusception, and often is the best initial study for evaluating inflammatory conditions such as appendicitis in children.

US has been quickly adopted as a bedside tool, which is a concern for many radiologists. Ultrasound is a very operator-dependent modality that requires considerable training and experience. Ultrasound has an excellent value at bedside, for line placement, looking for pleural effusions, and for post examinations of trauma patients. I think there will be an increasing use of US at bedside during the physical examination, and recently medical students are starting to be trained in simple US techniques. US is a tool that's here to stay in emergency medicine and emergency radiology. US as practised by radiologists in the United States is largely performed by technologists, with the radiologist as back-up for problem cases or coming in for certain difficult diagnoses. This has caused challenges for training our residents. We need to be careful to maintain the level of training of our radiology residents to ensure they don't lose that skill set.

With the implementation of the Affordable Care Act in the United States, what's your view on the effect it will have on utilisation of emergency departments?

There are still a lot of unknowns and there is conflicting data about whether the ACA will increase or decrease use of emergency rooms (ER). For example, Massachusetts saw a decrease in use of the ER (Miller 2012-2013), while Oregon saw an increase in use by Medicaid patients (Taubman et al. 2014). There are many other things that need to change in order to substantially alter the way emergency departments are used in this country. The ER is still the most efficient place to get your care, the one place you can get care any time of the night or day. Even if patients have insurance and the ability to go to a primary care physician, if they have difficulty getting an appointment or if they have symptoms that develop when offices are not open, they are more likely to use the emergency department. A culture has developed in the U.S. that causes patients to go to the emergency department for every type of healthcare problem. We need to change that culture. We must ensure that an adequate number of primary care physicians are available to care for the increased number of insured patients. I suspect there will be an increase in use of ERs before we see a decrease. The potential benefit of the new healthcare laws is that emergency departments may get more adequate compensation for the patient care that they provide. Currently, many of the patients in the emergency room have no insurance and no ability to pay their medical bills. Over time hopefully practices will develop that will make it easier for patients to get healthcare at a convenient time so they don't feel compelled to use the emergency room for non-emergent conditions.

HealthManagement is a journal devoted to multidisciplinary working. Can you comment on the importance of multidisciplinary working for the emergency radiologist?

Specialities working together are extremely important in the emergency setting. Trauma patients may require care by multiple specialists, such as orthopaedic, vascular or abdominal surgeons, in addition to medical specialists for other pre-existing or complicating conditions. Radiologists have to be conversant with the needs of all those specialties, and are important members of that team. Emergency radiologists have an excellent opportunity to work in multidisciplinary teams. In an emergency centre all specialists come to the patient, creating an environment that can foster better communication and collaboration.

Multidisciplinary teamwork is important for the entire specialty of Diagnostic Radiology. Every subspecialty in radiology needs to recognise that medicine is changing. We have to be patient-focused and work well in high level teams. Emergency radiologists are very well positioned to participate in and contribute to those kinds of healthcare teams, and can make an enormous difference in the outcomes for emergency and trauma patients. ■

Further information

American Society of Emergency Radiology
http://www.erad.org

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DIGITAL BREAST TOMOSYNTHESIS FOR SCREENING AND DIAGNOSIS OF BREAST CANCER

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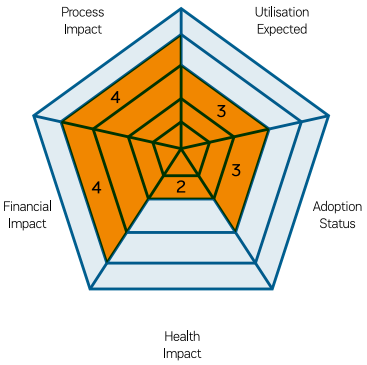
The report (reproduced in part here) is from a recent Health Technology Forecast from ECRI, which evaluated digital breast tomosynthesis (DBT) as part of its Health Technology Assessment Information Services (HTAIS). An expert panel was convened by ECRI Institute to review information on this topic.

Ratings and Rationales of Potential Impact



Note: *The following ratings and comments reflect the opinions and consensus of an expert panel convened by ECRI Institute.*

Anticipated Utilisation: 3 (Expected to be used by 40% to 60% of patients with the anticipated indications)

Digital breast tomosynthesis (DBT) is a 3D breast imaging technique based on full-field digital mammography (FFDM) technology, designed to reduce unnecessary callbacks during mammography screening and to replace other diagnostic tools. If DBT becomes accepted as a screening exam and is reimbursed, based on additional evidence of clinical benefit, it will likely displace conventional mammography screening. However, if DBT is reimbursed for only specific patient subgroups (e.g., those with dense breasts) within the general screening population, it is unlikely to completely replace conventional FFDM. If DBT is used primarily for diagnostic purposes, it will be another option among many follow-up test options after an inconclusive mammogram.

Estimated Adoption Status: 3 (0% to 25% of facilities that would be expected to adopt have adopted)

Since the first DBT system's marketing approval in 2011 (Hologic Selenia), Hologic estimates 600 to 800 of its Selenia systems have been put in use in the United States (since time of writing the latest estimate is around 1100 purchases (Beck 2014). Since 2011, Internazionale Medico Scientifica has entered the European market, Fujifilm has entered the European and U.S. markets, and GE Healthcare and Siemens Healthcare are developing DBT systems. GE Healthcare intends to submit data from a trial expected to be completed in November 2013 to support its premarket approval application in the United States. Siemens Healthcare is awaiting FDA approval for its system. Fujifilm offers the Amulet Innovality (FDA-approved and marketed as Aspire Cristalle in the United States). The significant costs of upgrading current FFDM systems to DBT systems or buying new ones are potentially slowing adoption.

Potential Health Impact: 2 (Expected to make a small improvement to patients' health and/or QOL)

DBT is likely to be used to follow up after an inconclusive mammogram. The technology could serve as an additional tool that could obviate the need for additional tests or unnecessary biopsies, but it is unlikely to find many cancers that would not otherwise be detected by other diagnostic tools. As a screening tool, the technology might increase cancer detection rates and reduce unnecessary recalls, particularly for patients with dense breasts.

Potential Financial Impact: 4 (Expected to have a substantial financial impact)

The expert panel thought that DBT systems will be expensive, with more advanced workstations and significant data archiving costs, compared with available mammography systems. Costs will depend on whether DBT is used as a screening or diagnostic test. As a screening exam, it will require about four gigabytes (uncompressed data) of data storage capacity per patient and could make screening large patient populations cost prohibitive, especially without adequate reimbursement.

Potential Process and Infrastructure Impact: 4 (Expected to have a substantial process impact)

Implementing DBT would significantly increase data storage, digital infrastructure requirements (i.e., bandwidth, archive volume, workstations), and workload for information technology staff, especially if used as a screening exam. As a diagnostic exam, DBT could reduce the number of patient biopsies and follow-ups using other diagnostic modalities. A two-view DBT exam could increase radiologist workload, because of the additional imaging data volume. Significant radiologist training may be required for the appropriate, accurate, and efficient use of DBT, "not only in the appearance of different abnormalities but also in the

widely varying appearances of normal tissues leading to negative findings," reported one DBT researcher.

Overview

Screening for breast cancer is typically done using full-field digital mammography (FFDM). About 10% of screened women are called back for follow-up of a suspicious or inconclusive spot on the screening mammogram. Follow-up can include diagnostic mammography, magnetic resonance imaging (MRI), ultrasound, fine-needle aspiration or surgical biopsy. Clinicians diagnose breast cancer in about 10% of patients called back for further testing. Avoiding the number of false-positive screening mammography results and unnecessary follow-up exams is desirable.

Digital breast tomosynthesis (DBT) is a 3D breast imaging technique based on FFDM technology. A tomosynthesis system's x-ray tube moves along an arc, in a sweeping or pause-and-shoot manner, around a portion of the breast to acquire 13 to 25 2D projections from slightly different angles in about 10 to 20 seconds (Anthem Insurance Companies, Inc.). Resulting 2D projections individually have lower resolution than FFDM 2D images; they are digitally manipulated to create tomograms (i.e., slices) in any plane and then combined for 3D reconstruction that reveals depth. The number of tomograms that can be created depends on the number of 2D projections captured during the x-ray sweep. Slices can be displayed individually (resembling conventional mammograms with sharper detail) or in dynamic "movie" mode. According to developers, a 3D reconstruction of the breast reduces the problem of overlying tissue that might be mistaken for lesions or that might obscure small cancers, particularly in dense breasts (McCullough 2011; Anthem Insurance Companies, Inc. 2013; Hologic 2011).

A DBT exam is similar to a conventional mammogram in how a technologist positions the patient's breast. Image acquisition typically takes 10 to 20 seconds (Anthem Insurance Companies, Inc. 2013). Once the images are taken, a radiologist interprets the scans. Several researchers are developing computer-assisted detection (CAD) software to help radiologists identify lesions from the images (Hologic 2011; Sahiner et al. 2012).

DBT can be used on its own or in combination with FFDM. When used on its own, software can translate 3D data into a 2D image similar to FFDM. A 2D image is useful to compare a patient's most recent exam with past exams that were performed using FFDM or film mammography.

Because DBT and FFDM systems share a common physical platform, some FFDM systems can be upgraded from the same manufacturer to add DBT capability, depending on the configuration. Upgrading an FFDM unit to offer DBT may require a new gantry (i.e., supportive framework), because some FFDM gantries are not designed for the precision movement involved in tomosynthesis (Siemens AG).

Manufacturers include:

- Hologic, Inc. (Bedford, MA, USA)
- Fujifilm Medical Systems (Düsseldorf, Germany; Stamford, CT, USA)
- General Electric (GE) Healthcare (Chalfont St. Giles, UK)
- Siemens Healthcare, Inc. (Erlangen, Germany)
- Internazionale Medico Scientifica (IMS; Bologna, Italy)

Hologic, GE Healthcare, and Siemens also offer commercially available FFDM systems that can serve as the platform for a new DBT system (Siemens AG; GE Healthcare 2013; Hologic 2013). IMS' Giotto Tomo system is built as a separate device requiring its own platform (I.M.S. Internazionale Medico Scientifica).

Hologic was the first manufacturer to reach the U.S. market, in 2011 with its Selenia Dimensions 3D DBT (Hologic 2013a) The Selenia system is optimised to take two breast views, craniocaudal (CC) and mediolateral oblique (MLO), under two breast compressions similar to FFDM. A CC view is taken from directly above a horizontally compressed breast, and a MLO view is taken at about a 45° angle to the side of a diagonally compressed breast. When used with FFDM, a DBT scan and FFDM scan from one view can be taken under one compression. Hologic has developed C-View 2D, software that creates computer-generated 2D images from DBT 3D images, which purportedly negates the need for concurrent FFDM scans and reduces the total radiation dose (Hologic 2013b). Hologic has also developed the Affirm Breast Biopsy Guidance system, integrative hardware and software that can guide biopsy sampling in real time, for use with its DBT system (U.S. Food and Drug Administration 2013b). Hologic is working to expand its contrast-enhanced FFDM into DBT to visualise vascularity more clearly (Froeling et al. 2013).

GE Healthcare is developing a DBT system called SenoClaire, which creates a 3D image using the MLO view only, purportedly reducing the necessary radiation dose. SenoClaire uses software to optimise views of lesions in dense breasts and microcalcifications in breasts of any density (GE Healthcare 2013). GE Healthcare is also developing software to generate 2D images from 3D data.

Siemens is developing its True 3D Breast Tomosynthesis system. The technology reportedly works by moving in a 50° arc around the breast—a larger angle than other scanners. Wider angle movement purportedly allows all imaging to be taken during a single breast compression instead of two (Siemens AG). Siemens is also developing a contrast-enhanced scan for DBT (Hornig et al. 2012).

IMS is developing the Giotto Tomo system, which is capable of varying the angle of its 13 projections and the dose, specifically for each patient. The Giotto is also compatible with IMS'

Company	System	FDA approved	CE marked
Hologic	C-View 2D imaging system	Yes	
	Selenia Dimensions	Yes	Yes
GE Healthcare	SenoClaire	Pending	Yes
Siemens	Mammomat Inspiration System	Pending for DBT use	Yes as upgrade for FFDM system to perform DBT
IMS	Giotto Tomo	N/A	Yes
Fujifilm	Aspire Cristalle	Yes	N/A
	Amulet Innovality	N/A	Yes

Note: *Compiled and updated by HealthManagement, July 2014*

stereotactic biopsy system (I.M.S. Internazionale Medico Scientifica).

Regulatory Status

Regulation in the United States of mammography facilities is the Mammography Quality Standards Act. The regulations permit only reversible image compression, not irreversible (i.e., lossy) compression of DBT images (Clunie 2013). As of 2012, the American College of Radiology had no official position on whether compressed DBT images are acceptable (American College of Radiology 2012). DBT images are supported by some picture archiving and communication systems (PACS) providers using Digital Imaging and Communications in Medicine standards (Sectra 2011).

Cost Issues

According to ECRI Institute's PricePaid database (as of October 17, 2013), the Selenia Dimensions 3D system had an average list price of about $786,000 [€586,654] and an average quoted price of about $398,000 [€297,059] (PricePaid a). FFDM systems had an average list price of about $546,000 [€407,523] and an average quoted price of about $278,000 [€207,493] (PricePaid b,c,d). DBT capability may be available by modifying some existing FFDM systems, which vary in cost depending on configuration and features. Upgrading an FFDM system to offer breast tomosynthesis may cost $100,000 [€74,638] or more (McCullough 2011). PACS-supported DBT imaging removes the need to purchase workstations solely for DBT-scan reading by radiologists (Sectra 2011).

DBT developers believe that the technology's greatest potential could be in screening, although pricing for DBT exams is not yet established. Some doctors are charging patients directly for DBT, generally less than $100 (Bassett 2013). Costs associated with upgrading digital infrastructure to accommodate the new workstations, networking requirements, and data archiving demands would likely be extremely high if the technology is used for screening. Hospitals or imaging centres using DBT in a diagnostic setting would likely require fewer costly upgrades to accommodate networking requirements and data archiving, because fewer patients undergo diagnostic scans than have screening scans. Widespread DBT screening might increase revenue for providers if they can recruit new patients, call back fewer patients for false positives, and improve workflow, as reported by KLAS (Bassett 2013).

Reimbursement Issues

As of October 2013, the U.S. Centers for Medicare & Medicaid Services had no national coverage policy for DBT, leaving coverage to the discretion of local Medicare contractors. Ultimately, reimbursement depends on how effective DBT is compared with standard technologies for screening or diagnosis. DBT's viability will likely depend on its ability to reduce the number of patient callbacks after initial breast imaging exams, an outcome that third-party payers are expected to be particularly interested in evaluating when making coverage decisions. Nine representative, major, third-party payers consider DBT to be investigational and deny coverage (Anthem Insurance Companies, Inc. 2013; Aetna, Inc, 2013; CIGNA Corporation 2013; Blue Cross Blue Shield of Alabama 2013; Blue Cross and Blue Shield of Massachusetts; United HealthCare Services, Inc. 2013; Medica 2012; Wellmark, Inc. 2013; Humana, Inc. 2013). Third-party payers are likely to require evidence of significant additional benefit from DBT before they are willing to reimburse tomosynthesis exams at a higher rate than conventional breast imaging modalities, especially for a breast cancer screening indication.

Some centres are working with third-party payers to develop reimbursement policies. Of 44 surveyed imaging centres in the United States using Hologic's Selenia Dimensions 3D system, 25% reported they were receiving reimbursement above the rate for standard mammography. Another 37% stated they were charging patients directly for DBT, generally less than $100 (Bassett 2013). Current procedural terminology (CPT) and Healthcare Common Procedure Coding System codes have not been established for DBT. Physicians performing DBT in conjunction with FFDM procedures have been advised by the American College of Radiology to report the CPT code that represents an unlisted diagnostic procedure code to describe FFDM. If CAD is also performed, the College recommends reporting it separately using a CAD mammography code.

DBT exams are likely to cost less than MRI exams, based on the amount patients are being charged out of pocket for DBT (i.e., $100 or less) (Bassett 2013). As a diagnostic follow-up to conventional mammography, payers may favour DBT over MRI if evidence shows that they are similarly effective. ■

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Available on the website or on request

The full article can be found online at *www.healthmanagement.org* or scan the *QR code*

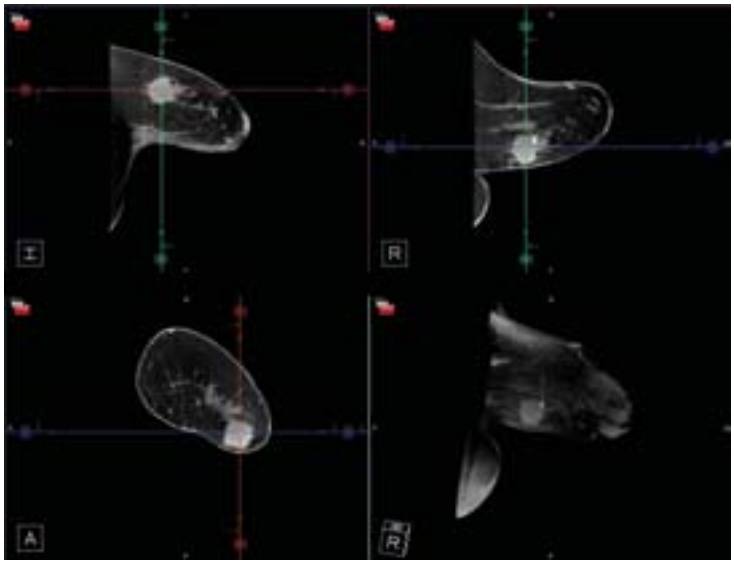
DEDICATED 3D BREAST CT

A NOVEL APPROACH TO BREAST CANCER DETECTION

Introduction

The goal of mammography is to detect breast cancers. Mammography is the current gold standard for screening asymptomatic women for breast cancer, and has been proven to decrease mortality (Fracheboud et al. 2004; Coburn et al. 2004; Jatoi et al. 2007). However, this technology does have some limitations. In women with dense breasts, mammography is not as sensitive as in the population of women with non-dense breasts. In reaction to this problem, various researchers have investigated digital breast tomosynthesis (DBT) as a way to eliminate the lesion obscurity or 'masking' resulting from overlapping tissue prevalent in women with dense breasts. DBT was made feasible with digital mammography technology and fast computer processors. DBT in combination with a conventional digital mammogram has demonstrated improved mass detection (Michell et al. 2009; Gennaro et al. 2010; Svahn et al. 2010), decreased recall rates and increased cancer detection (Michell et al. 2009; Gennaro et al. 2010; Svahn et al. 2010; Skaane et al. 2013). However, DBT is a 'pseudo' 3D technique, since the images of the breast are acquired in a range of angles usually limited to 15 -30 degrees and mammographic breast compression is still utilised.

Dedicated breast CT (DBCT) is a new imaging modality that provides 3D data that can be reconstructed into multiple imaging planes, similar to breast magnetic resonance imaging (MRI). DBCT is performed without breast compression and is not limited by breast density or breast implants. The radiation dose level is similar to the dose of a conventional two-view digital mammogram. Recently, research in the field has focused on the development of low radiation dose scanners with fast image acquisition times and with improved spatial resolution (Boone et al. 2001; Lindfors et al. 2008; McKinley et al. 2012).



DBCT: How Does It Work?

One breast at a time is imaged, as with mammography. Unlike mammography, the patient lies prone, with the breast to be imaged placed through a hole in the DBCT scanning table. The breast to be imaged is pendent (not compressed) in the scanner. Some DBCT systems can stabilise the pendent breast to decrease any patient motion, but there is still no 'mammographic type' compression. From below the table, the technologist can observe that the subject's hanging breast is centred in the device. Some DBCT systems have open access to the breast for patient positioning or biopsy access. The imaging hardware is beneath the scanning table and does not touch the patient.

The basic imaging hardware of a cone-beam DBCT system consists of a flat panel detector, x-ray tube and generator and drive motors to move the system 360 degrees around the pendent breast while the patient is breath-holding (Lindfors et al. 2008; McKinley et al. 2012). During the acquisition of the images, the technologist has access to the system position and real-time projection images of the breast.

The acquired image data of the breast is used to reconstruct a volume dataset for image display. Since DBCT is true 3D imaging and does not compress the breast, it allows for registered orthogonal views of the breast in any projection for viewing (see Figure 1). The viewing software allows the radiologist to review images in multiple planes, window and level the images, and magnify and adjust slice thickness of the images for interpretation. Areas of concern can also be measured and annotated. In addition, multi-intensity projection image can also be visualised as part of the software display also seen in Figure 1.

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Figure 1.
Dedicated Breast Computed Tomography representative slice in three projection views (sagittal, transverse, and coronal) with multi-intensity projection image (MIP), lower right-hand image. A mass is seen in the cross-hair of the reference marker.

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DBCT Performance

Clinical trials with DBCT have shown promising results when compared to 2D mammography and MRI. Lindfors et al. demonstrated in 69 women with BI-RADS® 4 and 5 lesions that non-contrast DBCT showed a significant increase (p<.002) in visualisation of masses; however, mammography was better for visualisation of calcifications (p<.006) (McKinley et al. 2012). In 2014, Kuzmiak et al. evaluated 20 women with a total of 23 BI-RADS® 4 and 5 lesions initially detected with diagnostic 2D full-field digital mammography (dxDM). Non-contrast DBCT imaging of these lesions showed an increase in radiologist reader visualisation confidence of the evaluation of mass shape (p<.010) and margin (p<.020) (see Figure 2). However, there was a significant decrease in reader visualisation confidence for calcification morphology (p<.001) and distribution (p<.002) (Kuzmiak et al. 2014). Thus, improvements in detector resolution of different DBCT systems continue, as well as exploration of other methods of increasing lesion conspicuity and characterisation.

One such method of increasing lesion conspicuity and characterisation is to use intravenous contrast in with DBCT. Zuley and colleagues compared contrast-enhanced DBCT to contrast-enhanced (CE) breast MRI in the characterisation of 24 cancers and 33 benign lesions. They reported CE-DBCT to be equivalent to MRI in diagnostic performance. With CE-DBCT, five radiologists classified 94.2% of the malignant lesions and 83.6% of the benign lesions correctly, versus MRI where 93.3 % of the malignant lesions and 86.1% of the benign lesions were correctly classified (p >.63) (Zuley et al. 2011).

Currently, there is no FDA-approved DBCT system in the United States. However, investigators from the Wende Logan Breast Center and the University of Rochester, Rochester, NY, in conjunction with the Medical University of South Carolina, Charleston, SC, are evaluating the Koning Breast Computed Tomography (KBCT) (Koning Corporation, West Henrietta, NY, USA) system for premarket approval. The goal of their study is to evaluate if 3D KBCT can improve the clinical performance of diagnostic workup for breast cancer detection and diagnosis compared to conventional 2D diagnostic mammography (Koning Corporation).

Conclusion

Although still in development, dedicated breast computed tomography is a novel imaging device of the breast that allows for a full 360 degree scan of the breast without compression. DBCT is currently under clinical investigation for patients who have suspicious findings from screening or diagnostic mammography. Initial studies demonstrate that this technology can help resolve the issue of overlapping tissue possibly obscuring a breast cancer, and may provide physiologic information when intravenous contrast is used. In addition, this technology may provide more flexiblity to our patients, since it has faster scanner times and possibly more availablity in our clinics than MRI. ■

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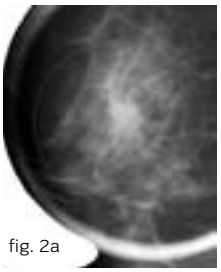
Figure 2.
57-year-old woman.
a) Medial lateral oblique spot compression magnification view of the right breast shows a possible mass (circle), but it is obscured by breast tissue.
b) Increased lesion conspicuity on this single sagittal non-contrast DBCT image demonstrates a 1.5 cm spiculated, high-density mass (arrow).
c) Close-up DBCT image. Core biopsy revealed invasive ductal carcinoma.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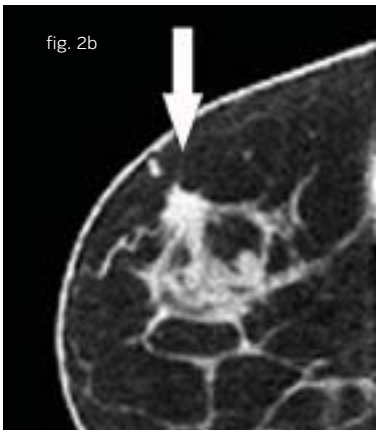
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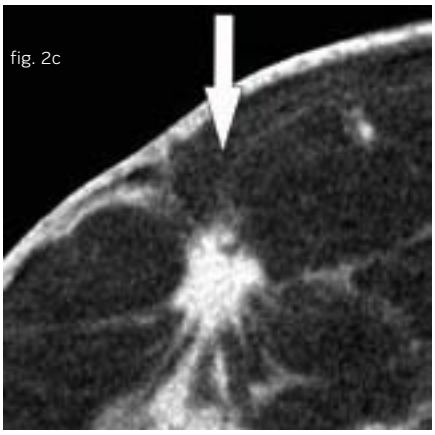
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DOSE MONITORING SOFTWARE

NEW TOOLS FOR RADIOLOGY QUALITY MANAGEMENT

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Introduction

In the last decades there has been a significant increase in the number of radiological examinations, resulting in an increase of radiation dose per capita (Schauer and Linton 2009; Frush 2009; Hall and Brenner 2008; Smith-Bindman et al. 2012). The largest part of this growth comes from computed tomography (CT) scans, as this modality underwent important technological developments, and can now give physicians very precise diagnostic information in a very short time (Brenner and Hall 2007; Furlow 2010). This means that nowadays we can save more lives than in the past: we surely have to consider that radiologic examinations are vital for modern medicine. On the other hand, this powerful tool is sometimes used in an inappropriate way, as some of the radiologic procedures are not sufficiently optimised. It is widely known that ionising radiations are a class 1 carcinogenic agent: some recent epidemiological studies showed an increased incidence of cancer in patients who underwent CT scans (Mathews et al. 2013). For this reason, it is important to reduce the radiation dose given to patients in every examination without impairing its diagnostic quality, according to the ALARA (as low as reasonably achievable) principle.

The Importance of Dose Monitoring

Constant and systematic monitoring of radiation dose is indispensable in order to increase the quality of radiological services to patients. This activity can lead to performance control, protocol optimisation and rapid correction of wrong practices. Furthermore, dose monitoring can increase risk awareness among hospital staff members, which is considered by experts one of the best way to improve their dosimetric behaviors (Goske et al. 2012).

Unfortunately, dose monitoring has not been a simple activity until now: first of all, less recent radiological equipment may not measure the amount of delivered dose for each procedure. Secondly, dose reports are often exported to the Picture Archiving and Communication System (PACS) as screen-captured images, so that it is not possible to use these data in an aggregated way, nor simply copy and paste them in worksheets.

Up to now, radiologists, radiographers and medical physicists have obtained dosimetry statistics by long manual work: that has been discouraging them, resulting in a lack of systematic dosimetric control. Moreover, even those who had the possibility and the will to monitor doses had to accept that their statistics were based on small amounts of data, not on the whole database.

Legal Changes in the EU

Lawmakers are interested in monitoring and reducing radiation doses, as shown by the newly published 2013 / 59 / Euratom Directive that contains more stringent radiation protection rules, especially concerning patients' protection (Council Directive (EC) 2013/59/EURATOM). In particular, the European Directive requires that patients are informed about the risk associated with ionising radiation, and that detailed information about radiation dose is included in every procedure's report. EU Member States must transpose the requirements of this Directive in their national laws by 2018.

How Technology Can Help

In the last few years, things have changed in a very positive way: new software tools that can automatically retrieve, store and analyse dosimetric data are now available. These IT resources can be installed on hospital networks, and are in most cases web-based, ensuring easy access to all authorised users.

These software tools recover dosimetric data in two ways: either by communicating directly with the radiological modalities or by retrieving dose information from the PACS, which receives dose reports from the modalities. The second type of communication may be easier to manage, as it does not require the collaboration of device vendors during the set-up phase: in any case, to make statistics reliable it is important that every single device has the ability to measure dose correctly.

Dose Monitoring Software for the Radiologic Team Day-to-Day

Automatic dose monitoring systems can be helpful during all the phases of radiologic procedures.

Before the examination starts, radiologists may include in their appropriateness assessment the dosimetric history of the patients, especially those who need to repeatedly undergo radiologic examinations.

To optimise examinations, radiographers can use another tool of dose monitoring systems, which consists of the visualisation of the technical parameters of the previously performed procedures. This tool allows the radiologic team to decide the appropriate dose for a specific diagnostic task.

In addition, a meticulously monitored

CT protocols database can assist the activity of the radiologic team. In fact, it is regrettably common that optimised parameters are modified with no clinical reason. These modifications may cause unjustified increases in patient dose, until someone notices them. A unified protocol database would allow optimal control, as this instrument can issue an alert every time a protocol modification is made.

"a multidisciplinary dose team is at least as important as any dose monitoring software"

Dose Monitoring Systems as a Quality Management Tool

Dose monitoring systems allow real-time and multi-parametric performance evaluations. In this way, at the end of the examination, the procedure dose can be compared with the doses delivered by other procedures with the same study description or concerning the same anatomical area. This tool allows rapid detection of outliers, resulting in their fast correction by prompting the change of the wrong acquisition parameters. Appropriate alerts can be automatically produced, so that improvement strategies can be quickly decided. In addition best practices can be found that can be used for staff training and protocol optimisation.

Some of these systems can calculate dose descriptors based on the specific body size of patients, such as Size Specific Dose Estimate (SSDE) for CT scans, which takes into consideration the difference between the real patient size and the standard size of the reference phantom. These descriptors allow better analysis, as dose changes significantly depending on the patient's size. At the same time it is possible to automatically evaluate CT off-centring, which is the gap between the patient's actual position and the CT gantry isocentre; this is crucial, as a patient's positioning mistake of only a few centimetres can increase the dose by up to 40% when automatic exposure control (AEC) is active. Moreover, dose monitoring systems may allow many retrospective analyses: for instance, to evaluate the Diagnostic Reference Levels (DRL) compliance and to analyse the variations of average doses for a single study description, in order to verify that they are solely due to clinical reasons and not to the operators performing the procedure, the day of the week or the hour of the day. Detailed graphs can be automatically produced, showing dose trends and distribution with any desired degree of detail.

The Experience of Pisa University Hospital

We established a multidisciplinary dose team at our hospital, and recently started to evaluate some commercially available dose management systems. The first dataset that we analysed concerned paediatric procedures and CT colonography. It is commonly known that children are more sensitive to radiation damage than adults: because of that, it is important to pay particular attention when performing radiological examinations on them. In particular, it is crucial to tailor the particular anatomical and physiological characteristics, following the recommendations that are available in the literature and that are strongly recommended by international awareness campaigns (Image Gently® http://imagegently.org, EuroSafe http://www.eurosafeimaging.org). Thanks to dose monitoring software, our dose team recovered and analysed retrospectively more than 12,000 procedures, 9% of which were CT scans. The original purpose of this work was to reduce average doses. Our analysis showed relevant dosimetric differences between examinations performed on similarly-sized patients and auditing, training and protocol optimisation were used to ensure a better homogeneity of dosimetric values. The improvements could be confirmed by the real-time analysis made possible by dose monitoring systems.

CT colonography or virtual colonoscopy is a low dose CT procedure that can be used as a screening test for colon cancer. Our PACS database contains over 1700 such examinations. As two different scanners were employed for virtual colonoscopy, the dose team analysed data in order to compare their performances. This analysis showed a general compliance with the predefined protocols, but spotted a protocol error that prevented full exploitation of the iterative reconstruction software available on one of the two scanners to reduce the dose. After protocol optimisation, dose values significantly decreased.

Conclusion

Dose monitoring software represents an essential part of radiologic quality management by allowing the systematic control of dose performances, by contributing to the reduction of wrong practices, and by supporting protocol optimisation.

However, a multidisciplinary dose team is at least as important as any dose monitoring software since only expert users (radiologists, medical physicists, radiographers) are able to ascertain which are the dose variations seen in our practices that are clinically justified and to help reduce those variations which are not. ■

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ENDOVASCULAR ABDOMINAL AORTIC ANEURYSM REPAIR

THE EXPANDING APPLICATIONS

Endovascular abdominal aortic aneurysm repair (EVAR) developed in the late 1980s, and has since then been steadily gaining ground as a minimally invasive alternative to open surgical repair (OR) in select patients.

The Evolution of EVAR

The impressive results first reported by the Argentinian surgeon Dr. Juan Parodi convinced many physicians to deepen their knowledge of this field, and soon different specialties – vascular surgery, interventional radiology, cardiology, cardiothoracic surgery and angiology – were involved in the treatment of the aortic pathology, until then historically restricted to pure vascular surgical subspecialties.

Progressive technological improvements facilitated the diffusion of this technique within the many medical specialties, and the satisfying results attained in several studies and trials spurred more and more physicians to pursue investigations in this field.

This led to significant progress regarding endoprostheses' characteristics, the procedural technique and the physicians' skill, making EVAR a universally recognised treatment option for patients affected by an abdominal aortic aneurysm (AAA).

Obvious Successes

At present, many limitations correlated with AAA morphology have been overcome, and inclusion criteria have been extended to ever more complex anatomical situations. As a consequence, the number of patients suitable for EVAR has steadily increased – a paradigm-shift from the early days, when endovascular treatment was reserved only for patients at high risk for OR, such as elderly people or those with co-morbidities.

Use of EVAR was also notably increased when, thanks to technical progress, new systems of mechanical closure for the femoral approach were introduced.

EVAR's popularity among patients and doctors is strictly linked to the dramatic reduction in hospitalisation time, blood transfusion, post-operative recovery time and invasiveness when compared to standard OR. Last but not least, any time traditional surgery has been compared with EVAR an unquestionable advantage has been noticed: a significant reduction in procedural time.

"dramatic reduction in hospitalisation time, blood transfusion, post-operative recovery time and invasiveness when compared to standard OR"

Ongoing Challenges and Possible Solutions

However, controversies remain over the presence of endoleaks (continuous perfusion of the aneurysmal sac), re-intervention rates and the durability of the endoprostheses.

Endoleaks are the most frequent complication reported in the literature. With a frequency ranging from 10-30%, this event can be considered EVAR's Achilles heel. New generation devices have been specifically designed to improve the sealing and to reduce the endoleak rates, but they are not yet fully validated and further research is necessary.

Technological advances have improved the proximal seal in patients with angulated proximal neck. At the beginning of EVAR's history, the proximal neck was the subject of severe restrictions (2 cm minimum length, absence of calcifications or thrombus, angulation >45°). But nowadays, even a complex anatomy can be successfully treated (angulation <45°, length <1.5 cm), and this means that patients who in the past were unsuitable for both surgery and endovascular treatment can now be considered for EVAR.

EVAR improvement is also correlated with the introduction of FEVAR (fenestrated endovascular aortic repair) in the late 1990s. FEVAR is applied to patients whose abdominal aortic branches are to be treated, and requires an individually customised endoprosthesis for each patient's morphological features, which introduces time and cost limitations. Luckily, a number of companies have recently launched a branched stent graft that can fit different anatomies and is available off the shelf.

To preserve the patency of the internal iliac arteries, a specific branched endoprosthesis is now commercially available. This stent graft allows exclusion of an aneurysm involving the common iliac artery, keeping the internal iliac artery patent. This technical improvement permits the indications for EVAR to be extended to patients with an occluded contralateral iliac artery, without resulting in buttock claudication or visceral ischaemia.

Towards True Minimal Invasiveness

PEVAR (percutaneous endovascular aortic repair) is a procedure which can be

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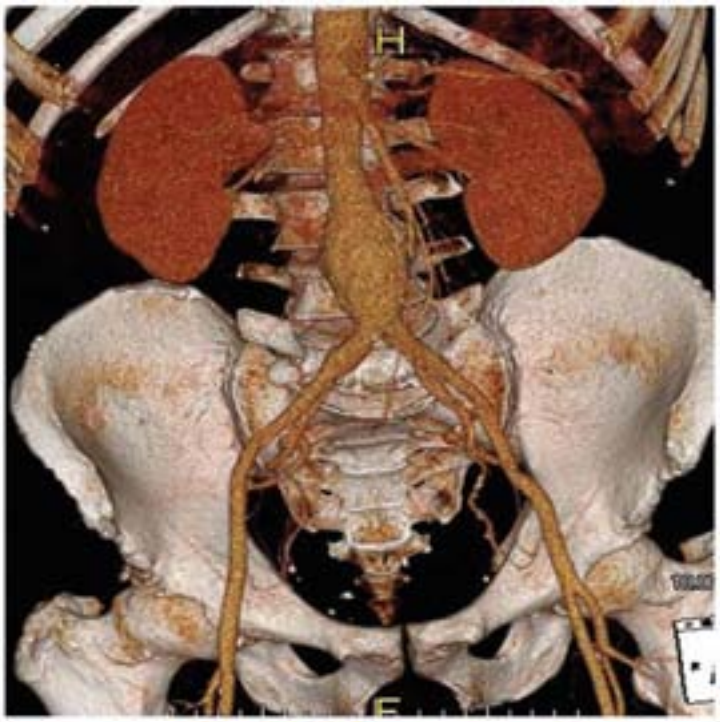

Figure 1.
A 3D reconstruction of a multi-detector CT-angiography shows an aneurysm of the abdominal aorta (Ø 65mm) in a 72-year-old patient. The common iliac arteries are not involved with the aneurysm.

performed with no surgical "cut-down", and consequently EVAR can be considered a true minimally invasive treatment.

The benefits of PEVAR lie, firstly, in the fact that the patient is capable of normal walking soon after being treated, and secondly, in the economic advantages of reduced hospitalisation and convalescence, meaning that working activity can be soon be resumed.

Obviously, PEVAR's technical success depends on accurate patient selection. Fundamental requisites are a femoral artery calibre > 4 mm and absence of parietal calcifications on the anterior wall of the vessel. Results from around the world are satisfying and encouraging, and demonstrate a very low incidence of complications.

More recently, an innovative new device design has been launched, which may overcome many of the limitations associated with stent grafts. Sealing devices, which employ balloon-expandable kissing stents, endobags and a fast-curing polymer, have been successfully used to form a cast of the lumen. Early results indicate that this might overcome the problems of endoleaks and device migration, as well as being suitable for a wider range of anatomies.

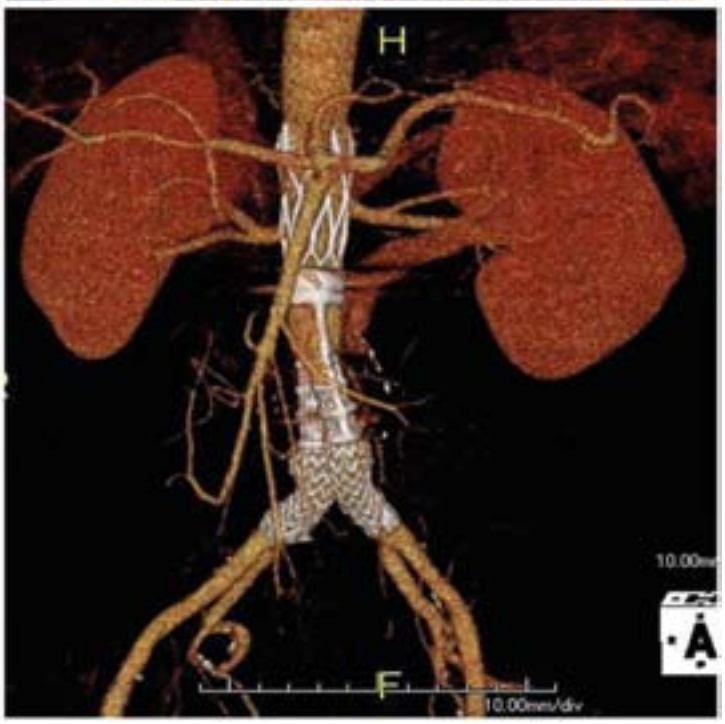

Figure 2.
Multi-detector CT-angiography at 1 year follow-up after EVAR. No reperfusion of the sac is evident. A new generation stent graft was deployed. The sealing rings of the stent graft improve the fixation of the endoprosthesis on the aortic wall reducing the risk of endoleaks.

A Team Effort

These advances and more open exciting new possibilities for treating "the silent killer" that is AAA. This plethora of treatment options should be thoroughly investigated to ascertain the optimal indications for each. Interventional radiologists will continue to play a key role, due to their skill in catheter management, but because of the complexity of aortic disease, cooperation with vascular surgeons can be considered fundamental for the continuous evolution of the aortic endovascular therapies. ■

Key Points

- *EVAR is a minimally invasive alternative to surgical repair for patients affected by an abdominal aortic aneurysm.*
- *EVAR means reductions in time in hospital, blood transfusion, post-operative recovery time and invasiveness.*
- *Controversies remain over the presence of endoleaks, re-intervention rates and the durability of the endoprostheses.*
- *A new device design may overcome the limitations associated with stent grafts.*

IMPLEMENTATION OF THE EUROPEAN DIRECTIVE ON PREVENTION OF SHARPS INJURIES IN THE HOSPITAL AND HEALTHCARE SECTOR

THE UK PERSPECTIVE

Author

Lee Campbell

Editor, HealthManagement

Research by MindMetre, a UK-based consumer and business analyst, has revealed that one third of NHS Trusts in the UK do not instruct staff to use safety devices 'wherever possible' in their sharps policies, despite this being an explicit requirement of the UK's Health and Safety (Sharps Instruments in Healthcare) Regulations 2013.

More than 1 million sharps or needlestick injuries occur every year, forming one of the most common health and safety threats in the European workplace. They are an extremely common occupational hazard for healthcare workers with nurses being most at risk. Needlestick injuries can occur during many procedures including injection administration and the handling of clinical waste.

The Framework Agreement and Directive

Directive 2010/32/EU - prevention from sharp injuries in the hospital and healthcare sector of 10 May 2010 implements the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by the European Hospital and Healthcare Employers' Association (HOSPEEM) and the European Public Services Union (EPSU).

The purpose of the Directive is to implement the Framework Agreement so as:

- To prevent workers' injuries caused by all medical sharps (including needlesticks);
- To protect workers at risk; and
- To set up an integrated approach establishing policies in risk assessment, risk prevention, training, information, awareness raising and monitoring;

It was the duty of Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, and ensure that the social partners introduced the necessary measures by 11 May 2013 at the latest. Member States also determine what penalties are applicable when national provisions enacted pursuant to this Directive are infringed.

The Directive applies to all workers in the hospital and healthcare sector. It tasks employers and workers' representatives to work together to eliminate and prevent risks, protect workers' health and safety, and create a safe working environment following the hierarchy of general principles of prevention via information and consultation.

The Directive calls for thorough risk assessment when injury, blood or other potentially infectious material is possible or present with a focus on how to eliminate these risks. The risk management measures are:

- Specifying and implementing safe procedures (including safe disposal);
- Eliminating unnecessary sharps use;
- Providing safety-engineered medical devices;
- Prohibition of recapping;
- Coherent overall prevention policy;
- Training and information;
- Personal protective devices and offering vaccination;
- Workers should report any accident to the responsible person; and
- The accident should be investigated and the victim treated.

Progress in the UK

In line with the EU Directive, the UK introduced the Health and Safety (Sharps Instruments in Healthcare) Regulations 2013. These new regulations particularly focus on requirements that are not specifically addressed in existing legislation.

Official guidance documentation from the Health and Safety Executive (HSE) notes that, "Where it is not reasonably practicable to avoid the use of medical sharps, the Sharps Regulations require employers to use safer sharps (incorporating protection mechanisms) – regulation 5(1)(b)." The safer sharps incorporate special features that prevent or minimise the risk of accidental injury. For example, syringes and needles equipped with a shield to cover the needle after use.

The majority of NHS Trusts are vigorously working towards compliance with the EU Directive on the prevention of sharps injuries. Five in every six have reviewed their sharps policies, and two-thirds have instructed staff to use safety devices 'wherever possible' in order to protect clinical, care and ancillary staff from injury and possible infection, but some Trusts are being left behind.

Findings from the MindMetre research report include:

- 84% of Trusts have revised and published their sharps policy in the light of the EU Directive, of whom 17% revised their sharps policy post-Directive and pre-UK statutory instrument;
- 59% of Trusts instruct staff to use safety

Working together to improve healthcare worker safety

and comply with the new EU Directive 2010/32/EU

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devices 'wherever possible' in their sharps policy; however 33% of Trusts do not make this instruction in their sharps policy;
- 29% mandate the use of safety devices in particular categories, particularly cannulation and phlebotomy; and
- Of those Trusts able to make an accurate estimate, safety device usage (measured in volume of procedures) has risen from 23% in 2009, to 67% by the end of 2013.

Talking about the research, Paul Lindsell, Managing Director of MindMetre Research highlights the strong level of compliance within the UK: "Evidently, the larger proportion of NHS Trusts are taking compliance ... very seriously. With almost a fifth of Trusts having revised their sharps policies in advance of the mandatory national regulation date in 2013, and with two-thirds of Trusts instructing staff to use safety sharps products 'wherever possible', it is clear that most are demonstrating their concern with clinical, care and ancillary staff safety with tangible action."

Lindsell admits there is much work left to be done, "there remains a proportion of Trusts that have not revised their sharps policies; moreover, one-third of Trusts are not encouraging their staff to use safety devices 'wherever possible', despite this being an explicit piece of guidance in the relevant regulation." But he is optimistic for the future and improved working conditions for health professionals, "We expect further progress to be made across 2014, both by pioneering Trusts in this regard, and also from those that have made slower progress. An estimated one million sharps injuries occur in the European Union each year. The risk of injury and possible infection (from bloodborne pathogens including Hepatitis and HIV) for the dedicated people working in our health service is clearly unacceptable and now has the force of EU law and local regulation behind it." ■

Further information

To read the report in full please visit: http://www.mindmetreresearch.com

WHAT IS NEW IN IMPLANTABLE DEVICE TECHNOLOGY?

Cardiovascular implantable electronic devices (CIED) have seen tremendous progress during the last 20 years, in the field of heart failure (HF) treatment, anti-bradycardia pacing and defibrillation. CIED and leads have evolved allowing easier implantation, improved long term reliability and longer battery life.

Implantable cardioverter defibrillators (ICD), initially reserved for highly selected patients, where the benefit of secondary prevention outweighed potential side effects, are now a safe and widespread therapy, and have become part of the standard of care in HF patients with severe systolic dysfunction. Cardiac resynchronisation therapy (CRT) is also coming of age. In patients with heart failure, left ventricular systolic dysfunction and wide QRS, CRT improves clinical status, leads to reverse remodelling and reduces mortality.

During the last decade, the number of complex device implantations has dramatically increased. Despite an overall low incidence (<5%), the absolute number of device-related complications has increased. The weak spot remains the endovascular lead, which can fail over time, get infected or lead to vein thrombosis.

Several new technologies are targeting the reduction of device complication rates, such as the leadless pacemaker or the sub-cutaneous ICD. Others are attempting to improve delivery of therapy, mainly for CRT – like the multipole LV lead or the development of alternative LV lead access.

Leadless Pacemakers

Recently, a major technological breakthrough has been made in the field of bradycardia therapy with the development of the leadless pacemaker, by both St. Jude Medical (with the Nanostim) and Medtronic (with the Micra). The miniaturisation of the device allows its direct implantation into the right ventricle, where it is anchored to the inter-ventricular septum, thus eliminating the need for an endovascular lead (see Figure 1). This technology has the potential to completely eliminate pocket and endovascular lead-related complications.

The results from the LEADLESS trial have been published this year, confirming the feasibility and safety of the St. Jude device in a cohort of 33 patients (Reddy et al. 2014). While still ongoing, the post-approval European study suffered a temporary setback due to safety issues, after reports of six perforations resulting in two deaths. Those were probably related to the learning curve of the leadless pacemaker implantation technique, and the study has since resumed. While in a more incipient phase, Medtronic has recently announced, during the 2014 Cardiostim conference, the successful implantation of the Micra in the first four patients.

Future challenges include the development of a dual chamber version and possibly a bi-ventricular leadless device with wireless connection between the pacing elements. Device removal long after implantation may prove problematic, despite the fact that both manufacturers offer technical solutions in case extraction is needed.


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Subcutaneous ICD

Despite undisputable benefits, ICD implantation is still associated with considerable risk, as major complication rates stand at around 1.5%. These include infection, pneumothorax, haemorrhage, perforation and death. Additionally, ICD-related risks persist after implantation such as late infection, lead endocarditis, the delivery of inappropriate therapy, vein occlusion, lead dislodgement, valvular dysfunction and lead failure due to intrinsic lead defects.

In view of these considerations, a completely subcutaneous ICD (S-ICD) system has been developed, with the first patients implanted in 2008. It has since been approved for commercial use by the European Union in 2009 and by the FDA in 2012. More than 1300 patients were implanted with S-ICD during the last 5 years.

The system comprises a pulse generator, which is introduced subcutaneously over the left thorax, in the axillary region, and a single subcutaneous lead placed along the left side of the sternum. The S-ICD can accurately detect ventricular tachy-arrhythmia, which is treated by high-energy shock (maximum 80J) (Gold et al. 2012) (see Figure 2). It can deliver temporary but not chronic pacing, so it cannot be used in patients with symptomatic bradycardia or frequently recurring ventricular tachycardia terminated with anti-tachycardia pacing.

Lambiase reported this year on early data from the multicentre EFFORTLESS S-ICD registry (Lambiase et al. 2014). He showed that in a real-life international population of S-ICD recipients, the S-ICD performed appropriately, with clinical event rates and inappropriate shock rates comparable with those reported for conventional ICDs.

Although longer follow-up data is still required for assessing lead reliability over time, the S-ICD has emerged as a valuable alternative to standard ICD in patients with no need for ventricular pacing, with the potential to prevent most of the aforementioned complications associated with intravascular ICD leads. Furthermore, it is today the preferred solution for patients in need of ICD, who suffer from vein occlusion, or who have had system extraction for infection. Future technological challenges include downsizing of the device, which is currently bulky, prevention of infections, and improvement of sensing algorithms to prevent inappropriate shocks (Gold et al. 2014).

Infection Prevention

Infection is the most serious complication following CIED implantation. It

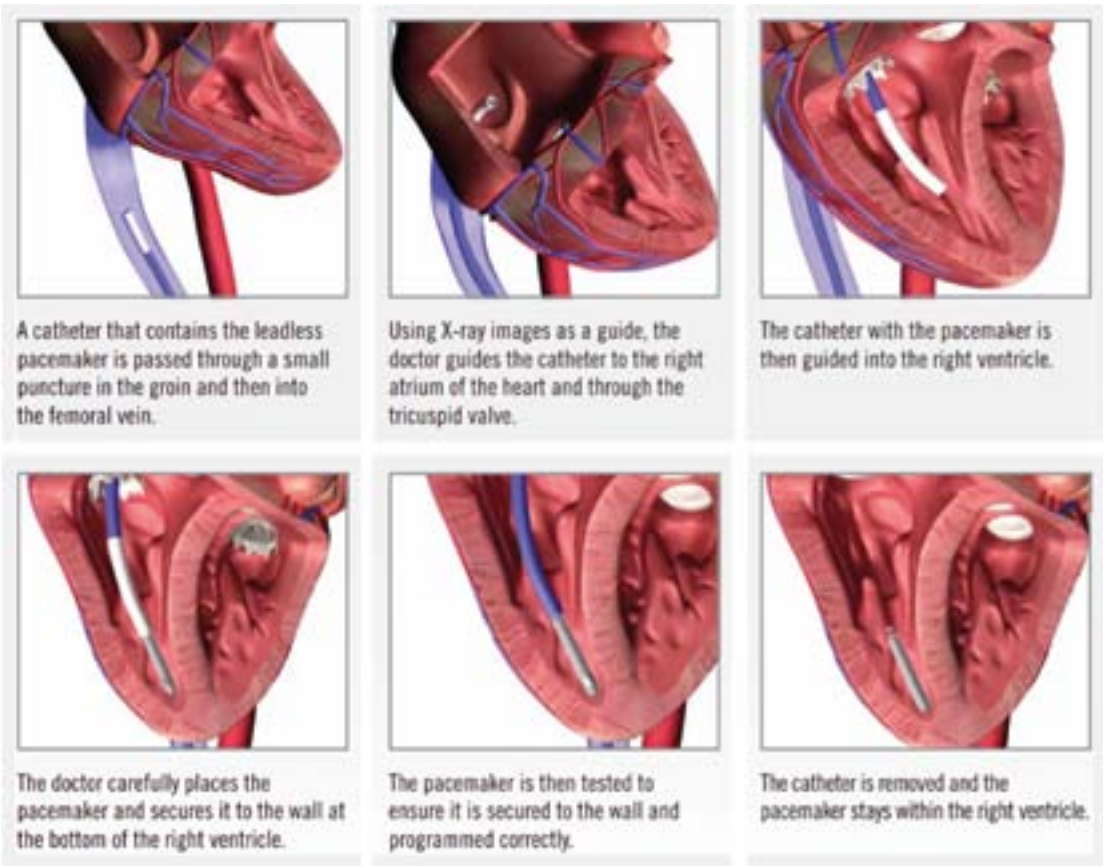

Figure 1.
Leadless pacemaker implantation technique.

is equivalent to implantation failure, as it necessitates complete system removal, at tremendous cost, lengthy hospitalisation, morbidity and mortality. Infection rates vary significantly between studies, but are commonly reported between 1 and 7 percent, and mostly involve pulse generator replacements. Prevention is the most effective way to deal with infections.

A new antibacterial envelope (AIGIS(Rx)) has been developed in the last five years for preventing CIED pocket infection. It is composed of biocompatible mesh coated with antibiotics (minocycline and rifampin), that dissolve within 7 to 10 days following implantation. In the retrospective COMMAND study, the use of this envelope was associated with a high rate of successful CIED implants (>99%) and a low rate of infection (<0.5%) (Bloom et al. 2011).

This promising initial data awaits confirmation by currently ongoing prospective studies.

Improving CRT Delivery

Delivering effective CRT can be very challenging depending upon the anatomy of the cardiac veins and the underlying myocardial disease.

Quadripolar LV lead configuration is seeming to be the better option for CRT when compared to standard bipolar LV pacing. The four-pole lead allows for multiple configurations, enabling LV pacing at the preferred site without compromising lead stability, and providing better management for common pacing complications such as phrenic nerve stimulation or high pacing thresholds. Eventually it was associated with a lower rate of LV lead re-intervention (Forleo et al. 2011).

The latest innovation comes with the St. Jude Quadra Assura MP cardiac resynchronisation therapy defibrillator (CRTD), which obtained the CE Mark in 2013. The device takes advantage of the quadripolar lead, which it uses in order to perform multipoint LV pacing. An acute haemodynamic study by Pappone in 2014 shows a benefit of multipoint over bipolar LV pacing, assessed with pressure-volume loop measurements (Pappone et al. 2014). The next step is to look whether multipole LV pacing will reduce the number of CRT non-responders, for which a randomised trial is currently underway (the MORE-CRT MPP trial).

For patients in whom LV lead implantation via CS is unachievable because of CS anatomy, several alternative approaches can be offered.

Using an atrial trans-septal puncture, the lead can be delivered to the LV endocardium without the CS-related anatomical limitations. From the haemodynamic point of view, endocardial pacing, due to optimal area location and fast propagation of the depolarisation wave front, results in equal or superior cardiac performance as compared to epicardial LV pacing (Shetty et al. 2014). The method does not affect mitral valve function, but the main drawbacks include difficult implantation technique (see Figure 3) and increased thromboembolic risk for which chronic oral anticoagulation with high INR ratios is required (Rademakers et al. 2014).

Auricchio et al. published this year the short-term outcomes of a new CRT technique (Auricchio et al. 2014), using a leadless ultrasound-based endocardial LV pacing system. This developing technology is promising as it may help overcome CS anatomy limitations and provide the advantages of endocardial LV pacing while preventing thromboembolic complications, due to complete endothelisation of the intracardiac LV receiver.

Lead Recalls

On average, an ICD lead is expected to last at least 10 years. However, due to its complex nature and for various reasons, the ICD lead may fail prematurely. Over the last decade there has been considerable evidence showing that the Fidelis leads (Medtronic) and the Riata leads (St. Jude Medical) may fail due to intrinsic problems. This has resulted in lead recalls for these models.

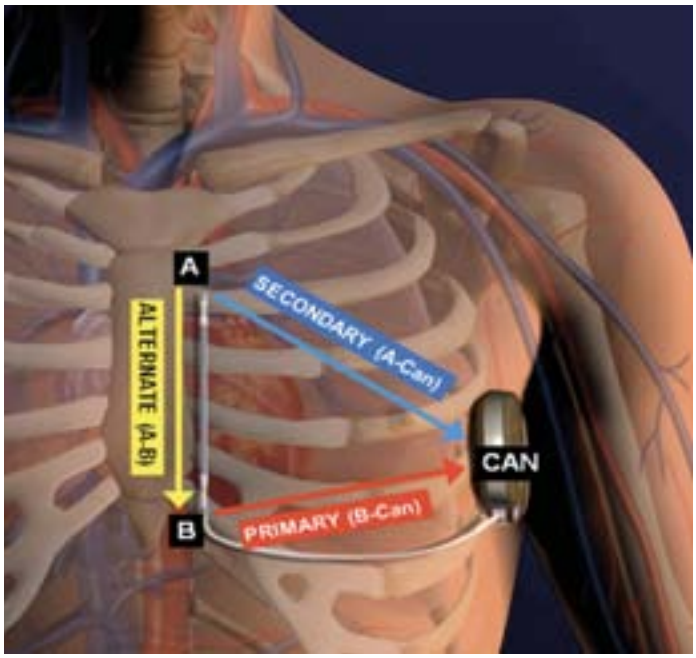

Figure 2.
The S-ICD system is completely extra-vascular and capable of delivering high-energy (up to 80J) trans-thoracic shocks, using multiple shock configurations

The Medtronic Sprint Fidelis is a high-voltage ICD lead, which has been demonstrated to be prone to fracture. Two locations account for more than 90 percent of the cases: at the distal portion of the lead, affecting the ring electrode (the anode), and near the anchoring sleeve tie-down (affecting the cathode) and occasionally the high voltage conductor. The 10 percent of remaining fractures occurred in the DF-1 connector leg and the proximal portion of the RV coil. The cathode-anode defects result in pace-sense failure, and account for multiple inappropriate shocks and/or loss of capture, while high voltage conductor fractures can result in the inability to deliver successful shocks. Medtronic voluntarily withdrew the lead from the market in October 2007 after 665 confirmed fractures and five reported deaths. It is estimated that worldwide approximately 268,000 patients at

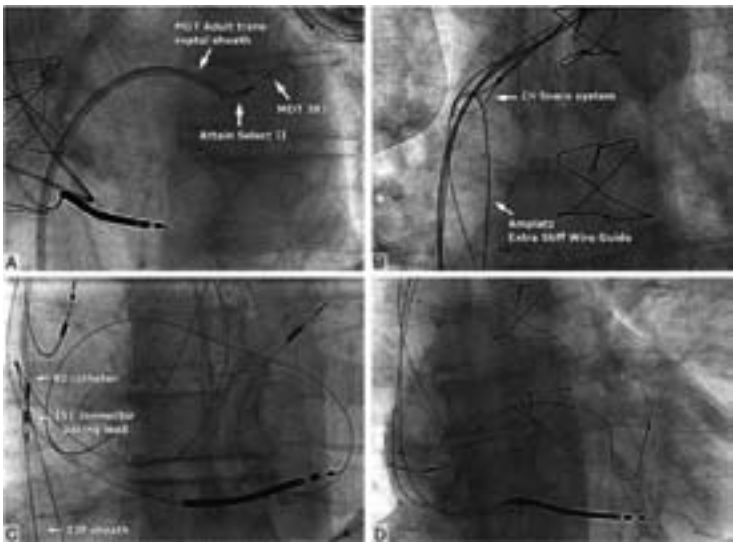

Figure 3.
Trans-septal endocardial LV lead implantation is a particularly challenging technique; the classical trans-septal atrial puncture is performed from below, allowing active LV lead implantation (A), which is then pulled endovascularly into the left prepectoral region using a complex technique involving snaring (B,C) (Gelder et al., 2011)

risk for sudden cardiac death have been implanted with Fidelis leads. Moreover, evidence suggests that the risk of Fidelis lead fracture is increasing with time (Cheung et al. 2012)

Subsequently, there was debate about prophylactically replacing still normally functioning Fidelis leads. Currently the FDA does not support routine removal of the lead, as it considers the risks of extraction to be higher than those associated with the potential development of lead fracture. Furthermore, Medtronic has implemented a device algorithm for early detection of lead fracture (the RV lead integrity alert – LIA). It is generally recommended to leave functioning leads in place. In which case two strategies can be adopted: either closely monitoring the lead for signs of lead fracture (complete device check-up every 3 months and also remote monitoring via Medtronic's CareLink network, including LIA check); or add a replacement lead without removing the Fidelis.

In November 2011, the St. Jude Riata and Riata ST were recalled due to documented premature erosion of the insulation around the electrical conductor wires, resulting in insulation failure. The insulation failure may cause some conductors inside Riata to migrate entirely outside the outer lead insulation – a phenomenon defined as externalisation, which can be documented by x-ray or fluoroscopy. As opposed to predominant pace-sense channel failure in the Fidelis, the main mechanism for electrical dysfunction in Riata is high-voltage failure, caused by short-circuits between high-voltage components and potentially resulting in the death of the patient (Hauser et al. 2012).

Currently the FDA recommends close device monitoring and periodic fluoroscopic imaging of previously normal Riata leads. For leads with normal electrical function, removal is not recommended, regardless of the presence of externalisation. For those with abnormal electrical function, replacing or adding a new lead is mandatory. The new St. Jude Durata ICD lead has seen the addition of an Optim coating, resulting in an increase of the distance between the conducting wires and lead edge. Furthermore the new generation of St. Jude ICDs are equipped with an automatic high-voltage lead integrity check (HVLIC), enabling early detection of ICD lead failure.

A recent real-life registry analysis has shown that the new generation ICD leads perform better than the recalled models (Liu et al. 2014).

Conclusion

The field of CIED has seen exciting new developments during the last decade. Progress and improvements have been made in pacemaker, ICD and CRT technologies, consolidating the role of device-based therapy and preparing the transition towards the next generation of devices. ■

Key Points

- *The leadless pacemaker is the latest breakthrough in bradycardia therapy, as it reaches phase 3 clinical trials.*
- *Subcutaneous ICD use is supported by early data from large international registries, showing a good safety profile and non-inferiority by comparison to standard ICD.*
- *Quadripolar lead and multisite LV pacing have the potential for better CRT delivery, as opposed to standard bipolar LV pacing.*
- *Current recommendations encourage conservative strategy when dealing with normally functioning recalled ICD leads.*

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Available on the website or on request

OPPORTUNITIES FOR CLINICAL RESEARCH IN EUROPEAN HOSPITALS: THE EHR4CR PLATFORM

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Introduction

Electronic Health Record (EHR) data is now being generated across Europe at an enormous rate, but the data which could help transform healthcare research and clinical trials is underutilised and disconnected.

Electronic platforms to allow clinicians and researchers to easily access patient data - in a way that remains compliant with data privacy, ethical, regulatory and legal policies - are therefore now vitally needed.

Three primary stakeholders need to be involved in the development of such a platform:

- Hospitals providing the Electronic Health Records data;
- Academia and industry using the data; and
- Technical service providers, whose tools and services will allow the parties to connect and collaborate securely.

Currently hospitals only connect with industry and academia on a one-to-one basis, and as a result it becomes difficult to reach the most appropriate patients.

The EHR4CR services encompass:

- Clinical Trial Feasibility (distributed queries);
- Patient Identification and Recruitment (distributing trial protocols to sites and collecting follow-up information on recruitment status from sites);
- Clinical Trial Execution and Serious Adverse Events Reporting (mainly EHR extraction).

New IT Platform Services

Setting these stakeholders within a digital ecosystem the EHR4CR platform now allows industry and academia to more easily access these data sources in order to identify patients who may be suitable to participate in clinical trials.

Specially constructed and robustly de-identified databases within each hospital, containing extracted summaries of health records, will be networked to the EHR4CR platform to enable research queries to be distributed, analysed locally at each site, and the results aggregated at regional, national and European levels. A simplified view of the EHR4CR platform is given in Figure 1.

Data will be anonymised and aggregated to protect patient privacy, but service users will be able to differentiate patients by e.g. disease area, geography or administrative domain.

Patient identification for recruitment into clinical trials always occurs inside the hospital, and will be undertaken by treating physicians to determine if their patients may be contacted to invite them to participate in a particular clinical trial. Any further use of electronic health record data will only take place with a patient's fully informed consent.

The EHR4CR platform is supporting distributed querying to assist in clinical trials feasibility assessment and patient recruitment, and links EHR systems and Electronic Data Capture (EDC) systems to enable clinical researchers to obtain key information about a patient's health and healthcare history before they arrive for a screening visit (but after patient consent has been obtained).

The platform is currently being piloted at several hospital sites across Europe. These sites are themselves active in clinical research, and are able to provide exemplary local governance requirements to complement the inputs from the EHR4CR Ethics Board.

Governance and the European Institute for the Use of Health Data

Such developments require acceptance from patients, the public and the research and health service communities. Therefore, in parallel to the technical developments, senior level decision-makers, ethics boards and industry executives have been involved in consultations to provide strategic insights into the most robust and acceptable technical and procedural approaches that should be taken to ensure privacy protection and compliance with European and national/regional regulations on data protection.

State-of-the-art information security measures are therefore used throughout the EHR4CR platform and a Code of Practice and Standard Operating Rules will govern the actions of all parties using the services.

Before project end a European Institute for the Use of Health Data will be established with the main remits of: governance, quality assurance, education and promotion. It will develop resources (e.g. maintenance of conformance criteria and testing tools) and governance frameworks, and provide services to registered members such as data providers, service providers and data users (see Figure 2). It will work

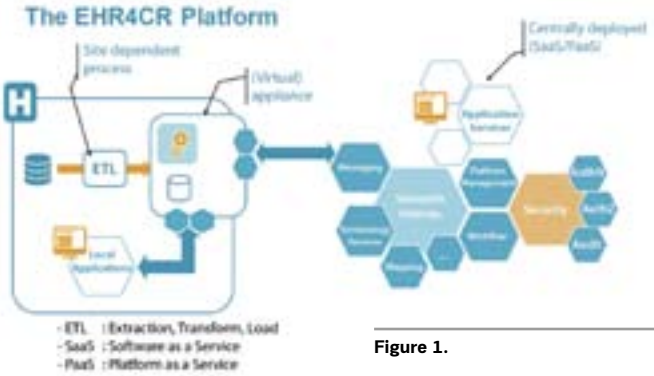

Figure 1.

Figure 2.

closely with industry, such as EHR system vendors, and clinical research organisations to encourage the adoption of standards and specifications so that the benefits of using electronic health records to advance research are not locked into individual hospitals and products, but can be analysed securely on a European scale. It will also work closely with hospitals to help them to assess and improve the quality of their data, which will not only benefit research but direct patient care, and help them to make more effective use of healthcare resources.

To enable wide adoption by EHR vendors and quality assurance of the EHR4CR platform within hospitals, the project will also provide governance through accreditation/certification programmes for establishing best practices. Acceptance and success will be made more robust by building on the well-accepted accreditation/certification mechanisms for clinical research units, platform service providers and EHR systems to prove their compliance with predefined criteria. This will serve as a powerful means for ensuring the reliability and trustworthiness of the research partners for the pharmaceutical industry (e.g. of data providers such as hospitals), and for controlling and monitoring the use of the platform(s), ensuring that anyone who uses the services complies with specific standards and requirements.

One of the most important functions of the Institute will be to regulate and monitor the use of the EHR4CR platform, ensuring that anyone who uses the services complies with specific standards and requirements. These standards will guarantee the overall trustworthiness of the electronic health records being analysed. The Institute will also work with societal stakeholders such as patient associations, health ministries and sponsors of clinical research to promote the value of publicly funded and pharmaceutical industry clinical research whilst strongly protecting patient privacy.

Since the platform architecture will in the near future accommodate connection with a variety of sources (e.g. with data unlocked from primary care settings, registries, mobile health sources etc.) -and thus not only with Hospital EHR data sources - the scope of the Institute will allow for collaboration with other big health data projects that are established or being established within countries and across Europe.

Conclusions

The platform is well placed to deliver a sound, useful and well accepted solution for the (re-)use of hospital EHR information to support clinical research studies. By investing substantial effort in the design of a robust business model framework and in the development of compelling value propositions across multiple stakeholder groups, EHR4CR is stimulating a marketplace of multivendor product offerings.

The new platform services will offer benefits to hospitals:

- Enhance the quality of patient-level EHR data for clinical research, and improve quality of care and health outcomes;
- Generate a new additional income stream by contributing EHR data into research;
- Conduct clinical trials more efficiently and increase hospital participation in a larger number of clinical trials;
- Improve hospital recognition as a clinical research centre of reference;
- Engage in a highly dynamic clinical research environment to improve the overall quality of care and knowledge transfer.

The intent of the new non-profit European Institute for the Use of Health Data (to be established before end 2014) is to attract new actors to join this network and to encourage pharmaceutical companies to continue to collaborate pre-competitively to evolve the services to meet new needs and to accelerate and improve the quality of clinical research. For the industry this will provide innovative integrated and cost-effective solutions to optimise the R&D value chain. For patients, it will prove to be a genuine revolution that accelerates the delivery of innovative medicines into healthcare and engages patients more in the clinical research agenda. ■

Further information

The Electronic Heath Records for Clinical Research (EHR4CR) consortium organised a Pan-European Conference in April 2014 in which decision-powered delegates both from hospitals (with excellence centres from 24 countries represented) and from 14 global pharmaceutical companies participated.

The EHR4CR project runs over 5 years (2011-2015) with a budget of €17 million and involves 34 academic and private partners (10 pharmaceutical companies). To date it is one of the largest of the Innovative Medicines Initiative (IMI) public private partnerships. The project is developing adaptable, reusable and scalable solutions (tools and services) for reusing data from Electronic Health Record (EHR) systems for clinical research purposes.

Animation video on You Tube
https://www.youtube.com/watch?v=Wcsl064F2pk

Conference programme
http://www.ehr4cr.eu/9april2014/

References

Available on the website or on request

Key Points

- *Moving towards deployment of EHR enabled clinical research in Europe*
- *Piloted IT platform services are about to be scaled up to a commercially supported service*
- *Hospitals will be offered higher efficiency in participating in clinical research*
- *ICT helps pharmaceutical industry to speed up the delivery of innovative medicines to healthcare*

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MEDICAL APPS – A VIEW FROM MEDICAL DEVICE AND DATA PROTECTION LAW

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The growth in the mobile devices market (smartphones and tablets) has been accompanied by a rapid increase in the number of software applications for mobile devices ('apps'). One of the fields propelling this market growth is the healthcare and life sciences sector and industry (Greenspun and Coughlin 2012). Modern smartphones and tablets are embedded with a variety of sensors, such as multi-touch touchscreen, accelerometers or gyroscopes, ambient light sensors, GPS, cameras, fingerprint sensors, facial recognition etc. These sensors are able to collect and store large amounts of data. Through an interface called Application Programming Interface (API), collected data can be accessed and processed by software programs or accessories, or a combination of accessories and software, that run on smartphones: what we call 'applications' or 'apps'.

Thanks to wireless communication networks – allowing continuous, real-time, exchange and 'crossing' of data, apps can be used for a wide variety of purposes, including the management of personal health, wellness, and wellbeing. For instance, many apps allow users to monitor their caloric intake for healthy weight maintenance: 'MyFitnessPal', 'LoseIt!', and 'DailyBurn' are just a few examples.

Apps can be used by healthcare professionals, nurses, physicians, and informal carers. For instance, the REACTION GlucoTab implements a mobile tablet-based workflow support system for nurses and physicians on the ward; its features include a validated basal/bolus insulin titration protocol. The Radiation Emergency Medical Management (REMM) app gives healthcare providers guidance on diagnosing and treating radiation injuries. Other apps allow for the monitoring of heart rhythm abnormalities, to carry out consultations on dermatology cases, etc.; and the list goes on.

As for most technological developments, e-health and mobile health technologies are laden with risks and uncertainties. Participants in studies highlight "clinical risks (misdiagnosis), social and interpersonal (interactional), personal and professional (overload of information, liability and role change), technical (failure) and organisational (poor integration)" (Finch et al, 2006). Two diffuse concerns relate specifically to the use of medical apps for medical purposes.

The first concern relates to the safety of the patient. Under EU law, safety requirements vary depending on whether apps are intended to be used for medical purposes or are instead intended to be used for 'wellbeing'. The second concern relates to the protection of personal data. Given the choice of the EU regulators to give leeway to the market in medical and pseudo-medical apps, a massive number of them are available in the market. Data protection law is summoned as 'second best' to regulate not the presence and the use of medical apps, but the personal data processing performed by those apps. In order to mitigate safety and privacy risks, technologically mediated healthcare provision must be compliant with the relevant legislative frameworks and requirements[1]. The relevant legal frameworks are the EU medical device framework and the EU data protection framework[2].

Medical Apps In The Medical Device Framework

The primary purpose of the EU Medical Device Framework (MDF) is to ensure the same level of safety to all EU citizens using medical devices (Directive 93/42/EEC)[3]. Article 1 of the Medical Device Directive (MDD) defines medical device as "software[...] intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception [...]". This means that software such as a medical app that works in combination with a device (a smartphone) is a medical device. Before being put into free circulation and used in medical practice, mobile technology and medical apps must satisfy the legal requirements detailed in Directive 93/42/EC. Once the requirements are fulfilled and validated by the competent national office (this can also occur by adherence to an internationally recognised software standard shown to be safe), the CE certification is granted. The CE certification guarantees that a medical device has been approved as meeting the requirements of the MDF and, being safe, must therefore be permitted circulation in all Member States.

Despite the obvious engagement of the MDF framework with medical apps, the EU regulator has been hesitant to take action in an area of obvious ongoing innovation and market growth (Mantovani et al. 2013). At present, there are apps being advertised or readily available which perform activities that fall within the aforementioned definition of a medical device, but which do not carry a CE stamp, and are not described by its manufacturer as intended for medical purposes. Arguably the main reason for this relaxed approach is economic. The costs involved with MDF compliance are estimated at up to €10m (EFPIA 2010; DiMasia 2007;

European Commission 2012). Under a literal interpretation of the regulation, apps that have a clear medical purpose would have no choice but to comply with the demands of the MDF, regardless of the intention of the manufacturer. This means that under a literal interpretation of the MDF a large numbers of apps that have a quasi or pseudo-medical purpose, such as ECG for self-monitoring, would disappear (Mantovani et al 2013).

Do apps that have a clear medical purpose have the obligation to comply with the demands of the MDF? In 2012 this question came under the scrutiny of the highest Court of the European Union: the European Court of Justice (ECJ). The case Brain Products GmbH v. BioSemi VOF, which was referred by the Federal Court of Justice in Germany, concerned an application called 'ActiveTwo' which enabled human brain activity to be recorded. The plaintiff (a company competing with Active Two) argued that 'ActiveTwo' was not marketed as a medical device, though what it did (record brain activity) very clearly fit into the literal description of medical. The Court disagreed, espousing not a literal, but a teleological interpretation of the MDF. The teleological (from ancient Greek telos= purpose, aim) interpretation gives decisive weight to the purpose intended by the manufacturer of the device or app. On the one hand, a medical device or app intended to perform an activity that falls within the definition (literal interpretation), must obtain the CE certification or satisfy the legal essential requirements, if its manufacturer expressly marketed it as a medical device. On the other hand, a device that de facto performs an activity that squarely falls within the letter of the definition, but is not intended to be used for medical purposes by its manufacturer, is not a medical device. Accordingly, in situations in which a product is not conceived by its manufacturer to be used for medical purposes, its certification as a medical device cannot be required (§ 30), says the Court (European Court of Justice 2012).

This means that manufacturers of medical apps that may incidentally be medical devices do not have to create them to the same standards required for conventional medical devices. As a consequence, many medical apps that are appearing on the market have not been checked for compliance with the essential requirements of the MDF. They are not as safe.

Medical Apps In The EU Data Protection Framework

The vision of mhealth elicts concerns about the security and confidentiality of medical records. In the pre-digital era, the duty of medical confidentiality required doctors and nurses to keep drawers closed and avoid sensitive talk in hospital cafeterias and elevators. In the digital era, a growing problem is the increased number of personnel who have access to patient data, who may not always be, or feel, subject to the duty of confidentiality. Another drawback is that data can be easily lost: news reported the NHS North Central London Trust losing a laptop containing an estimated 8.3 million patient records. The same source reported that thousands of notes belonging to cancer patients have gone missing from the abandoned Belvoir Park hospital in Belfast, which closed in 2006 (The Independent 2011; The Daily Mail 2014). Many healthcare operators are careless in storing and exchanging medical information records, e.g. they carry diagnoses or x-rays in memory sticks without a password. With the advent of apps, the doctor's obligation of confidentiality becomes more complex to navigate. A recent study indicated that privacy policies were only present in 74% of the free apps, and in 60% of the paid apps. Such privacy policies were either included in the app, or externally available on the developer's website (Lie Nije 2013).

In addition, apps are generally not bound to a precise purpose. Data can be used for secondary goals, and there is little transparency about the duration of data storage, processing and the rights of app users. Apps often leave the user alone and even require him/her to open additional links to find information on external sites (Lie Nije 2013).

Apps that process sensitive data collected in any of the EU Member States must adhere to the EU data protection rules. The rules for processing and storing of medical data are found in Directive 95/46/EC, currently under revision (European Commission 2012) and in the so-called e-privacy directive (2002/58/EC). Because of their sensitivity, medical data can be processed only in a restricted series of circumstances. Aside from cases of emergency, or when the vital interests of the patient or others are at stake, two relevant conditions for the processing of medical data are: a) explicit informed – written – consent of the 'data subject'; and, b) when data are processed by a health professional subject to the obligation of confidentiality (Article 8 Directive 95/46/EC)[4].

However, it is crucial to point out that being the principal carer or having received consent does not legitimise any use of the data not originally foreseen. Under the circumstances in which the processing is lawful, the data protection principle of data minimisation applies. As enshrined in the fundamental right to data protection (Article 8 EU Charter of Fundamental Rights; Article 6, Directive 95/46/EC) "...

"a safe medical app with a CE mark and software compliant with data protection rules will grant developers a solid competitive advantage"

[1] The law is one of the tools through which risks can be mitigated and arguably not the most important one. In medical practice, audit of services and clinical evaluation (trials) are the most widespread ways to stem perceived risks.

[2] The EU Medical Device Framework (MDF) is one the most important EU initiatives promoting the establishment and running of a European single market for medical devices. The primary purpose of the MDF has been to provide common rules for the free movement of goods throughout the EU, and, at the same time, to ensure the same level of safety to all EU citizens using medical devices (Directive 93/42/EEC). Similarly, the EU Data Protection framework is one the most important EU initiatives promoting the establishment and running of a European single market in which personal data can flow freely while the fundamental rights of individuals, in particular the fundamental right to privacy, are safeguarded (Preamble (3) and article 1, Directive 95/46/EC)

[3] The MDF is at present composed of three different directives: Council Directive 90/385/EEC on active implantable medical devices (AIMDD), Council Directive 93/42/EEC on medical devices (MDD), and the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (IVDD). In 2012 the Commission released a proposed new regulation.

[4] Other exceptions include the protection of the vital interests of a subject unable to consent; when and for public health purposes, law enforcement or emergency. Under these circumstances data processing is allowed, but this does not mean that any kind of processing is legal (Article 8 Directive 95/46/EC).

[5] These cases are retrievable from the Court search engine http://hudoc.echr.coe.int/sites/eng/Pages/search.aspx#{%22documentcollectionid2%22:[%22GRANDCHAMBER%22,%22CHAMBER%22]}

data must be processed fairly for specified purposes". Data minimisation mandates that all processing is both adequate for and limited to a specific purpose.

In addition, the EU data protection framework lists a series of rights of data subjects and obligations of data controllers and processors (the entities, like a hospital or a doctor or app developer controlling the purpose and the means through which personal data are processed). Data subjects have the right to receive information (Article 10, 95/46/EC). Pursuant to articles 12 and 13 of Directive 95/46/EC, app users must be put in a position to exercise their rights to access, rectification, erasure and object to their data being processed. Data controllers are under the obligation to keep the data secure, accurate, and to act promptly in case of data breach or leakages (adapted from Article 4 Directive 2002/58/EC). In a string of cases – Z v. Finland (1997), I v. Finland (2008) and, more recently, L.H v. Latvia (2014)[5] - the European Court of Human Rights (ECHR) penalised states that failed to take appropriate steps to secure medical data, so that it cannot be accessed improperly. According to the Court, "what is required [...] is practical and effective protection to exclude any possibility of unauthorised access occurring in the first place" (I v. Finland, § 46).

The implications of the data protection regime for medical apps are as manifold as the risks, which are created by processing medical data through mobile health technologies. Some basic recommendations based on the legal framework can, however, be put forth.

1. Incorporate the principle of data minimisation in apps. *Whoever controls or owns medical data should not process more personal data than necessary, and must not do so for purposes not defined and for indeterminate or excessive periods of time. As the case law of the European Court of Human Rights indicates, doctors and hospitals should not disclose patients' data to third parties, including law enforcement agencies and health or social security departments.*

2. Improve security measures. *– The use of mobile health technologies means that more people have access to personal sensitive information. As the case law of the ECHR suggests, the conditions for the lawful processing should be incorporated in the design of the device and of the apps. The controller should implement appropriate technical and organisational measures and procedures in such a way that the processing will ensure the protection of the rights of the data subject.*

3. Increase transparency of apps. *Users of medical apps have the right to receive information, exercise their rights to access, rectification, erasure and object to data processing. It is important to provide users with instructions that clearly state whether apps are certified (the CE stamp) for medical purposes, and ensuring awareness of the kind of data that are being accessed and processed. Ideally apps developers should ensure 'by design' the proportionality of the data collection; customise information about data subjects' rights, including the provision of updates and adequate information; and notify any breach of personal data or security problems.*

4. Make room for 'granular' consent. *This recommendation is closely linked to transparency. Patients must understand what an app does before they can give valid consent in an informed, specific, truly free fashion. Consent must be obtained before information is gathered, but also before the information stored in the device – or accessible by the app, is processed. It should also be noted that patients withdraw de facto their consent when they 'un-install' apps. In this case, all personal data stored by the app developer and in the servers of the third party data controller(s) should be removed.*

5. Include different capacities. *The ability of an individual to truly gauge the exact nature of his/her situation in an mhealth environment will vary enormously between a teenager and an elderly patient. It is questionable if apps processing data for medical purposes can be used without any supervision at all. In this regard, Portuguese data protection legislation allows users to have only indirect access to medical data through a physician. Similarly, the Belgian Commission for the Protection of Privacy advises patients to access their medical dossier under the supervision of a physician whenever possible.*

Conclusion

Many apps performing medical activities are not considered medical devices in a strict legal sense. Developers can get their way out of the requirements mandated by the MDF simply by not stating that the app has a medical purpose. The difference between considering an app to be a medical device or not is relevant for the safety of the patient, for doctors' liability, as well as for the relationship between patient and doctors. As a rule of thumb, it is advisable to read carefully the instructions that come with the app and verify the presence of the CE mark. Patients and doctors should avoid taking decisions relying on measurements provided by the hundreds of apps that are not certified medical devices. In any case, app developers and users are bound by data protection principles, rights and obligations. A safe medical app with a CE mark and software compliant with data protection rules will grant developers a solid competitive advantage. ■

Key Points

- *Medical devices and non-medical apps*
- *Medical apps in the context of data protection*
- *Processing sensitive data*
- *Recommendations for developers*

References

Available on the website or on request

BIG DATA HISTORY

Big Data: two short words with unlimited complexity, indicating that a set of information is too voluminous or varied to be processed using traditional means. Technically-speaking, it is comprised of the multi-formatted records of what everybody does these days, from every log-in to every keystroke and every save, until the sign-out process and even beyond.

Author

Kelly Ann Callahan

Editor, Healthmanagement

The creation and saving of more and more data over the years has been facilitated by cheap storage, despite the absence of any master plan behind its accumulation. As such, Big Data is not necessarily a new idea, but the scope and scale of its potential power has ballooned into the clouds, quite literally. NSA and competing agencies have long understood its dormant power. Indeed, "Big Brother" is dwarfed by Big Data.

Big Data In Healthcare

The now-buzzworthy phrase Big Data pervades industries ranging from banking to business, from finance to forensics, from marketing to medicine. Indeed, its applications in healthcare are as unlimited as the data being generated every second by academia, clinics, insurers, patients and vendors.

As vast amounts of healthcare-related data are digitised, organised and analysed, what may once have been the technical terrain of engineers has attracted the attention of industry leaders eager to capitalise on system improvements, cost savings and profit hikes. According to the McKinsey Global Institute, the US could save $300 billion -- that amounts to approximately $1,000 per person -- by the efficient integration and analysis of data from sources such as clinical trials and insurance transactions.

Historical Cases

The accumulation of data that are too abundant or too abstract to manipulate by hand is not a new phenomenon, but sophisticated tools did not always exist for its manipulation. Napoleon took data to the battlefields by using mathematical models to make strategic decisions. It did not always work in his favour; there is a famous map of his army's losses in 1812 and 1813 that presents a graphic analysis of information that would be otherwise difficult to envision.

Big Data is not new to healthcare, either. A cholera outbreak in London in 1854 was traced to a public well after an inquisitive doctor mapped the addresses of the 600 people who died. The fatalities clustered around a single point, a public water well, and when the handle of the pump was removed, cholera cases diminished. The story illustrates the value of looking at data not just as numbers in isolation and out of context, but finding interconnections and patterns that relate facts and behaviour.

Using Big Data to Forecast the Future

Data-driven visualisation of trends such as the ones described above can facilitate the determination of a cause for a particular effect, but it also has predictive power when structured effectively. The ability to forecast the behaviour a population of consumers has obvious value to marketers. The potential to predict the dimensions of disease or the success of therapies can save lives. Whereas the mapping of the London cholera epidemic solved a medical mystery at the level of a single neighbourhood, Big Data now supports the timely tracking of epidemics across the globe.

One notable example is Google Flu Trends. Over the past five years, Google engineers have monitored the correlation of search terms that might be used by people feeling under the weather, such as "flu symptoms" and "local pharmacies", to show locations of outbreaks. Initially, Google's number-rich but theory-free analysis was as accurate as the tracking of influenza cases by the Centers for Disease Control, but much faster.

Figure 2.
The map originally accompanied the second edition of Snow's Of the Mode of Communication of Cholera (London: John Churchill, 1854).

Snow's decisive, iconic map, showing how cholera deaths clustered around the Broad Street water pump. Using a commercial map of the Soho District, Snow stacked his black line symbols that represented individual deaths inward from the street address. This visual innovation combined an accurate location with a measure of intensity.

Big Data Challenges

But in the winter of 2012, as news outlets began reporting on the dangers of the flu, Google Flu Trends showed cases of the flu where they did not exist, according to the later CDC report. The failure was due to healthy people using the same search terms as sick people owing to the media hype about the topic, and Google not knowing the difference.

Google Flu Trends is not the only example of Big Data failures. Prior to September 11, 2001, intelligence existed in computerised databases which could have

raised a flag about the imminent threat of hijacking. However, without having some direction about what to look for, it can be difficult to separate the signal from the noise.

Industry leaders and data scientists continue to grapple with how to reign in the vast volumes of information and to structure it for efficient analysis and value extraction. In healthcare, the size of data sets is not the only problem; the variety of file types (audio, video, scans, electronic health records, lab notes, clinical trial results) and related issues of compatibility are real challenges.

Like physical obesity, information overload interferes with normal function by slowing some processes, such as metabolism and movement, and preventing others altogether.

Structuring data is essential to eventually being able to extract meaning; some estimates indicate that only 10 percent of all data being captured are structured. Beyond architecture and interoperability is the challenge of how to ensure data quality. Real threats include not only tampering and fraud, but verifying the integrity of information collected haphazardly or without a purpose. The confidentiality of sensitive information and system security are major concerns for Big Data in healthcare, where breaches of either type can be costly in terms of customer confidence and financial fortitude.

Data feeds knowledge. Knowledge is power. It provides a basis for action, and as such, professionals skilled in the use of scientific methods to extract or create meaning from raw data are in great demand. Last year, the New York Times declared data science a hot field that promises to transform not only individual companies but entire industries, including healthcare.

Up Next:

HealthManagement considers Big Data a game changer, and we will look into all its different aspects in due course. The following article will delve deeper into the Five V's of Big Data: volume, velocity, variety, veracity and value. Each presents its own opportunities and obstacles for healthcare. ■

References

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BIG DATA IN HEALTHCARE: OBSTACLES AND OPPORTUNITIES

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Healthcare organisations are facing an unprecedented accumulation of data from academic research, clinical trials, electronic health records (EHR) and the proliferation of mobile health and remote monitoring devices. "Big Data" is not only transforming individual companies which capitalise on its inherent yet untapped value; without a doubt, it is changing the industry. To structure the discussion of Big Data as it relates to healthcare, it is helpful to look at five factors that contribute obstacles and opportunities: volume, velocity, variety, veracity and value.

The size of data sets is attributable to its multiple sources, necessitating the elasticity of storage sites. Speed becomes a factor as the size of data sets increases and as they are interconnected and shared across authorised user groups. This is especially relevant in healthcare where rapid access to solutions can save lives. However, quantity does not guarantee quality; data become meaningful and useful only when they are structured, verified and interpreted. One of the biggest challenges to Big Data is how to manage the variety of file types that contribute perspectives to medical research and patient profiles for optimum interoperability. Another is how to verify and protect the integrity of so much information.

There are two ways to think of Big Data as valuable: financially, it has the potential to reduce healthcare costs for patients and organisations when they are empowered with structured information. From a human perspective, there is no price to put on improved outcomes from novel medical solutions generated by the access to and sharing of information. The "big" in Big Data takes on a new meaning when it refers not only to size but to the power to save lives and resources.

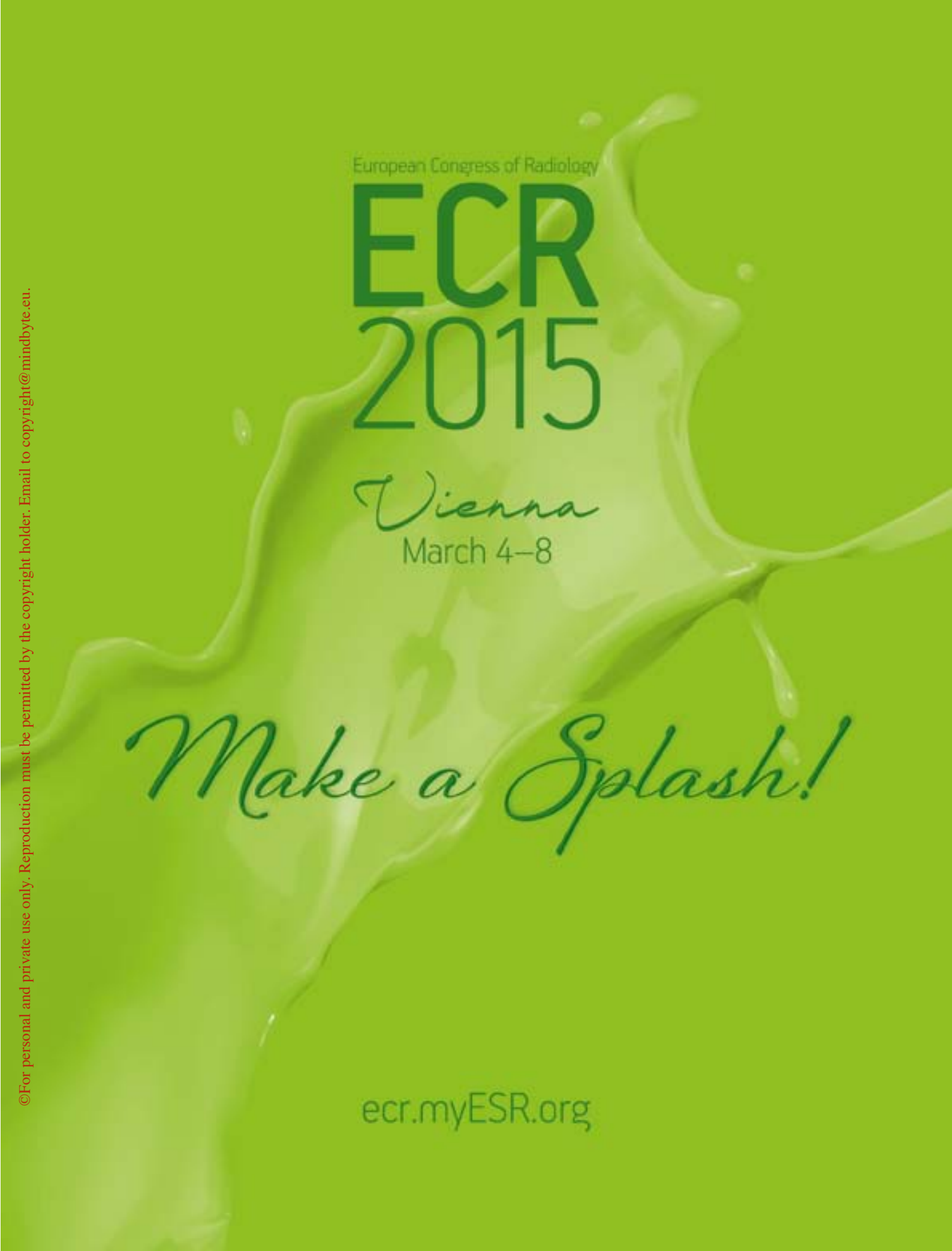
Volume: Abundant But Unstructured

Big Data will continue to grow in size and importance for the healthcare industry. An ageing population is increasing the demand for services, and a shortage of care providers creates an opportunity for technology to move in and help to manage the situation for organisations. So-called closed-loop systems connect home- and hospital-based devices for biometric data exchanges. Meanwhile, academic and clinical research continually contribute data about diagnostic and therapeutic methods, all of which should be as accessible as possible to improve outcomes and prevent duplicated research efforts.

To this end, some healthcare companies are hiring data scientists to manage their internal datasets, and to link them with external sources. The associated costs only seem extravagant until they are compared with the value left on the table when the stores of study results, clinical records and claims data go unanalysed and therefore remain useless.

User-Generated Data

Big Data is not confined to institutions.



People are taking charge of their health through fitness apps and the home-based tracking of vital statistics, causing an explosive generation of useful data. It is not only chronically ill or elderly patients who are becoming active participants in their own care; younger generations are now empowered by technology to prevent prevalent threats to their good health.

Sensors and Sensitivity

Already, people with chronic conditions such as diabetes can monitor their blood sugar from home. Implanted pacemakers serve cardiac patients and the physicians who treat them. Through remote monitoring, physicians are able to follow patients without office visits, all thanks to the efficient uploading of data from home-based devices. And it is not only prescribed devices that capture data: smartphone applications are changing the way healthcare is administered thanks to sensors built in to wearable technology such as the fitness-related FitBit and Jawbone. Google Glass assists surgeons by allowing them to augment operative procedures while the patient is still in the OR, and the company is now developing contact lenses with sensors to monitor diabetic blood sugar levels.

Cloud Elasticity

The infrastructure required for healthcare organisations to house and process data go well beyond the capacity of file rooms and warehouses. That is why no discussion of Big Data can avoid another buzzword: cloud computing. Essentially, the phrase refers to the storage and access of data and IT platforms not on individual hard drives but in "the cloud", a web-based space accessible via the Internet. Cloud-based data and platforms synchronised with remote sets and systems serve authorised users in ways never before imaginable. Of course, elasticity is essential as data accumulates and connections increase. According to a 2013 survey by global management consulting firm McKinsey & Company, the market for cloud computing is on a path toward generating $100 billion per year.

Velocity: Patients and Impatience

As the volume of data increases, so does the threat of system crashes from too much influx and the slow transfers of outgoing data. The speed at which users can access health data impacts user satisfaction, to be certain, but can also be a matter of life or death. The challenge for healthcare organisations in the process of capitalising on Big Data is how to allow authorised customers to quickly access or transfer the right information, in a user-friendly manner, without sacrificing safety and security.

The Power of Now

Healthcare IT workers are familiar with the frustrations of pleasing demanding doctors and industry professionals, many of whom were not trained to be tech-savvy. Despite a real lack of training, clinicians and managers increasingly rely on web-based communications, devices and platforms. To take advantage of Big Data without slowing service delivery, apps must be as user-friendly as possible. For example, the surgical app DocSpera provides members of a coordinated care team with a platform for the secure exchange of patient information. Team members can work together from remote locations; a nurse might use the platform to upload a cardiac patient's diagnostic test results upon hospital admission, which are then shared with a consulting cardiologist, who confers with a surgeon across town, while an operating room is being reserved in the appropriate facility for the necessary medical procedure.

Big Data in the pharmaceutical industry is improving the speed of care solutions. A day can feel like a lifetime for someone waiting for an effective treatment for a life-threatening illness. However, according to a recent study, 55 percent of prescribed medications do not work for patients, and the number is closer to 70 percent for cancer therapies. Considering what is now known from epigenetic research, it should not be surprising that there is not a blanket cure for common illnesses. Individual genetic expressions, turned on or off by environmental factors, will always vary from patient to patient. When healthcare becomes personalised through the combination of a patient's genetic record and known triggers in the environment, physicians will be able to use the combined data to prescribe highly individualised, and likely more effective, treatments and prevention plans.

Learning From Other Industries

Care administration is becoming evermore portable with mobile-health apps that deliver results rapidly, but traffic can disrupt the flow of information. Fortunately, healthcare is learning something from the way the financial industry handles its Big Data. Soon, mobile health services may adopt streaming technologies like the ones which empower economic trading. The hope is that eventually, more people will benefit from a new kind of healthcare experience. Providers will be able to administer advice or care solutions immediately upon the receipt of relevant information, through the real-time analysis of patient data. ■

The full article can be found online at *www.healthmanagement.org* or scan the *QR code*

HOW TO OPTIMISE YOUR LAB AND FACE THE CRISIS

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One of the many challenges modern hospital management faces is the economic issue with steadily increasing costs in every corner of the hospital. Seen from a laboratory point-of-view, the laboratory seems to reflect the hospital in terms of increased workload, increased test demands and increased economic demands. In general, the demands for a modern hospital laboratory can be summed up as follows:

- Increasing amount of blood samples;
- Increasing demands for analyses available on the test menu;
- Increasing demands to improve turn-around-time (i.e. the faster the better);
- Increasing quality demands;
- And at a low or no increased cost.

This seems impossible to overcome. However, there are some opportunities to be grasped. There is growing focus on the area from both the hospital administration as well as from the international companies producing analysis equipment. Attention from the local administration makes it feasible to define demands within the hospital and get specified requirements from the departments using the laboratory. Focus from the companies has led to a dramatic increase in new technologies supporting faster turn-around-times (TATs), which is the time measured from when the blood sample is taken until the analysis result is presented in the lab information system. These technologies include transportation of the blood samples, automated receipt of the samples at the lab, and a track combining different types of analysis instruments in order to decrease manual sample handling. IT solutions have improved considerably, enabling the laboratory to handle requests more rapidly and also to transmit the results as fast as possible.

Finally, the possibility of using point-of-care equipment, i.e. small analysis units placed on the wards and operated by local staff, makes it possible to tailor the laboratory service to the needs of the individual departments in terms of analysis availability, TATs etc. With all these new opportunities it therefore suddenly seems possible to reach the goals set in a modern hospital.

We will briefly describe our experiences with a lab automation process and the outcome in terms of TATs, analyses produced and fiscal issues. Our goal was to quantify the monetary value of process improvements due to implementing automated instrumentation and process optimisation. For this, production numbers from 2007 and 2011 (before and after the automation process) were used.

Local Experience

Odense University Hospital has 1,115 beds, 1,025,000 ambulatory treatments (2011 numbers), while the laboratory has 260 employees with an academic staff of ten involved in routine analyses. The Lab has a 24/7 service, incl. phlebotomy, which means that routine production continues 24 hours every day, and lab technicians are responsible for the main part of the blood sampling over the entire period. The Lab receives samples from in- and outpatients, including from general practitioners, which gives a total of approximately 6,000 tubes per day. As shown in Figure 1, the number of tests performed has increased steadily during the last six years. To meet these increasing demands possible process optimisations at the Lab were investigated:

Very simplified, the logistic flow can be divided into the following processes:

- Test requisition;
- Blood sampling;
- Blood sample transportation;
- Blood sample handling at the Lab;
- Analysis;
- Storage.

Here, we address the issues of sample transportation, sample handling and analysis.

Sample Transportation

If sample transportation is automated several things are achieved. Overall, the key issue is of course faster TATs, but also, more uniform, simplified sample handling facilitates optimisation of the sample flow at the Lab. Most new equipment is capable of receiving samples from transportation systems, which enables faster, automated handling and reduces manual handling. Finally, the risk for samples getting lost or too old for analysis (due to stability issues) is minimised. To achieve this, we introduced a sample transportation system capable of sending samples from phlebotomy wards and hospital wards continuously, which can reach the Lab within 40 seconds. Also, a bulk receiver was installed, where samples automatically are registered as arrived at the Lab and then sorted for different analysis instruments (see Figure 2). The samples do not yet arrive at the analysis track, but this will be the next automation step.

Figure 1.
Number of tests performed at the Lab in the years 2007-2013.

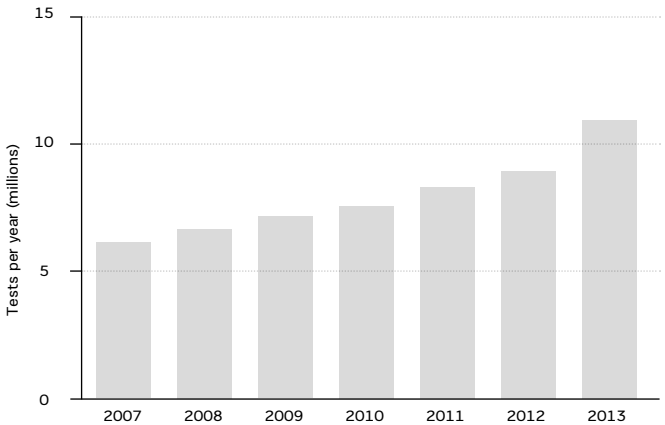

Figure 2.
Instead of transporting samples from ward to ward on trolleys, an automated pneumatic transportation system, capable of sending every tube one by one (no packing needed), was introduced along with a sample bulk sorter to receive the samples.

Consolidation

As shown in Figure 3, an important key to optimisation was consolidation of tubes and equipments, respectively:

- Consolidation of the sampling tubes minimises the number of phlebotomies, the number of samples to be transported and thereby the number of manual sample handlings. Also, fewer tubes will make alternative transportation strategies more feasible. Finally, each tube generates additional work and cost in terms of production and disposal after use.
- If more analyses can be performed on the same equipment, this will give many benefits. It will require fewer tubes, and, due to fewer instruments, it will require less preventive maintenance (which is costly), improve laboratory environment due to fewer instruments making noise and heat, and in the end improved workflow due to the fewer tubes and instruments required (Figure 4). This will in the end improve TATs, which was also one of our key parameters.

Serum analyses were converted to plasma analyses where possible, in order to perform more tests in the same tube. Also, tests were moved from other equipment to the same analysis platform. Worth mentioning is that the track arrangement connecting these instruments enabled automated storage, so again manual sample handling was minimised. This arrangement makes it possible to easily retrieve samples for additional analyses, if the clinicians wish to add a requisition to an already obtained sample.

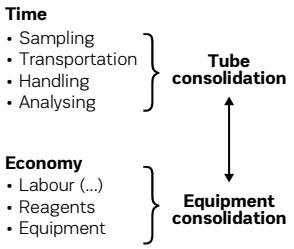

Figure 3.
The two main drivers, time and economy, are both vastly affected by consolidation processes due to the effect on the different sub-processes mentioned. As indicated, consolidation of tubes gives a synergistic effect with equipment consolidation.

Outcome

As shown in Figure 5, the number of instruments was reduced by 25%, which gives an economic advantage in terms of lower service costs, less electricity and less space needed. The number of tubes was reduced by 20% (from 6.6 tests per tube to 7.9 tests per tube), which enabled the Lab to perform an increasing number of tests in the same number of tubes.

Just as important, TATs were reduced by 55%: from median TAT/test 14.1 hours (IQR 1.9-30.2) in 2007 to 2.0 hours (IQR 1.7-2.6) in 2011.

And finally, the reduction in instruments, employees etc. gave an overall saving of approximately 37% as shown in Figure 5.

Conclusions

Despite continuous economical challenges it is possible to not only improve the laboratory service, but also to achieve savings through this process. One key word is automation, and as shown above it has resulted in a number of solid improvements at our University Lab. The savings mentioned should of course be interpreted cautiously, as some of the employee savings were used to transfer

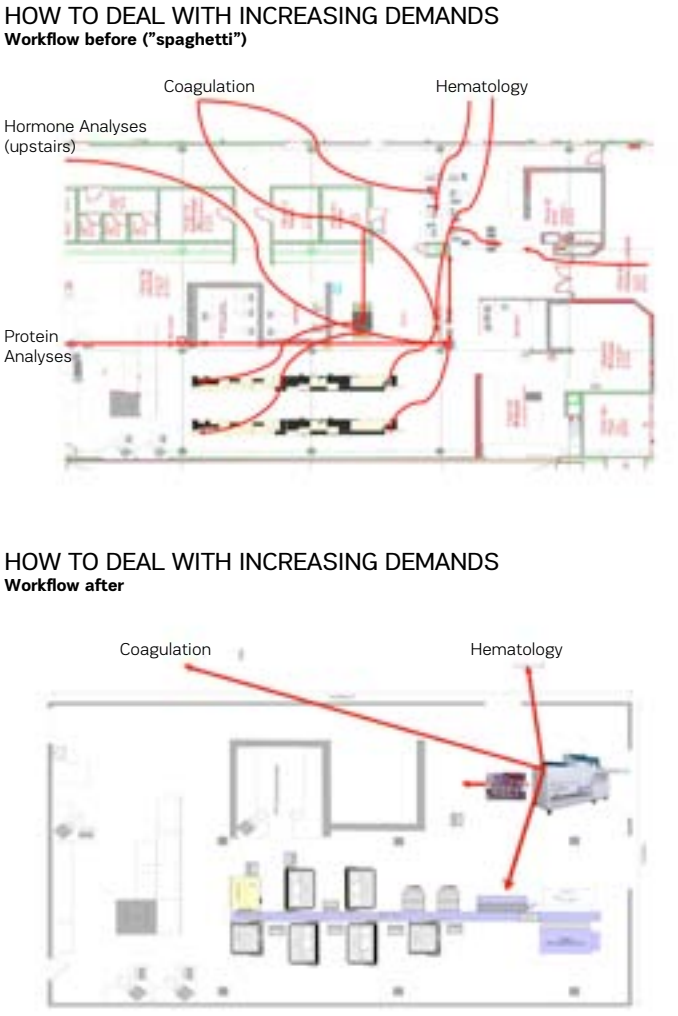

Figure 4.
Workflow before and after consolidation. As described in the text this was obtained by consolidating tubes and consolidating instruments whenever possible.

personnel to other tasks, and the savings made it possible to invest in a continuous automation process: As depicted above, such a process needs investments to get started, here by introducing new transportation solutions, automated sample reception and a consolidated track solution for the analyses.

Another key word is continuous, as this is merely the beginning of a process, where a number of further improvements still lie ahead. A number of areas can be addressed, and here some of the forthcoming issues should be mentioned. On the request area, so-called "diagnosis-oriented analyses panels" (anaemia, fatigue, cancer suspicion) need to be optimised, and also, unnecessary and/or repeated requests must be eliminated. For blood sampling, there is an ongoing debate concerning the possibility of robot sampling – this does, however, seem to lie some time ahead. Other possibilities are increased local sampling (which will require training of nurses etc.) and the use of capillary samples, e.g. for point-of-care analysis as mentioned. For sample transportation, pneumatic tube transportation of all samples, sorted directly onto the instrument track, is more or less available for all instruments on the market today and must be acquired. And as for analyses, continuous consolidation of additional analytical platforms is of course mandatory.

Altogether, automation is indeed an opportunity for every laboratory to trim their processes and improve their service, but it is also a process that will continue as long as laboratory services are needed. As emphasised, other parts of the process also need scrutiny in order to refine the laboratory service. Again, remember that such processes need investments to get started, but the payback indeed seems to be worth the investment. ■

Cost reduction per test	÷ 37%
Reduction in TAT	÷ 55%
Reduction in blood drawings	÷ 20%
Less instruments	÷ 25%
Less maintenance	-
Less space, noise and working places	-
Less inventory and consumables	-
Less cost for consumables	-
Less waste - better for the environment	÷ 70.000 €/year savings
Less manual work - saves > 3 hours/day	750 h/year reallocated
Minimising hands-on	
Fewer persons overall	4 FTE re-deployed

Figure 5.

Outcome of the automation process. Please see text for specific details.

Key Points

- *Despite steadily increasing costs hospital laboratories are under pressure to improve their services to the hospital.*
- *A lab automation process provides opportunities to improve workflow and productivity.*
- *This article describes the outcome of such a process as conducted at Odense University Hospital, Denmark.*
- *Through consolidation of blood samples (reduced 20%) and analyses instruments (reduced 25%), an overall economic saving of 37% was achieved.*
- *Turnaround times (time from sampling to answer) were reduced by 55% (median 14.1 hours (IQR 1.9-30.2) in 2007 to 2.0 hours (IQR 1.7-2.6) in 2011).*

THE SANITATION OF HOSPITAL STAYS: NEW STRATEGIES FOR THE REDUCTION OF HAIs

Based on the results of experimental research conducted in several Italian hospitals and in the Hospital of Lokeren (Belgium), a new intervention protocol is proposed (PCHS Probiotic Cleaning Hygiene System), which involves the use of a probiotic product containing Bacillus subtilis, Bacillus pumilus and Bacillus megaterium.

These bacteria are able to colonise the surfaces on which they are applied, counteracting the proliferation of other bacterial and / or fungal species potentially pathogenic (law of Gause).

The results obtained demonstrate that the microorganisms' load decreases by over 80% compared to the values obtained through traditional chemical protocols.

The introduction of a measuring scale (Microbial Quality Index - MQI) of the pathogenic load is proposed in order to provide an objective evaluation tool of any cleaning process' effectiveness.

Research Classification

The effectiveness of the sanitation procedures was assessed by comparing the value of the potentially pathogenic bacteria load (detected on the surfaces of nosocomial environments) treated with probiotic products to that treated with traditional products by calculating the percentage difference (Frabetti et al. 2009; Mazzacane 2011).

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The microorganisms investigated were: Staphylococcus aureus, Pseudomonas species, coliforms (including Escherichia Coli), Candida albicans and Acinetobacter spp.(Mazzacane et al. 2012).

The experimental tests have affected both Italian hospitals and the Hospital of Lokeren (Belgium).

The use of protocols with probiotics (PCHS) results in a constant compression of the pathogenic load in time, over the use of chemical disinfectants (Table 1).

- the measurement of the CFU/m2 for single microorganism potentially pathogenic at 7 hours after the morning sanitation (around 2 p.m.); reason being that the bacterial load increases with time, therefore it is not appropriate to measure it immediately after the cleaning of the environment.
- the adoption of a Microbiological Quality Index (MQI), by detection, with the Rodac plates, of the load of the following pathogens:Stafilococcus aureus, Pseudomonas spp., coliforms, Candida spp., Acinetobacter spp., Clostridium spp.

Percentage reduction of pathogens obtained with the use of the PCHS protocol in comparison with the use of chemical disinfectants

Sampling point	Microorganism	Reduction %
Corridor	Staphylococcus aureus	81 %
	Coliforms	79,7 %
	Pseudomonas spp.	88,4 %
	Candida spp.	68,4 %
	Acinetobacter spp.	44,7 %
Bathroom floor	Staphylococcus aureus	85,8 %
	Coliforms	78,3 %
	Pseudomonas spp.	78,5 %
	Candida spp.	71,7 %
	Acinetobacter spp.	74,2 %
Bathroom sink	Staphylococcus aureus	95,6 %
	Coliforms	85,1 %
	Pseudomonas spp.	95,1 %
	Candida spp.	94,8 %
	Acinetobacter spp.	75,6 %

Table 1.
The two main drivers, time and economy, The results obtained (25.748 microbiological samples) with the use of PCHS system are exhibited in Figures 1-5.

Proposal For New Indicators of Environmental Hygiene

Microbial contamination is commonly assessed by counting the CFUs (colony forming units) per unit area.

To evaluate the effectiveness of the sanitation system, the following is proposed:

Based on the results shown in the previous figures, it was possible to identify a scale of values of the acceptability of the procedures of sanitation (Table 2).

2 p.m.	MQI - Microbial Quality Index
S.aureus	< 1.000 UFC/m2
Pseudomonas spp.	< 500 UFC/m2
Total Coliforms	< 500 UFC/m2
Candida spp.	< 1.000 UFC/m2
Clostridium difficile	< 2.000 UFC/m2

Table 2.
IQM Acceptability scale of the Microbial Quality Index (MQI)

Probiotic Product Safety

Bacillus strain probiotic bacteria, and in particular the Bacillus subtilis (Logan 2004), have been studied for a long time. A decade ago, the genome has been completely sequenced and three research studies have been published in favor of its safety as a probiotic (Cartwright 2009).

The beneficial effects of B. subtilis, as prebiotico preparation, are related to the balance of the intestinal microflora for the treatment or the prevention of intestinal disorders (Sorokulova 2009).

The potential pathogen B. subtilis is generally described as low or absent (7). Also in the genome of Bacillus subtilis the genes responsible for the production of toxins or other harmful substances were not found (Tompkins et al. 2009; EFSA 2005).

In 2008, a study on antibiotic resistance of the strain Bacillus was conducted; all strains were found sensitive to most of the antibiotics (EFSA 2011) used in the medical field. "In vitro" studies were performed on a number of species, including B. subtilis var. natto , B. indicus, B. coagulans and B. subtilis 2335 without detecting any side effect (Endres et al. 2009).

Bacillus subtilis is used in the production of food grade enzymes; recombinant strains of Bacillus subtilis

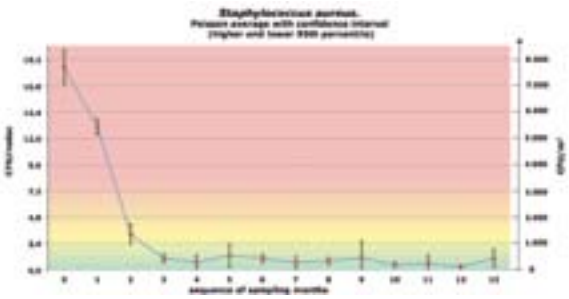

Figure 1.
Staphylococcus aureus load trend.

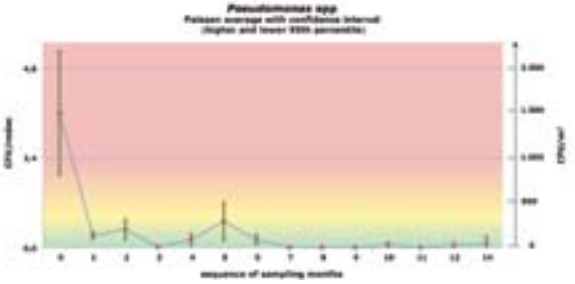

Figure 2.
Pseudomonas spp load trend.

were used in the manufacture of a variety of edible bio-industrial products, such as enzymes, vitamins, antibiotics, biopolymers, and additives for the production of certain foods such as miso in Japan.

B. subtilis is classified as Class 1 (no risk) from the National Institute of Health (NIH - US); it is not toxigenic according to the criteria of the US Environmental Protection Agency (EPA) and it is one of the 10 host organisms benefitting from the exemption Tier I under the EPA regulations, concerning the classification of risk; it is also used as a soil inoculant in agriculture and horticulture.

B. subtilis strain QST 713 (marketed as QST 713 o Serenade) has natural fungicidal activity, and it is used as a biological control agent (Endres et al. 2009).

The Bacillus spp. based products were popular before the introduction of antibiotics as immunostimulating agents to help the treatment of the diseases of the gastrointestinal and urinary tract.

The Bacillus strain bacteria Bacillus, as considered safe, are used in agriculture (Endres et al. 2009), horticulture, in human supply and in veterinary medicine (EFSA 2011)

Several Bacillus species have been classified as GRAS (Generally Regarded As Safe), because they are used in food processes or in pharmaceutical preparations, and therefore recognised by the FDA (Food and Drug Addiministration) as treatments for human purposes without side effects (FAO 2002).

Although, until today, the data available in the literature are quite reassuring in this regard, procedures for the testing of the sensitivity of microorganisms Bacillus spp. to the action of common antibiotics present on the surfaces sanitised were also adopted. In the current research, the antibiograms performed on bacteria belonging to the genus Bacillus spp collected in the field from the surfaces treated with the PCHS system, confirmed the sensitivity of the same PCHS system Bacillus to the tested antibiotics.

Conclusion

The probiotic based PCHS System is capable to lead to an 80% reduction of the number of potentially pathogenic microorganisms present on the hospitals surfaces. These microorganisms' load, expressed in CFU/m2, it is useful to define a scale for measuring the effectiveness of any sanitising protocol. The values of surface contamination, shown in Table 2, may serve in this respect as a minimum criterion of acceptability of any sanitation protocol. ■

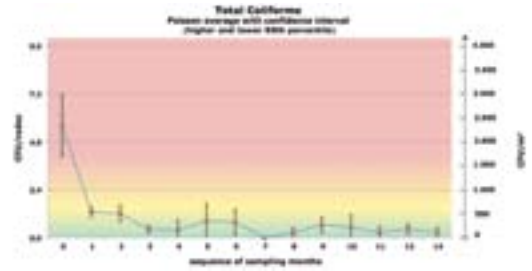

Figure 3. Coliformi totali load trend

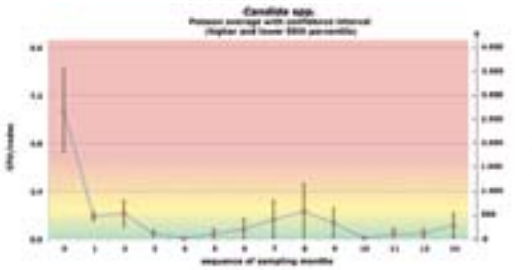

Figure 4. Candida spp. load trend. From the use of traditional chemical products (month 0) to the use of the PCHS system, the microorganism load progressively decreases, with a consequent decrease of the risk of infection.

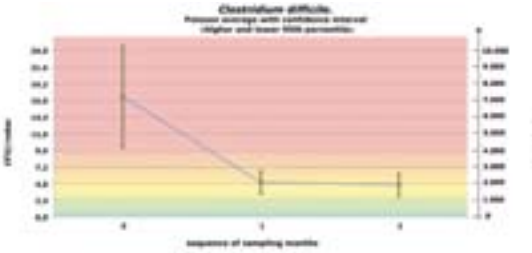

Figure5. Clostridium difficile load trend.

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Key Points

- *This article addresses the issue of sanitation of hospital stays and criticalities inherent in the techniques commonly used for cleaning surfaces and furnishings.*
- *Experimental research proposes a new intervention protocol which involves the use of a sanitising probiotic product containing Bacillus subtilis, Bacillus pumilus and Bacillus megaterium in the vegetative and spore form.*
- *Compared to customary cleaning techniques, tested surfaces showed an 80% reduction of pathogenic agents with the use of the new cleaning protocol.*
- *This P.C.H.S. (Probiotic Cleaning Hygiene System) also offers direct economic benefits, with savings of about 5-15% compared to traditional techniques of chemical disinfection, reseach findings are based on in vitro and in situ trials.*

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eHEALTH FOR INDIA

PATH TRODDEN AND THE VISTA BEYOND

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All views expressed are personal

India is the software capital of the world and over the years many companies have created teams here, grown them consistently and have allowed the expertise levels to mature resulting in a suave software engineering talent pool. Healthcare is transforming to align with the global reality of damp markets and uncertain economic growth. An era of accountable healthcare has emerged where the patient is not patient anymore but actively participates in the care process. There is no ambiguity that we need to move from sickcare to healthcare viz., wellness, prevention and early detection are the need of the hour. Information and Communication Technology (ICT) has been consistently evolving in the last four decades enabling this transformation. Change management remains a major hurdle for this transformation in addition to the misfit of Information Technology (IT) that essentially emerged to automate the office work space being force fitted on Healthcare. Major UX/UI-user experience/user interface changes are needed to assist busy clinicians and not add to their already overflowing task lists.

Introduction

Healthcare globally has reached a tipping point, beyond which it is not sustainable in its current form, in both the socialist and market driven models. Health economics, preventive medicine and wellness are now the new mantra to evolve from sickcare to healthcare. Healthcare systems yearn to restructure, whereby primary/GP-general practitioner/FP-family physician are empowered to manage the major chunk of work. They are the gateway through which all referrals are made for specialty work. Patients' hospital stays need to be minimised to bring down overall costs (direct and indirect) with rational antibiotic usage and minimising of practice variability. Technology has been playing a major role in healthcare during the last century; with the advent of ICT in the last few decades de novo avenues have opened up which are still being explored. Healthcare IT (HCIT), though a relatively young entrant to healthcare, has enabled transparency, integrity and patient safety. The dismal success rate of IT implementations is seen in healthcare too, but recent publications are unravelling the mystery around HCIT failures and offer hope. Being cognisant of the pitfalls and working towards a goal with clearly defined milestones and all major stakeholders committed can ensure successful HCIT deployment.

"healthcare globally has reached a tipping point, beyond which it is not sustainable in its current form"

Government has a major role to play in enabling this transformation with regulatory and financial support; in India both central and state governments have initiated major strides in this direction. The Indian government's Ministry of Health and Family Welfare (MOHFW) has used medical informatics experts to study global HCIT implementations and then recommend EMR interoperability standards. It has purchased a Snomed CT (SCT) national license and become a member of (IHTSDO – International Health Terminology Standards Development Organization). The rollout of eHealth India- wide is ambitious, but a conscientious effort is required for it to succeed.

Healthcare Renaissance in India

Indian Healthcare System:

India inherited the British NHS (national health services) model of healthcare. It is a socialist model with healthcare provided as a service free at the point of care, funded by taxpayers. Health was on the concurrent list (central and state government responsibility) but today is within the mandate of the state government. The government of India plays a regulatory role with overall control of medical education/research, public health/epidemiology/infectious disease control and all clinical specialties. They also fund national disease control programmes via the National Health Mission (NHM). A separate wing of the ministry entitled AYUSH (Ayurveda, Unani, Sidha, Homeopathy, and Reiki) monitors complementary medicine.

Indian healthcare underwent a radical transformation in the 1980s with corporate hospitals emerging in urban India. These hospitals deliver world-class health services for a fee and are almost exclusively concentrated in the cities. The advanced capability that these hospitals have acquired is evident from the fact that they are accredited by international standards bodies such as the Joint Commission International (JCI), the International Standards Organisation (ISO), and the National Accreditation Board for Hospitals and Healthcare Providers (NABH). Relatively lower cost of health care in comparison to developed countries, coupled with international quality, has positioned India as a major destination for health care services.

The Change From Hospital To Home Based Care:

There is a tendency in the western world to move from hospital-based to home-based care today. Better and more effective antibiotics mean patients do not have to stay in hospital for treatment of most illnesses. Nosocomial MRSA (methicillin resistant staphylococcus aureus) added to making home-based treatment preferable to being an inpatient (MRSA and other hospital acquired infections are almost impossible to treat with known antibiotics and result in great morbidity and mortality). The elderly population, whose numbers are increasing as a ratio of the population, benefit most from such home-based treatment. It is making more economic sense to be able to provide the services of specialists, to as many as possible, in fields such as dermatology, radiology and pathology. Gustke and colleagues concluded positively after evaluating patient satisfaction in using telemedicine for home based care (Gustke et al. 2000). Personal health records (PHP) are emerging where patients own, maintain and decide who their medical records are shared with. Online consultation and telemedicine for accessing specialist services are already being offered in India today.

Clinicians are adapting to the increasing presence of technology and HCIT in their everyday practice. Radiologists, dermatologists, psychiatrists, cardiologists and pathologists are some of the specialists who are early adopters.

Globalization, eHealth And The Need to Transform

As was the case with telecommunications a decade ago, India has been able to leapfrog to adopt the latest technologies without undergoing the long, painful, risk prone and costly adoption rigmarole of early adopters. Healthcare IT is following a similar path, resulting in the best technology being identified and deployed to optimise healthcare system performance.

Virtualisation, cloud based software and SaaS (Software as a Service) technology are mature technologies, which developing countries such as India are adopting rapidly. The low capital expenditure is an added bonus with the cost getting built into operating costs, on a pay-per-use model. India, being the software capital of the world with captive engineering centres for most top multinational companies, has the engineering skills and expertise to tackle the many healthcare system challenges head on. Taking a cue from Prof CK Prahlad's bottom of pyramid (BOP) theory (Prahlad 2014) many MNC (multinational companies)have started researching the needs of our healthcare workers that are distinct from those in western countries. Once the problems are identified, it is only a matter of time and business fitment to put together a team and find not one, but multiple solutions.

Quality Healthcare For All – EMR Role

Electronic medical record/electronic health record (EMR/EHR), though used interchangeably, are distinct concepts. They are healthcare record data in an electronic form; ensuring data integrity at point of capture, ability to store infinitely in various forms and provide fodder for powerful analytics to be run, thereby data is reorganised into information from which knowledge emerges. Literature and experience reveal gaps in the care process resulting in preventable morbidity/mortality exceeding 100,000 per annum in the most advanced healthcare system in the world, USA (IOM 1999). Reliable data availability at the right point, and using it to continuously improve the processes, can reduce this figure. The accuracy, integrity, reproducibility at multiple points, analytic capabilities and transparency that EMR brings into the care process nails down quality (PCAST2011).

EMRs have kept pace with Moore's law (chip performance doubles every 18 months) over the years. As computer science/information technology (CS/IT) has moved away from client-server to a cloud and social, mobile, analytics & cloud platform (SMAC), so has the EMR. EMRs have been continuously evolving from being a collector, documenter (automation), helper (CDSS-clinical decisions support system), colleague (workflow support) to mentor (guided care). The ubiquitous nature of IT spanning mobile, tablet, laptop to workstation is used effectively by EMRs to be always available at point of care (POC) for patient safety. In 2014 EMR hosted on a cloud (SaaS-software as a service & IaaS-Infrastructure as a service) paid for by usage (pay-as-you-go model) built on SCT-Snomed CT, HL7 and DICOM standards with UI/UX-user interface/user experience ensured, is being demanded by clinicians.

TeleICU is a good example of how technology when deployed correctly can solve healthcare problems. Intensive care units in multiple tier 2/3 towns are connected to a central command centre manned by clinicians round the clock. Many benefits accrue; reduced length of stay, antibiotic use rationalisation, ongoing skills enhancement, ability to handle complications and the reduced need for shifting patients to tertiary care.

Choosing The Right EMR for a Healthcare Provider

EMRs should be chosen carefully by medical informatics professionals who understand the clinical domain, after mapping the existing workflows and processes. A clear road map needs to be defined with milestones and destination agreed by all stakeholders. Medical informatics research is showing that to start with, a vendor sells a concept to the customer, with the customer being unaware of the full capabilities of the product. As customer becomes familiar with the product he begins to identify many possibilities that were never in scope to begin with. Requirements hence will never be known in totality, and with time they continue to bloat, leading to the much disdained 'Scope Creep'/'Requirements Drift'. EMR

vendor and the customer need to work in tandem over time to build a solution that will continuously solve the customer's problems. Service oriented architecture (SOA) should allow the product to be dynamically fine-tuned. Choosing an EMR is akin to marriage; due diligence in picking a spouse, followed by harmony amongst the couple post wedding, is an absolute need. It doesn't help (as is current practice) if it is done impulsively, akin to going on a date. Either way, the secret of success in a marriage lies in both spouses working in harmony once in a relationship, the same works in HCIT.

Total cost of ownership for procuring, deploying, training end-users and keeping an EMR running can be high. With multiple departments competing to get a share of the limited funds in the system, failure is not an option for EMR deployment. When failure occurs, it reinforces the strong negative perception that IT/EMR doesn't work in healthcare.

Key Adoption and Integration Challenges in EMR

UI/UX has until recently not been a priority in IT, even more so in Healthcare. In one of the most demanding, multi tasked, zero-fault-tolerant environment that healthcare is, expecting clinicians to play clerical roles does not help. IT systems have matured in the office space over last three decades; they have entered other niche areas only recently. Industry is adapting to clinician demands, but much work needs to be done using voice recognition (VR), pattern recognition (PR), artificial intelligence (AI), natural computing (NC), data extraction from free text (HL7 CCD-continuity of care document) in order to help the busy clinician who is mostly mobile with both hands preoccupied. This is a far cry from office usage where one sits at a desk and types using a keyboard, which evolved from typewriters not too long ago. Like Steve Jobs clearly understood and transformed the entertainment user with his iPad/iPhone simplicity and ease of use (they actually carry no user manual), both hardware and software needs to adapt to healthcare. Change management and end user buy-in cannot be an option if success is expected. Management ownership and a top down approach have shown better HCIT adoption rates globally.

Integration was never a need when computers were dumb machines churning data in silos. After communication/ethernet/intranet/internet arrived on the scene users naturally found it strange that these machines and software did not permit communication. Interoperability is so complicated and intricate that it has spawned a new industry in both hardware and software. Clinical terminology is the alphabet in which the healthcare language is written, HL7/DICOM/LOINC etc. ensure interchange between systems, HL7 CDA (clinical document architecture) provides the framework to write sentences/paragraphs and convey the clinical story. Changing old systems to work on modern standards is too expensive a proposition, thereby spawning the interoperability industry, allowing start-ups to quickly build products on Lean, Agile, and FastWorks principles. Health information exchanges (HIE) have started appearing, which enable data flow between disparate systems of multiple generations, technologies and versions. ■

"an era of accountable healthcare has emerged, where the patient is not patient anymore but actively participates in the care process"

Consequences of Choosing the Wrong EMR

Using the marriage analogy, if there is mismatch amongst spouses, unnecessary post-wedlock friction occurs, eventually leading to separation. After an EMR is rolled out, changing to a different vendor is like changing the tyres of a moving bus. Change Management issues are so big that it leaves the end users frustrated and cheated, bringing bad name to all HCIT.

The full article can be found online at *www.healthmanagement.org* or scan the *QR code*

Key Points

- *Healthcare renaissance in India*
- *Quality healthcare for all*
- *iHIND & EMR interoperability standards – Government leadership*
- *Challenges ahead*

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CURRENT STATUS OF BREAST IMAGING IN INDIA

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Breast Cancer Incidence, Mortality And Trends in India

In India, breast cancer is the second most common cancer (after cervical cancer). Breast cancer accounts for 22.2% of all new cancer diagnoses and 17.2% of all cancer deaths among women in India (Agarwal and Ramakant 2008). The incidence of breast cancer ranges from 31 to 36.6 cases per 100,000 per year in metropolitan cities. In rural India, the incidence is much lower and ranges from 7 to 14.4 cases per 100,000 per year. There are estimated 144,937 new diagnoses and 70,218 breast cancer related deaths, every year (Ferlay et al. 2012) . Based on the consolidated data of the peripheral cancer based registeries the estimated number of new breast cancers during 2007 in India was 82,000 (NCRP 2004-5). It is alarming to note the rising trend of steadily increasing rates since the mid-1980's, with the largest increases observed in metropolitan cities. In fact, breast cancer has overtaken cervical cancer to become the leading site of cancer in most urban populations of India. Though the incidence of breast cancer in India is one-third that of Western countries, the mortality rates are disproportionately higher (Agarwal et al. 2009).

Epidemiology of Breast Cancer in India

Age incidence rates in India suggest that the disease peaks at a younger age (40-50 years) than in Western countries and as a result, the majority of new diagnoses occur in pre-menopausal women. The majority of new cases are locally advanced or at higher stage at the time of diagnosis (Chopra 2001).

The increasing burden of disease may be associated with lifestyle factors such as later age at marriage, age at first birth, reduced breastfeeding and westernisation of diet and physical activity patterns (Dhillon et al. 2011). Breast cancer rates tend to be higher in women of higher education and in specific communities that have adopted a more westernised lifestyle, such as the Christians and the Parsis, and is lowest in the Muslim communities (Yeole and Kirkure 2003).

Recent evidence suggests that breast cancer in Indian and Caucasian women may differ given the younger age at diagnosis, higher proportion of high-grade (45.7% for grades III & IV vs. 38.7%) and hormone receptor-negative tumors (30.6% ER-/PR- vs. 21.8%), higher incidence of inflammatory cancer (1.4% vs. 0.8%) and larger proportion with early-onset disease (16.2% <40 yrs vs. 6.23%) (Kakarala et al. 2010; Leong et al. 2010).

Economics of Breast Cancer in India

The WHO Global Burden of Disease showed that the number of disability-adjusted life years (DALY) attributable to breast cancer was 6,629,000 worldwide and 1,222,000 in South East Asia (Organisation WH 2008). Although there are no available data estimating the cost of the breast cancer burden in India, the DALY would be comparatively high considering the younger age and more advanced stage at diagnosis for Indian women compared to those in the West.

Breast Cancer Survival in India

Nearly all breast cancer cases are clinically detected in India, the majority presenting with locally advanced disease. Nearly one-third of breast cancer patients have skin/chest wall involvement at the time of diagnosis, and the stage at diagnosis is often worse in younger patients (Mathew et al. 2004) . A later stage at diagnosis and lower survival have been linked to poor access to healthcare facilities and lower awareness, as well as demographic factors such as lower education and literacy (Ali et al. 2008; Somdatta and Baridalyne 2008). Even in states with higher literacy and awareness levels such as Kerala, only 15% of cancer patients seek medical assistance in a localised stage of disease (Jayalekshmi et al. 2006). Data on cancer survival is limited in India due to scarce resources and incomplete follow-up of cancer registry cases although a few cancer registries meet the minimum criteria acceptable for the Cancer Incidence in Five Continents (CI5) series (Parkin et al. 2005) . A recent study based on these cancer registries (Bhopal, Mumbai, Barshi, Chennai and Karunagapally) found that the average 5-year age standardised survival for breast cancer in India was 52% (range, 31%-54%) (Sankaranarayanan et al. 2010). There are multiple factors that delay diagnosis in Indian women ranging from limited availability and access to health services, lower health literacy and social stigma attached to breast cancer.

Breast Cancer Screening in India

There is no organised population-based screening program for breast cancer in India. Mammography screening for early detection of breast cancer is a resource intensive proposition. It is not a viable option for most of the developing countries. Limited availability of mammography units and trained manpower, large population, inadequate financial allocations and other more pressing medical needs have so far precluded mammographic screening in India. Several small

pilot projects are currently in progress to assess mammography screening in our population. BISI will observe and evaluate preliminary results of these studies so as to make recommendations on feasibility of mammography screening in India.

There is no scientific evidence for an overall mortality reduction for breast self-exams or clinical breast exams, but in developing countries such as India, the lower incidence rates, limited access to healthcare, fewer treatment facilities, and advanced stage distribution of disease may yield different optimal screening strategies, such as clinical breast examination (CBE) and ultrasound.

Image.
BISICON 2013, First Annual Conference of the Breast Imaging Society (India). Hands on work-shops on mammography, ultrasound, MRI, & intervention techniques using phantoms & simulations were the highlight of the conference.

Diagnostic Breast Imaging

Non-availability of mammographic screening does not undermine the importance and need of quality breast imaging in less resourceful countries. Reducing breast cancer mortality using screening may not be an immediate goal in India at present. Downstaging the disease at presentation by promoting increased public awareness, quality breast imaging and delivery of optimal treatment is the primary objective. Diagnostic breast imaging to evaluate diseases of the breast in women presenting with breast related symptoms such as lump, mastalgia and nipple discharge is the major area of breast imaging in non-screening setup. It is also required preoperatively in women already diagnosed with breast cancer to define extent of the index tumor and detect additional masses, as this may have implications in management decisions. Women already treated for breast cancer need regular surveillance with breast imaging to detect recurrences or metachronous breast cancers.

Challenges in Breast Imaging in India

Major challenges in our country include limited availability of mammography and well experienced radiologists. Symptomatic women may present to surgeons, oncologists, gynaecologists, internists or family physicians and there may be variable trends in referral for breast imaging. Utilisation of breast imaging in such a setup is also governed by beliefs of the clinician and quality of breast imaging services available to them. In this situation, breast imaging does not form a major part of radiology practice and hence, there are not many full time dedicated breast radiologists. In most situations, a general radiologist with little time and experience in breast imaging has the responsibility to cater to these patients. There are also wide variations in type and quality of mammography units. Screen-film, CR based and at major centres in most parts of India, Full Field Digital mammography (FFDM) systems are available. However, lack of mandatory Quality Assurance (QA) requirement leads to non-uniform (mostly poor) quality and this conversely affects the output and contribution of breast imaging in diagnostic setting. A systematic approach is the key to standardise and evolve diagnostic breast imaging.

Breast Imaging Society (India)

In India, there are several radiologists who have always had special interest in breast imaging and have been practising this speciality for long. However, there was no appropriate and dedicated platform for professional interaction. Many senior breast radiologists of India dreamed and worked hard to form a pan-Indian breast imaging society. Their vision and hard work finally culminated into formation and registration of Breast Imaging Society (India) or BISI. Main objectives of the society include promotion of world class breast imaging practice and emphasising its role in healthcare. These will be achieved with regular conferences, CMEs, workshops, fellowships and training programs. BISI will promote high quality, well designed clinical research to test and validate country-specific breast imaging protocols. Recommendations and guidelines specific to the needs of our country will be formulated. BISI will also interact with organisations of breast surgeons, oncologists, NGOs, industry, policy makers and others who are directly or indirectly involved in breast cancer awareness and management.

Progress So Far

Since its inception in August 2013, BISI has witnessed a very enthusiastic response with a fast growing membership. Currently there are 121 registered life members of the society, radiologists who have been practising or have an interest in breast imaging. The

society has conducted several training programs for them which included not only didactic lectures, but also hand-on practical workshops covering mammography interpretation, image guided breast interventions and MRI training courses. The first annual conference of the society 'BISICON 2013', held in November 2013 was attended by 220 delegates (see image). The scientific programme featured lectures, case discussions with electronic voting, and hands-on, practical workshops on image-guided biopsies (stereotactic, ultrasound, MRI).

BISI is in the process of starting a one-year dedicated breast imaging fellowship in BISI accredited centres across the country with a standardised curriculum and examination process. During this structured training programme, the trainee will familiarise his/herself with all aspects of breast imaging and intervention by case-by-case hands-on teaching on routine clinical cases.

A task group consisting of eminent experts has been created to help formulate India-specific guidelines for appropriate conduct of mammography, breast ultrasound, MRI and breast interventions. These guidelines would cover the basic requirements in equipment, indications, technique and reporting so as to promote standardised, quality breast imaging care across the country.

BISI is also formulating a proposal to our health ministry to promulgate laws to ensure mandatory accreditation and quality assurance of all the mammography centers in the country. National Accreditation Program for Breast Imaging Centers would then require the breast center to satisfy a set of quality standards for all aspects of breast imaging and interventional procedures.

BISI has identified 5 regional breast imaging centres in the country which can adopt a leading role in the development of state-of art breast centers in their respective areas. This would promote better coverage of our large population with uniformly high quality breast imaging services.

Breast imaging in India stands where developed countries were, probably 30 years back. We hope, it will not take us 30 years to reach where the developed world is today. In this endeavour, BISI seeks affiliation with the established major societies in the world like the SBI and EUSOBI, so that with their guidance and collaboration we can progress at a much faster pace.

Conclusion

Quality breast imaging has been recognised as a critical component of multidisciplinary breast cancer care, the world over. Up-to-date technology and adherence to scientific guidelines are the key factors for improvement in breast imaging and developing countries rely on the developed countries for this. However, it is important that western models are not blindly replicated in developing countries as they have different background, clinical needs and resources.

"breast imaging in India stands where developed countries were, probably 30 years back. We hope it will not take us 30 years to reach where the developed world is today"

Main challenges for breast imaging in India include a large number of women presenting with advanced breast cancers, inadequate breast imaging facilities and its variable quality. Breast imaging is still not practised as an independent subspecialty or as an important component of the radiology practice and hence, there is scarcity of trained breast radiologists.

BISI has identified the key areas to work upon. Some of these include better co-ordination and exchange of knowledge among professionals; promotion of quality control of equipments and clinical practice, regular training of radiologists and technologists, improvement in public awareness, interaction with health professionals, community workers and policy makers to develop guidelines which should lead to optimal utilisation of limited resources. So far, the response to BISI activities in first year of its existence is encouraging. ■

India Statistics (2012)

Total population:	**1,240,000,000**
Gross national income per capita (PPP international $)	**3,910**
Life expectancy at birth m/f (years)	**64/68**
Probability of dying under five (per 1000 live births)	**56**
Probability of dying between 15 and 60 years m/f (per 1000 population)	**242/160**
Total expenditure on health per capita (Intl. $ 2012)	**157**
Total expenditure on health as % of GDP	**4.1**
Number of hospital beds (per 1000 population)	**0.7**
Number of doctors (per 1000 population)	**0.7**

Available from:
http://www.who.int/countries/ind/en/

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Prof. Lars Lönn – Editorial Board Member Imaging

Professor Lars Lönn, Consultant Interventional Radiologist and Professor of Vascular Surgery at the National Hospital in Copenhagen, is a valued member of HealthManagement's Editorial Board.

We asked Professor Lönn our seven questions:

1. What are your key areas of interest and research?
Endvoascular research in general, and endovascular abdominal aortic aneurysm repair (EVAR) and thoracic endovascular aortic repair (TEVAR) in particular, and on top of that education and simulation development within the endovascular field.

2. What are the major challenges in your field?
Collaboration.

3. What is your top management tip?
Collaboration and listening.

4. What would you single out as a career highlight?
The first time our team saved a ruptured infected TEVAR patient, very young, still alive after 15 years...

5. If you had not chosen this career path you would have become a...?
Actor or guitar-player

6. What are your personal interests outside of work?
Besides being a workaholic, outdoor training, yoga, ecological sustainability, reading, philosophy.

7. Your favourite quote?
And ye shall know the truth, and the truth shall make you free (John 8:32).

Professor Lönn was born in Sweden, and gained his MD and PhD from the University of Gothenberg. He is qualified to practise in Sweden, Norway and Denmark. Prior to moving to Denmark he worked as Senior Consultant Radiology Sahlgrenska Academy at University Hospital Sweden, Abdominal Imaging Radiology Department Endovascular Programme Developer and CEO Radiology Axess Akuten Private Hospital, Gothenburg, Sweden.

Currently, in addition to his Copenhagen appointment, he is a Consultant to the King Fahad Medical City, Riyadh, Saudi Arabia Simulation Center, Medical Director Mentice Inc, Medical Director Orzone Inc, European Consultant J&J Endovascular Radiology programme Europe and is a consultant for several life science companies. He is Editor for Acta Radiologica, an Editorial Board member for Journal of Endovascular Therapy (JEVT) and the Journal of Cardiovascular Surgery and is a referee for 10 international scientific journals. In addition he sits on the Board of the Swedish Research Council Radiology.

The full article can be found online at www.healthmanagement.org

Mr. Nikolaus Koller – EAHM Board Member

Mr Nikolaus Koller, MAS, MBA, who graduated in Hospital Business Administration, is the Hospital Manager of the State Hospital of Bruck/Mur and President, Federal Conference of the Austrian Hospital Managers, as well as member of the EAHM Executive Committee.

In 2012 the coordination of the Health Care System of Styria was split into three separate regions. The following year Styria was further divided into four regions with four different regional coordinators. Mr Koller is presently the coordinator for the Northern Styrian Region, the biggest of the four regions, with three nursing homes and six hospitals serving more than 400,000 inhabitants.

Interested in getting to know Mr. Niklaus Koller better, we asked him seven questions.

1. What are your key areas of interest and research?
My important areas are financial planning, quality management and communication in all fields.

2. What are the major challenges in your field?
The collaboration between the internal treatments and organisations (hospitals) and the treatments of external organisations (especially in terms of an ageing society). Also a major challenge is the problem with the working time directive from the European Union for the physicians. In general we have to reduce the acute hospital beds and have to do more outside of the hospitals (health centres, day care treatments, etc.).

3. What is your top management tip?
The most important things are to make decisions, manage and control, communication, innovation and vision, and the efficient use of budget

4. What would you single out as a career highlight?
Personally: President of the Regional and National Hospital Managers for more than ten years. Also the functions at the European Association of Hospital Managers (EAHM) and the European Hospital and Healthcare Federation (HOPE), and finally I'm a member of the International Hospital Federation (IHF) Board.

For the organisation: We got some quality awards like EFQM and HPH and certifications for environmental management.

5. If you had not chosen this career path you would have become a?
Maybe I would be in a different profession as a CEO in bank management.

6. What are your personal interests outside of work?
All kinds of sports; I like reading, travelling and spending my free time with my family.

7. Your favourite quote?
"Anyone who stops learning is old, whether at twenty or eighty. Anyone who keeps learning stays young". (Henry Ford) and "Nothing stays, if nothing changes"!

The full article can be found online at www.healthmanagement.org

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