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The Journal

LEADERSHIP • ECONOMY • TRENDS • TECHNOLOGY • INTEGRATION

COVER STORY

Ageing

GERIATRIC MEDICINE, SMART AGEING, HOSPITALS FACING AUSTERITY AND AGEING, DESIGN FOR CARE, CARDIOVASCULAR AGEING, TECHNOLOGY SUPPORTS PATIENTS AT HOME

MANAGEMENT MATRIX

Organisational Development

Creating Stronger Bonds Between Health Managers and Clinicians

Putting Quality and Safety for Patients First

Breast MRI

Dangerous Boobs Tour Targets Dense-Breast Tissue Awareness

Nuclear Medicine and Prostate Cancer

Controlling Patient Workflow in a Radiology Department

Real-Time Monitoring in Radiology

Medical Device Integration in the OR

TeleCardiology in The Netherlands

COMPASS
Geriatrics In Turkey

DATEBOOK
ECR, ECCMID

Screening with breast tomosynthesis: An emerging reality

The amount of clinical proof for the efficacy of Tomosynthesis in screening is significantly larger than the proof available in the early days of the transition from analog mammography to FFDM. Results from studies in Europe using Tomosynthesis in population based screening and results from screening with Tomosynthesis in the USA are concordant around an increase in invasive cancer detection and a reduction in recall rates. As screening programs begin the adoption of Tomosynthesis, many questions arise around the practical implementation of the technology; however, current literature is primarily focused around the clinical results. Presenters at the symposium will share their experiences with the challenges, the solutions and the early results from implementing Tomosynthesis in primary screening for breast cancer.

Moderator of Session:

Prof.emer.Per Skaane

Speakers/Presentations:

- Sarah M. Friedewald, MD. Chicago, USA
  The American experience

- Dra. Marina Álvarez Benito / Dra. Sara Romero. Córdoba, España
  The Spanish experience

- Dott.ssa Daniela Bernardi. Trento, Italia
  The Italian experience

- Prof.emer. Per Skaane. Oslo, Norge
  The Norwegian experience

Friday, March 6th
14:00 - 15:30
Room C

Join us on our booth
For a post-symposium celebration and a chance to meet the speakers

Booth #320

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EMPOWERMENT OF OLDER PERSONS

TOWARDS A SUSTAINABLE AGEING SOCIETY

Prof. Heung Bong Cha

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Population ageing is one of the major global phenomena of the 21st century. Despite the great achievements of improved longevity that all human beings have dreamed of, we are faced with the challenging situation of needing to advance a sustainable future with an ageing population, while having to address the heavy burden imposed on societies, based on irrational assumptions on ageing per se and older people. Presently most societies worry about the social burden arising from the social exclusion of older people from mainstream society and the need to provide them with social welfare provisions.

Human life can be seen as exchange resources among individuals and/or social institutions. Imbalanced exchanges may result in imbalanced power relationships. Those with less power may fall into disadvantaged situations, such as poverty, social exclusion or unemployment as a result. Empowerment aims to make power more balanced through increasing and/or improving resources.

Older persons have fewer chances to make their resources superior, due to social forces, such as ageism, irrational social discrimination and institutionalised social exclusion (such as mandatory retirement systems), and negative perceptions. Therefore it would be expedient to balance power relationships between individuals and/or social institutions by helping older people improve existing resources, increase resources or acquire new resources. Ageism and negative perceptions of the ageing society built upon prejudice and non-scientific assumptions seem to have reinforced the image of older people as powerless. The social welfare perspective of supporting and caring for older people after their exclusion from mainstream society, which has been the main social institutional arrangement in advanced welfare states, has serious limitations in integrating older people into society and thus building a sustainable ageing society.

One effective and desirable way to integrate older persons into society and thus to develop sustainable ageing societies, is to empower older people so that they improve resources or acquire new resources in intellectual, health, socioeconomic, psychological and political aspects.

The social welfare system for older people is no longer an effective and efficient model to resolve problems associated with individual and population ageing, because of the increasing economic burden borne by society. An ageing society is generally feared by governments, because of its perceived increasing burden to society. However, this is an assumption based upon widespread negative perceptions of ageing and older people that disregards the increasing body of scientific evidence that shows that older persons can develop their capacities, even well into advanced old age. The social and legal system of retirement demarcated only by chronological age derives from these negative perceptions and in turn reinforces them. Capacity-building and empowerment for both ageing and aged people has been shown by growing evidence to be possible. Along with the need to reform social welfare programmes, it is essential to plan for capacity-building of older people and their consequent mainstreaming into an ageing society. Without embracing the potential of the ageing population as a basis for future development through empowerment, it will be far more difficult for society to bear the economic burden arising from individual and population ageing.

An ageing society with empowered ageing people could be developed into a sustainable future in which all ages have the means to better themselves and to contribute to the betterment of society according to their capacities. This future ageing society would be totally inclusive, and its development would mark a new milestone in the progress of society.

In conclusion, we at IAGG strongly believe that the sustainable development of an ageing society depends upon the empowerment of ageing and older people through systematic education and training. ■

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👤 ZOOM ON PROFILES

🔍 IN FOCUS

THE CARE CONTINUUM

Jeroen Tas

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Thinking Digitally

IT is critical to the way Philips designs, develops and brings to market our products and services. IT is not just internal to the company, but integral to what we do. As CIO, having transformed the IT organization internally to be much more agile, I started working on the digital strategy of the company – not just e-commerce and knowing your customer through digital means, but by looking at what's happening in the technology world and how we can apply that to what Philips is doing. For example, the Internet of Things, monitors, senses and leveraging mobile technology.

Big Data

The biggest opportunity is with big data. We are truly in an exponential world where not only technology is moving very fast, but the adoption of technology is also moving way faster than ever before. If you look at the time it took for, let's say, radio or television to become truly widely accepted and compare this to social media or new mobile technology, you also see acceleration of adoption of technology by consumers. What you also see is that many businesses are kind of trailing behind and institutions are completely trailing behind.

Continuous services

New business models are emerging, and we believe that there's going to be a big shift from capital investments to moving towards continuous services. For instance, instead of buying an MRI, you're buying a relationship that optimises both clinical workflows and the resource and assets. So instead of buying an MRI scanner, you buy an imaging service that has the outcome of optimising the number of patients you can put through the system in a very efficient way.

Monitoring Chronic Disease

Similarly, we are moving to models where, for instance, monitoring people with multiple chronic diseases from home is the most effective way to manage their care, and this is backed up by the evidence. It is effective in the sense that re-admissions are down 30-50 percent and visits to the ER are down by 70 percent. Clearly this has a big impact on the care and health of the people we support and also on the health system. Philips will optimise the technology, bring in the software, train healthcare staff and the health provider pays per patient. We are even willing to have a stake in the outcome, so that if readmissions don't hit their target, then we'll take the pain. We used to sell hardware and software, and now we are basically selling you a service, which is linked directly to your outcomes. This can only be enabled through these technologies, because it allows you to monitor, to really understand what metrics you are hitting, and to do preemptive work. To me, digital means not only e-commerce, but new business models that are grounded in those technologies and are really creating better outcomes, in this case in the clinical world.

"SERVICES LINKED DIRECTLY TO YOUR OUTCOMES"

Care Continuum

There is a change in the way healthcare systems are looking at incentives – from fee-for-service to reimbursement for outcomes on a population basis, for example for patients with congestive heart failure (CHF) or patients with prostate cancer or patients with CHF and diabetes, etc. The incentive is to actually optimise on outcomes, for example how quickly patients can move about, or get back to work, mortality rates, readmissions and so on.

There are a number of areas where you can look at whether you are getting better outcomes or better health at a lower cost. At the population level, if you impact peoples' lifestyle you will have a big impact on population health. In the Western world 80 percent of healthcare cost is taken up with chronic disease: heart, diabetes, COPD, and many forms of cancer these days are chronic as well. You continue to monitor and treat them, and if you look at where the real cost is, you understand that lifestyle is a big aspect of that, and you start thinking about how we can impact the health of the population. You have to start thinking beyond just acute care. Acute care will always be very important, but the real cost and impact is in a different area: how to help people live a truly healthy life. If you are at risk for congestive heart failure, how can I help you to avoid acute situations? How can I help you with the way you eat, with the way you are active? How can I mobilise not just the formal healthcare system but maybe also your friends and family?

I'll give you an example. My father lives at home. He has cancer, but with many complications, and he is on 15 different and very complex medications. We know that more than half of the people don't comply with their treatment plan, including medication, so what we have is a connective medication device where the tray pops open if you need to fill it or beeps if you don't take out the pill. An alert goes off. When he doesn't take his medication, I may be the best person to call him up. When that alert goes off, I get an alert and I call him up and say hey, you've got to take your medication. I just say I told my dad to take his medication, so the care team knows what happened.

We engage care in a wider context, and get healthcare staff the tools and make them feel a part of the care team that also consists of friends, family and volunteers. For example, the NHS in the UK has one and a half million volunteers, people who are willing to give their time to help other people. How can we give them the tools to be very effective and to really make an impact on people's health? The reason this is happening is because we are starting to move towards outcomes rather than procedures that are typically executed when things are too late.

We are moving more towards early detection, much more continuous monitoring, and we are starting to look at healthcare as a way to manage larger populations, but always at this point in time, as they can be anywhere.

At any time, a health professional wants to know which person need an intervention. You can do that by streaming the

data, combining that with what you know about the patient, and then decide on algorithms. Now you need an intervention, for example taking medication or sending an ambulance or anything in between. What is the right intervention, under these conditions at this point in time? You are trying to move from a system that is kind of reactive, to a system that becomes very proactive, to provide the right intervention at the right time with the right person, which is a much more scalable model, a much more efficient model.

In the US there is much waste in the healthcare system. If you have a system that is based on having to go physically to a doctor, and the patient only goes to a doctor when something goes wrong, and then has to wait in a waiting room or wait for an imaging system to be available, then you are not optimising your resources. People are not aligned around the patients that need the intervention now. Only now can you give people a monitor at home which is affordable. The infrastructure is already there.

Already in the world, 96 percent of people have access to mobile phones, so can we leverage technology to bring it to such a price point, and combine it with large-scale automation?

I used to work in financial services, and there I saw three phases in trading. Phase one, you have very smart traders on the floor, making trades from their guts. Phase two, they sit behind screens where you have highly visualised information. Phase three is algorithmic trading, fully digitized, which is the rule today. We are still in phase one when it comes to healthcare. We have well-educated, experienced people doing diagnosis and treatment, largely on their experience and expertise. They may look at an image that a radiologist has prepared, but we haven't yet collated all the relevant information about the patient. We are ready for the second phase where at the least you can visualise a holistic view of the patient so that you can make the right diagnosis.

My belief is that 70-80 percent can be made quite predictable if you have all the data, and therefore you can create new models. When it becomes predictable, you don't really need insurance. You need insurance for the unpredictable stuff. It will ultimately change the entire system, because payers and providers will start

looking at it differently. Patients will also be given the tools to take more control themselves. So, you almost see risk moving from the payer to the provider to the patient. The provider is going to be more than just a professional provider. There are going to be care teams that take care of groups of patients at scale.

This is the best way to deal with problems that we haven't been able to solve: the greying population and escalating costs in the Western world, and in emerging markets access to care.

Data been collected without finding solutions. How is Philips envisioning this amazing opportunity which data brings?

You can see it on many levels. If you want to move to an outcome based model, you have to move to population heads. That means you've got to understand where the population is. You've got to understand where they are, what they are spending, what the outcomes are, and then you start to analyse how you can optimise behind it. Then, for instance, you may set up a program where you monitor patients at home, but you have to identify who are the right persons to enroll in those programs, and what are we measuring? Then we use the big data to identify, basically to segment, a population and help with optimising service for those populations. Then you use big data to determine who should enroll in what programs.

I call it the killer app — to me, the killer app

"DIGITAL MEANS NEW BUSINESS MODELS THAT ARE GROUNDED IN NEW TECHNOLOGIES AND ARE REALLY CREATING BETTER OUTCOMES IN THE CLINICAL WORLD""

is basically taking the monitoring data that comes from patients you monitor at home, taking the medical data, the clinical data of the patient, and then based on that you use big data algorithms to determine which people need what kind of intervention. Then you're really making the data actionable. You can make it actionable for the care team, but you can also make it actionable for the patient. Based on where you are today, now you should do this. We're working together with salesforce.com and there's a very simple reason for it. If you look at what Salesforce has done, they have really created a software platform that allows companies to collaborate around customers, to know everything about the customer but also to market to those customers. Basically, if I want to sell you a product, I can do what we call drip marketing. I can send you a message. I can send you an email. I can

show an ad when you browse. When we started sitting with them, we said okay, you have this entire infrastructure where we're using your software to dispatch our field engineers. We are using your software to work together on our bids. Now what if we use your software to work together on a patient? What if we used the billions of dollars you guys have invested in marketing software to use the same mechanics to convince people to take their medication on time or to do almost the opposite of what other people do, stop drinking drinks with 30 percent sugar or stop eating processed foods?

I was talking to one of the biggest healthcare organisations in the world and the person told me they have nurses that go around in cars and that have appointments scheduled to meet with patients. Everything is always scheduled. I said, well I don't think that's an efficient way to do it. If you have our eCareCoordinator, you know exactly who needs to get a visit when and you optimise. But then you use software to dispatch your field engineers to tell them exactly which field engineer is where and you can dynamically reschedule. Hey, there is a patient three blocks away that needs an intervention now. Now, you go there — so you dynamically tell people where to go.

Other industries have solved these problems. Just like I said around traders, industries have solved the issue of how to deal with very, very complex data and information. Other industries have solved dynamically managing your resources to optimise your outcome. In healthcare, we don't need to reinvent it. We need to bring it in the right context, and we understand that we are dealing with life and death issues, so maybe we issue mission-critical capabilities there.

Salesforce will become Healthforce?

Yes, that's the whole idea. Basically that's why we are working with them. Of course, they don't have the clinical background which we are bringing, but they have all this off-the-shelf software. We are working with Radboud University Medical Center, one of Europe's most innovative hospitals in setting up a health community. I just want to configure it. I don't want to write software for that. We are not the first company that has gone and created community. That's been done in other contexts, many times over, so I just want to use the core capability to do that

and then configure it for our specific environment. How can we help people with a chronic condition to hook up with other people?

This would be one of the killer apps?

Yes, this would be one of the killer apps. For me, killer apps are really about, how do I know exactly when to do the right intervention at the right time and how can I mobilise the right people to do it? It may be for your desk, or it may be a cardiologist, because at this moment it is so complex, he is the only one who can make the right judgment on this. But it's got to be dynamic and it cannot be "I'll do it eight weeks from now" or "I have an appointment in three weeks" because it may be too late. I think the industry is still highly inefficient but it's primarily driven by the business model.

So, getting all this big data, showing which treatment for that small percentage that need it, then feedback into appropriate use and avoiding unnecessary....?

Exactly. You don't have to do fee-for-service because you want to do another test because it helps you reach your litigation and get reimbursed. Then there is no down side. It's a strange system. Clearly, I cannot claim that I am a healthcare specialist, but I looked at other industries and how they leverage information technology. We have seen all around how it is transforming industries and it was a big theme at the World Economic Forum. Digital is no longer a website or a mobile app. Digital is the fabric of your company. If you don't jump on it, you may be standing there in a couple of years and saying why didn't I see that coming?

You can redirect on the spot a parcel from A to B, so why shouldn't you be able to do the same for a nurse?

Yes, it's dynamic. The world has become real-time dynamic. Things change and therefore the system will allow me to change. The concepts are simple. It's just so far away from the traditional way of doing it, but at the same time, I see people doing it. They are forward-looking organisations, new organisations. I met a guy at the World Economic Forum whose mother passed away from complications of diabetes, and he started looking and he said this model is so broken. So he set up 40 or 50 diabetes centres around Mexico in a

similar concept. You come in; we'll screen you. We'll capture the data. We'll give you tools to manage it and we'll do it on a fixed price. So he does it for $200. The average cost for a diabetes patient is a $1,000. He said, I do it at 20 percent of the cost, and I give you better outcomes because this is all I do. I have my teams organised and it's all automated. I don't have my best

"START THINKING BEYOND JUST ACUTE CARE"

people in the clinics. I have my best people in Mexico City, as support staff.

Twenty years ago, you would go to a bank branch and the specialist would sit there. Now there is no bank branch in the world where they put their best people in the branch. They put it in New York or London, and they will support the people in the branch. That's a scalable model. Trying to put everybody so you've got to leverage the technology to really apply your expertise to when and where it is needed. These are simple business principles. They just have not been applied at scale. So, that's going to happen now because the technology will be there to apply it at scale.

The informed patient is an empowered patient. Encouraging them is a good thing?

I think so. A lot of it will be education, so I think if you look at this without really, really, thinking through how you educate the patient to understand what impacts their condition and how to nudge the patient to deal with their condition, it's not going to be effective. You've almost got to think as much about education, taking them by the hands, drawing them in, truly engaging them as well as making sure they take the medication on time and they stand on the weight scale once a day, etc. But again, other industries have done that as well. They spend a lot of time getting into the skin of a consumer and understanding how a consumer thinks. At Citibank, I was responsible for internet banking. We were one of the first companies to launch internet banking. We spent most of the time trying to understand how people are doing their finances. We didn't say technology is the answer. We thought, what are people struggling with? What do they need to get in control of their financial health? ∎

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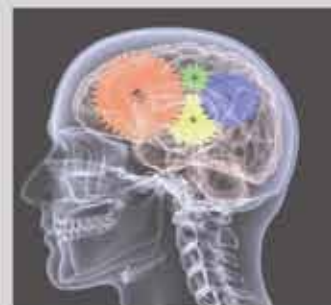
Hear from top healthcare managers and directors on key management issues within imaging departments

Topics include:
- Workflow
- Outsourcing
- Teleradiology
- Project management
- Building business cases
- Managing change
- Appraisal revalidation
- How to answer management questions in interviews

Following its success last year, this event is back for a second time due to popular demand

Who should attend?
- Trainee radiologists
- New consultants
- Early career radiology managers

Delegates who attended in 2014 said:

"This event provided useful pointers for trainees showing the potential challenges and frustrations of management"

"Very interesting topics that were very well delivered by knowledgeable speakers"

EUROPEAN CONGRESS OF RADIOLOGY 2015

HEALTHMANAGEMENT'S HIGHLIGHTS

The 27th European Congress of Radiology 2015 opens in Vienna on 4 March, with over 20,000 delegates from 101 countries expected. This year also marks the 10th anniversary of the European Society of Radiology (ESR).

New for 2015

Many of the educational format sessions are organised according to the different levels of the European Training Curriculum for Radiology, providing a well-structured teaching programme for medical students, trainee radiographers, residents, general radiologists and subspecialty experts. New formats added for 2015 are the European Diploma Prep Sessions, ECR Academies and ECR Master Classes.

Delegates will also be able to vote online for the best paper awards.

Plenary Sessions

Wednesday 4 March
17:45–19:00
Opening Ceremony
Presentation of Honorary Members

Thursday 5 March
12:15–12:45
Josef Lissner Honorary Lecture
Is the 'Art of Medicine' dead in the era of population health management?
James A. Brink, Boston, USA

Wilhelm Conrad Röntgen Honorary Lecture
Hybrid imaging: let the two worlds of radiology and nuclear medicine come together
Gerald Antoch, Düsseldorf, Germany

Saturday 7 March
12:15–12:45
Nikola Tesla Honorary Lecture
Brain tumour update 2015: What's new and why you should care
Anne G. Osborn, USA

ESR/ EFRS meets…

Friday 6 March
10:30–12:00
ESR meets Germany
All Levels
Tradition goes digital: getting ready for the future

16:00–17:30
ESR meets the European Association of Urology
Level II + III
Prostate cancer session

Saturday 7 March, 10:30–12:00
ESR meets the Republic of Korea
Level II
CT in lung cancer screening and COPD evaluation
Sunday 8 March, 10:30–12:00
ESR meets Turkey

Special Focus Sessions

Thursday 5 March
08.30-10.00
Advanced applications in ultrasound
Level II
16:00–17:30
Breast imaging modalities: beyond the conventional **Level III**

Saturday 7 March, 14.00-15.30
Cardiac CT: cutting edge techniques
Level III

Sunday 8 March, 08:30–10:00
Technology for supporting clinical research in radiology
Level II

Professional Challenges Sessions

Wednesday 4 March
16:00–17:30
Radiologist: imager or doctor?
Level II + III

What are the concrete benefits of structured reporting?
Level II

Thursday 5 March
08:30–10:00
Looking into the future of radiology
Level I + II

Imaging Biobanks: from genomic to radiomic in the era of personalised medicine
Level III

16.00-17.30
Integration of imaging biomarker activities on a European level
Level II

Imaging in population-based studies
Level II

Friday 6 March
08:30–10:00
Personalised medicine in radiology
Level II

16:00–17:30
European imaging in Europe: myth or reality?
Level III

Medicolegal aspects in daily practice
Level II

ECR Master Classes

Saturday 7 March, 16:00–17:30
Breast imaging: improving the information to women
Level III

Pros and Cons Session

Thursday 5 March, 16:00–17:30
Breast cancer: to screen or not to screen?
Level III

Refresher Courses

Wednesday 4 March, 08:30–10:00
Mobile IT in radiology
Level III

Saturday, 7 March
08:30–10:00
IT tools for dose tracking and workflow optimization
Level III

ECR 2015 EDUCATIONAL EVENTS HOSTED BY TOSHIBA

Toshiba Medical Systems invites you to the educational events we offer at ECR to learn more about how we are bringing innovation to life. In addition to two lunch symposia, which we will be hosting on Thursday and Friday, our comprehensive hands-on workshop program throughout the day from Wednesday to Saturday provides the opportunity to gain in-depth knowledge and skills on the latest imaging technologies (**Toshiba Lounge, room 0.90, entrance level**).

Please visit our **Booth #322 at Expo C/lower level** for live demonstrations of our latest innovations helping you to provide better patient care with greater efficiency. On our booth and through the resources section of our website, you will be able to access a wealth of clinical white papers and case studies covering a large bandwidth of diagnostic imaging topics.

SATELLITE LUNCH SYMPOSIUM 2015

BETTER OUTCOMES FROM DETECTION TO TREATMENT

Date: Thursday, March 5
Time: 12:30 – 13:30
Room: G

Chairperson: Prof. Catherine Roy
University of Strasbourg, France

Speakers:
Prof. Dr. Thomas Fischer
Charité University, Berlin, Germany
Advanced ultrasound applications for multidisciplinary use

Prof. Dr. Vito Cantisani
La Sapienza University, Rome, Italy
Elastography – improved detection and characterization

Prof. Afshin Gangi
University of Strasbourg, France
Advancements in ultrasound-guided biopsy and treatment

NEW DETECTOR TECHNOLOGY IMPROVES PATIENT SAFETY

Date: Friday, March 6
Time: 12:30 – 13:30
Room: C

Chairperson: Prof. de Roos
Leiden University Medical Center, The Netherlands

Speakers:
Jeffrey Hall, Clinical Marketing Manager
Toshiba Medical System Corporation, Japan
Safer imaging – clearer outcomes

Dr. R. Bull, Consultant Radiologist
Bournemouth Hospital, UK
New detector technology in clinical practice

Prof. Dr. M. Prokop
Head of Radiology Department, Radboud University Medical Center Nijmegen, The Netherlands
Widening the scope of clinical CT applications

Booth #322

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Screening with Breast Tomosynthesis
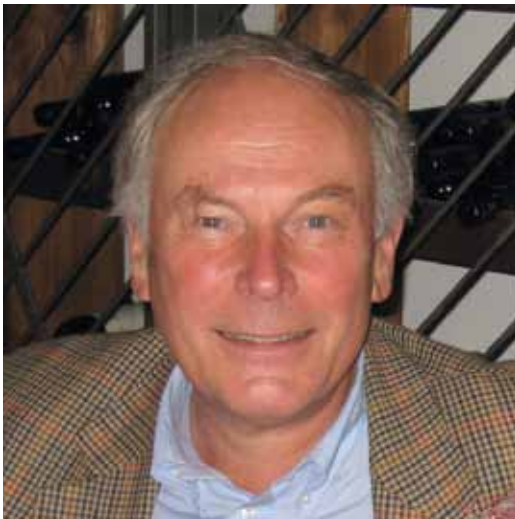
Per Skaane

MD, PhD, Department of Radiology,
Oslo University Hospital, Oslo,
Norway, will moderate
the Symposium and present
on the Norwegian experience.

What are the key benefits of implementing tomosynthesis in screening programmes?

The key benefits are the higher sensitivity (i.e., the higher cancer detection rate) and the higher specificity (i.e., the lower recall rate) using this new technique.

What the key points from the Norwegian experiences that you will be presenting?

My experience from the Norwegian experience is based on the preliminary results from the Oslo Tomosynthesis Screening Trial (OTST)[1]. A main important finding is the significantly higher cancer detection rate. The additionally detected cancers are all invasive cancers, and the number of ductal-carcinoma in-situ (DCIS) is practically unchanged. A further important finding is that the use of synthetic 2D images (instead of full-field digital mammography FFDM 2D) in combination with tomosynthesis gives comparable results with FFDM 2D + tomosynthesis. Consequently, the combination 2D+3D is possible with a radiation dose comparable with conventional 2D FFDM.

What are the major challenges in implementing tomosynthesis into breast screening programmes? How should these be addressed?

The "cost-benefit" aspect is important. Two recently published papers have, however, shown that tomosynthesis seems to be cost-effective[2,3].

The examination time (for the technologist) must not be much longer than for the conventional 2D FFDM carried out today, but Hologic offers fast tomosynthesis examination time with only some very few seconds longer than FFDM. The combination 2D+3D needs approximately the double interpretation time by the radiologists (from about 25 sec. to 60 sec. per examination). An efficient hanging protocol is thus mandatory. The radiation challenge is solved using synthetic 2D images reconstructed from the 3D (tomosynthesis) data set.

What more evidence is needed to bring screening with breast tomosynthesis into reality?

So far, there have been published some few retrospective studies from US and three European prospective trials on tomosynthesis in breast cancer screening. The results of nearly all of these studies are similar, demonstrating a higher cancer detection and a lower call-back rate. The three prospective European trials are very different in study design - although the results are comparable! Some people might want to have these results confirmed in a couple of more prospective studies before making the final decision. What is important is the fact that tomosynthesis is not a new "modality" but should be considered as a better "technique" (i.e., a better mammogram!). Implementation of new "modalities" like ultrasound and MRI would be much more complicated, whereas tomosynthesis (as a better tomogram) can easily be implemented in the existing screening programs.

Refernces

1. Skaane P, Bandos AI, Gullien R, Eben EB, Ekseth U, Haakenaasen U, Izadi M, Jebsen IN, Jahr G, Krager M, Niklason LT, Hofvind S, Gur D, Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-Based Screening Program, Radiology April 2013.

2. Lee CI, Cevik M, Alagoz O, Sprague BL, Tosteson AN, Miglioretti DL, Kerlikowske K, Stout NK, Jarvik JG, Ramsey SD, Lehman CD. Comparative Effectiveness of Combined Digital Mammography and Tomosynthesis Screening for Women with Dense Breasts, Radiology October 28, 2014.

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Friday, March 6th
14:00 - 15:30
Room C

Join us on our booth
For a post-symposium
celebration and a chance
to meet the speakers

Booth #320

Sarah M Friedewald

MD, Assistant Professor in Radiology,
Northwestern University Feinberg School
of Medicine, led a multi-center study
in the United States[4], which compared breast
cancer screening performance before and
after introduction of tomosynthesis.

The study involved 13 sites, which included academic and non-academic centers, and specialist and nonspecialist radiologists. A total of 454, 850 screening mammograms were interpreted by 139 radiologists, of which 281,187 were digital mammograms and 173,663 were digital mammography + tomosynthesis. The volume of examinations across institutions ranged from 4,801 to 53,181 for digital mammography only and from 2,613 to 34,119 for digital mammography + tomosynthesis.

An analysis of the data indicated that the model-adjusted rates per 1,000 screens were as follows: for recall rate, 107 with digital mammography vs 91 with digital mammography + tomosynthesis (an overall decrease in recall rate of 16 per 1,000 screens, relative decrease of 15%); for biopsies, 18.1 with digital mammography vs 19.3 with digital mammography + tomosynthesis; for cancer detection, 4.2 with digital mammography vs 5.4 with digital mammography + tomosynthesis (increase of 1.2 , relative increase of 29%); and for invasive cancer detection, 2.9 with digital mammography vs 4.1 with digital mammography + tomosynthesis. Adding tomosynthesis increased the positive predictive value for recall from 4.3 percent to 6.4 percent and for biopsy from 24.2 percent to 29.2 percent. When tomosynthesis was added, the PPV for recall increased from 4.3% to 6.4% (relative increase of 49%).

The authors suggest, "The association with fewer unnecessary tests and biopsies, with a simultaneous increase in cancer detection rates, would support the potential benefits of tomosynthesis as a tool for screening. However, assessment for a benefit in clinical outcomes is needed."

Professor Friedewald will be speaking at the Hologic Syposium about the American experience. She will present data from the JAMA paper including:

- Increase in cancer detection
- Decrease in recall
- Showing statistical significance with large numbers
- Discussing the strengths and limitations of this study
- Reviewing areas needing more research

What lessons can be learned from the American experience?
Consistent results are observed regardless of the practice environment (i.e., academic institution, private practice, experienced radiologists, general radiologists) and therefore similar results would be expected going forward regardless of where tomosynthesis was implemented.

In the US, our recall rates are generally much higher than in Europe. Implementation of tomosynthesis enables US sites to decrease unnecessary recalls and therefore decrease patient anxiety and downstream costs. This also significantly increases our positive predictive values.

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ECR 2015: HEALTHMANAGEMENT'S HIGHLIGHTS CONT.

Management in Radiology @ECR

Those involved in the field of healthcare are experiencing a time of increasing pressure, stress and change. The demand for efficiency and effectiveness in all business and administrative matters is constantly growing. MIR addresses current challenges and provides a forum for education and the exchange of ideas and concepts.

Session 1:
13.00-15.00
- Overview on MIR activities and why to attend MIR conferences

Updates:
- Radiology: a strategy for the future
- Imaging Biobanks
- Decision Support for Radiology
- Social Media in Radiology
- Economics

Session 2:
15:30 - 17:30
- Improving Quality and Safety in Radiology
- First Experiences from a

Nationwide Peer Review in Radiology
- How to organize meaningful Audits in Radiology
- Errors in Radiology - how to learn from a systematic approach
- Panel Discussion: Learning from Critical Situations or Errors - Examples from around the World

ESR Patient Advisory Group for Medical Imaging Sessions

Saturday 7 March,
10:30–12:00
Level II + III
The challenges of providing true patient-centred care: moving forward together

Sunday 8 March,
10:30–12:00 **Level I**
Communicating the results of radiological studies to patients: from high-tech to human touch imaging

EuroSafe Imaging Sessions

Thursday 5 March
14:00–15:30
EuroSafe Imaging Session 1
Level I + II
Clinical decision support: making imaging referral guidelines work for patients, doctors and hospital managers

Friday 6 March
14:00–15:30
EuroSafe Imaging Session 2
All Levels
EuroSafe imaging call for action

Friday 6 March, 16:00–17:30
Refresher Course: Good radiation and bad radiation? How to assess and communicate radiation risk to patients and referring physicians
Level III

Saturday 7 March
14:00–15:30
EuroSafe Imaging Session 3
Level II
Dose-tracking leads the way to dose-reduction

16:00–17:30
EuroSafe Imaging Session 4
All Levels
How can clinical audit enhance patient safety?

REVOLUTIONIZING ORTHOPAEDIC IMAGING

INTERVIEW WITH MARIE MEYNADIER, CEO, EOS IMAGING

What are the main areas of EOS Imaging's business interest?

Bringing solutions to musculoskeletal radiology. Bone imaging has not seen a lot of innovation since the invention of x-ray more than a century ago, and bone imaging will not go much longer with just plain x-ray and recumbent CT.

EOS, as a platform, offers pure radiographic imaging, low dose, and the capacity to image the whole body and extract 3D information. From this platform derives a lot of applications that are surgeon-, therapist-, prescriber- and orthopaedist-centred – all the specialists that use the clinical information that we provide.

What are your key products?

The key product is the EOS platform for 2D/3D low dose imaging, into which we are adding constantly innovation and peripheral products. We are pushing new products for instance in planning software for orthopaedics, based on the unique EOS information derived from the capacity to do 3D weight-bearing imaging and have clinical data embedded in the EOS 3D image.

If at all, where do you experience major difficulties?

We don't face difficulties. We're just executing a very ambitious plan, which is to bring a technology that did not exist ten years ago to become a worldwide gold standard in bone imaging. That's obviously challenging, but it's a great experience and we're getting there.

We started in Western Europe, in France, we have expanded our operations to the U.S., and we are present in Asia and will soon be in Latin America.

The technology as it goes worldwide is more and more considered as a gold standard not only in paediatrics but in all bone imaging, with a lot of momentum being built on spine pathologies and joint pathologies, hip and knee, and all associated imaging procedures.

Where do you see the opportunities?

When you have disruptive technology you cannot go in a single area of the world. We have a large opportunity if you look at the number of sites worldwide that do medium to large volumes of orthopaedic surgeries, and all of them should be equipped with an EOS. The market opportunity is huge – potentially 12,000 sites.

How important is management, leadership and cross-departmental collaboration?

We haven't produced equipment just for radiology. Radiology serves prescribers, the end customers that the radiology exam is made for, together with the patients. We are in the unique position in that we have a dedicated specialty offering for those prescribers, whether they are chiropractors, rheumatologists or orthopaedic sur-

"WHEN I WAS TEN I WANTED TO BE AN ARCHAEOLOGIST"

geons, and we help radiologists serve those prescribers with the best offering, not just a generalist offering, which provides them with the right data for the patient.

Our experience, in more than a hundred sites that we have worldwide, is that by bringing EOS in an institution, the partnership between the radiology department and the orthopaedists or rheumatologists is really building up around EOS.

We designed the equipment with orthopaedists and radiologists. We added the third dimension, the large size of exams, because we knew that the actual skeleton exam requires a large size. We reduced the dose, because we knew that bone imaging

is where you have to put the most dose. It really makes that fit between radiology and orthopaedics happen.

What is EOS Imaging's story?

I met Georges Charpak, a Nobel prize-winner in physics, in the late 1990s, and he had started a company with a great technology for measuring radiation. That company really restarted in the mid 2000s around that, because we found with a small team of MDs and engineers that Charpak's technology could actually help us do better bone radiographs. So we put it at work in what is now EOS by bringing the detector technology and bringing more technology from outside academic partners for 3D and that's how it all came about. It really was a meeting of us, engineers, Charpak, a radiologist and a surgeon.

What is your top management tip?

Keep your 360° degree radar going on at all times.

If you had not chosen this career path, what would you have become?

When I was ten I wanted to be an archaeologist. I think today, if I were to look into it again, I might choose medicine. I'm absolutely fascinated by the value brought by medicine.

What is your favourite quotation?

It's one quotation, which I use a lot for EOS. It's a quotation by a French philosopher. The first half of the quotation is easy and usual: "To understand the whole you have to understand the parts." Then it goes: "But to understand one part, you have to understand the whole." And that's all EOS is about. If you want to understand lumbar back pain, you might have to look globally at your patient and not just be trying to reduce your thinking to a very local area. ∎

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ECCMID 2015

WHO, WHAT, WHEN

From April 25 to April 28, the 25th European Congress of Clinical Microbiology and Infectious Diseases will be held in Copenhagen, Denmark. ECCMID is the global meeting place for microbiologists, infectious disease specialists and related fields. This year's Congress will offer diverse and clinically focused insight on topics through a series of keynote lectures, symposia, educational workshops and meet-the-expert sessions on parallel tracks, covering the entire field of infectious diseases and clinical microbiology.

Hospital-acquired infections (HAIs) represent an ever-increasing economic burden costing hospitals billions of euros every year. They threaten the life of patients and cause thousands of deaths. The ECCMID is the platform where specialists from the field offer insight and recommendations on how to deal with HAIs more effectively.

Scientific Programme

ECCMID offers an exciting programme for participants. There will be more than 2000 contributions from scientists from all over the world. The programme will include sessions on basic science, pathogenesis, infection control, clinical hygiene and clinical infectious diseases. Some new discoveries are also expected to be discussed.

Keynote Lectures

Opinion leaders will discuss hot topics from Clinical Microbiology and Infectious Diseases. ESCMID Excellence Awardee will also be presented. The keynote lectures will include:

- World immunisation week 2015 – WHO perspectives on vaccines
- Chasing beta-lactamases in times of economic difficulties

- Device-related infection
- Behavioural science applications in antimicrobial stewardship and infection control
- The modern ICU: are antibiotics used to save the patients or to soothe the minds of the doctors?
- Infection control in settings of viral respiratory viruses including MERS
- Current trends in global fungal epidemiology and resistance
- Analysis of social networks wording: how to understand and fight against vaccine scepticism
- Towards hepatitis C eradication
- Systemic analysis of human-associated microbes in health and disease arranged with the ESCMID Study Group for Anaerobic Infections

Scientific Symposia

Over 150 hours during the ECCMID 2015 will be dedicated to Scientific Symposia. These will include joint sessions with other Societies and co-organised symposia from ESCMID's Study Groups. Parallel symposia will convene with renowned speakers from Europe and other continents who will cover a wide range of recent developments in their fields.

Oral Sessions

In parallel to the symposia, there will also be sessions from abstracts selected for oral presentation.

Educational Workshops

At the start of ECCMID, a series of Educational Workshops will take place. They are organised in cooperation with ESCMID Study Groups and partnering organisations. There will be 19 Educational Workshops, some of which will feature a new interactive format where questions from the audience prior and during the session will be accepted and discussed.

When: Saturday 25 April 2015

Meet-the-Expert Sessions

Meet-the-Expert Sessions will be led by experts in their fields. Sessions will start early mornings and will cover a variety of topics from Clinical Microbiology and Infectious Diseases. These sessions rely on active participation of the audience. After a short presentation, the expert will open the session for discussion.

When: **Sunday through Tuesday at 07.45 a.m.**

TAE Trainees Day

The Trainee Association of ESCMID (TAE) hosts the European Trainees Day, a day of teaching dedicated to the unique needs of trainees. During this session, various topics in Clinical Microbiology and Infectious Diseases will be discussed in a highly interactive way between trainees and experienced specialists. A second and equally important aim of the day is to give trainees an opportunity to meet and network with each other.

When: Saturday, 25 April 2015

ePoster/Poster Sessions

Most of the accepted abstracts are scheduled for poster presentation. The selection is based on a blind review by at least three experts in each field.

When: Saturday through Tuesday

To view the complete ECCMID schedule, please scan the QR Code or visit **http://www.eccmid.org/scientific_information/session_descriptions/** ■

25th ECCMID
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COPENHAGEN, DENMARK
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[1] Zimlichman et al., JAMA Intern Med published online September 2, 2013
[2] Shepard et al., JAMA Surg. 2013;148(10):907-914 published online August 21, 2013
[3] Diekema et al., Infect Control Hosp Epidemiol 2011;32(10):1042-1044
[4] Chen et al., Clin Orthop Relat Res 2013;471:2383-2399

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FOSTERING GERIATRIC MEDICINE IN EUROPE

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INTERVIEW WITH THE EUGMS PRESIDENT

People are living longer, partly due to advances in medicine. On the other hand, older people can be seen as a burden on health and social care. Please comment.

First, longer lives should be seen as a success story, because it is the result of society being able to provide more healthy conditions throughout the lifespan, but also because we understand better how to postpone age-associated chronic diseases, and how to reduce their impact due to modern geriatrics. People usually appreciate this. Because more people die when they are old, rather than prematurely in middle age, then many live long enough to acquire more than one medical problem, so healthcare gets more complicated. The challenge is to adapt healthcare systems to cope with this. Geriatricians and the European Union Geriatric Medicine Society (EUGMS) can be champions in this process of change, but ultimately it is a challenge for most medical and health specialists and their services.

But we need to remember that it has always been the first few and the last few years of life when people need most support, irrespective of life expectancy. Optimally, it would be the number of healthy years that are increased and the years of morbidity compressed at the end of life, as James Fries visualised in 1980, but we are not there yet.

What is the EUGMS doing in relation to prevention of and recognition of age-related diseases and conditions?
EUGMS aims to foster geriatric medicine in Europe. An important document was the Silver Paper, published in 2008 (**www.eugms.org**), which sought to summarise relevant actions needed (Cruz-Jentoft et al. 2009). It includes aspects of prevention, medical treatment and care for older people - what we know and what we ought to know. I warmly recommend that all policymakers read the Silver Paper.

EUGMS has several working groups ("task and finish groups") and special interest groups for various topics in geriatric medicine. These groups gather specialists, and, based on best research evidence and practical experience, produce recommendations and reviews.

Best practice and newest research are presented annually during the EUGMS Congress, which will next be in Oslo, Norway, 16-18 September 2015 (**www.eugms.org/2015**). These congresses gather around 2000 participants annually.

EUGMS has its own journal, *European Geriatric Medicine* (EGM) **(www.euro-peangeriaticmedicine.com)**, devoted to research and reviews about health and healthcare of older people. It also publishes guidelines and recommendations for action. EUGMS has started cooperation with other geriatrics journals, and last year with a high-profile general journal, *JAMA*.

What are the hot topics in geriatric medicine?

There are many:

- **Active and healthy ageing (AHA)** - how to attain and ascertain. Old age is a stage in a journey. Optimising old age is an issue of how we live our lives from childhood on. But in addition maximising the social role and relevance of older people is a major challenge for all societies. Marginalised older people will become dependent older people!
- **Frailty** is a key concept in understanding the accumulative vulnerability of many older people. It is a novel approach, because we begin to understand older people as a whole rather than as a list of individual medical conditions. Leaders within EUGMS have been instrumental in seeking useful definitions for clinical practice and research, and highlighting ways of prevention and treatment of this very important geriatric syndrome.
- **Sarcopenia** – weaker muscles –is a key component of frailty, and contributes to the loss of the functional independence that older people want to retain. EUGMS has led work to define this syndrome and review the evidence for the best strategies for prevention and rehabilitation.
- **Multimorbidity and polypharmacy** add complexity to the treatment of older people. Shaping treatments for individuals means avoiding too much medicine or too little medicine! EUGMS has been very active at the European Commission and elsewhere in campaigning for more inclusion of older people in clinical trials so that the medicines that they receive have been tried and tested in people like them, not only fit younger people.
- As a geriatrician I also think that

biogerontology and research on molecular mechanisms of ageing and senescence are important to point us in the direction of likely new therapies.

- **Prevalent chronic conditions, cardiovascular diseases, cancer, and cognitive disorders (like Alzheimer's disease),** their prevention and treatment, are ever important.

"GERIATRICS IS GAINING POPULARITY AS A 'HOLISTIC' SPECIALTY"

Are enough physicians choosing to specialise in geriatric medicine? Does the status of the specialty vary across EU countries?

I do believe that geriatrics is gaining popularity as a "holistic" specialty, not concentrating on special organs, but taking the individual as a whole. But there are certainly differences among European countries. An important goal of EUGMS is to harmonise geriatric medicine and its training.

What lessons can your own country of Finland offer to other European countries?

Finland has sought to invest in geriatric medicine. All medical faculties have a professorship in geriatrics, geriatrics is an independent specialty since the early 1990s, and we have national training schemes (5 years). The national society of geriatricians (SG) actively lends its expertise to policymakers on issues related to older people's care. One aim is to have geriatric units in all general hospitals, and increasing geriatric expertise also in emergency care. Legal actions by our Parliament aim to improve and harmonise older people's care, and the media are actively watching how these materialise in practice.

HealthManagement promotes multidisciplinary healthcare. How important is the multidisciplinary team when it comes to geriatric medicine?

Comprehensive geriatric assessment (CGA) is an important and central tool for geriatricians, and this is intimately related to multidisciplinary healthcare (Bernabei et al. 2000; Stuck et al. 1993). EUGMS strongly aims to promote use of CGA. There is strong evidence that it helps older people recover from illness or injury in hospital and also that it helps older people in the community avoid crises in their health.

Potential discrimination exists when it comes to including elderly people in clinical trials, and in evaluating safety of drugs for older people. What is the EUGMS position on this?

This is very important and EUGMS is proud to have active individuals in its ranks interested in these issues. EUGMS has also acted at the EU/EC level to improve drugs treatments and their research.

Should we be concerned about gender differences in geriatric medicine?

If it exists, definitely yes. There have been gender differences in treatments, for example, in cardiovascular diseases, but the situation has been improving. We need more research on problems related especially to older women (for example frailty), who constitute the majority in older age groups. This is also a gender difference of concern, why men do not live as long as women. But probably actions before the geriatric age are needed to correct this imbalance. ∎

11th EUGMS Congress in Oslo

OSLO

16-18 Sept 2015

📖 **REFERENCES**

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SMART AGEING

A STRATEGY FOR THE SUPER-AGED SOCIETIES

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Smart Ageing International Research Center

The Smart Ageing International Research Center was established on 1 October 2009 with the aim of promoting international cooperative research on "Smart Ageing" as explained below. It aims to encourage individuals and societies to cope effectively with the changes brought on by ageing, and to mature intellectually.

In Japan the percentage of elderly people aged 65 years or over was 25.1 % in 2013, an unprecedentedly high percentage, making Japan the world's first super-aged society. In such a super-aged environment, it is necessary to form a society in which each individual can play an active role even as one becomes older, and in which people can share knowledge and wisdom regardless of their age and gender in order to maintain and improve the quality of life of all people and to maintain a healthy society.

The Center promotes research and development focusing on the following two issues to be resolved to formulate effective countermeasures against a super-aged society at the earliest time possible.

The first issue is the challenges resulting from the longer lifespan of individuals. The Center is developing a system to support a healthy and longer lifespan so that individuals can continue to maintain intellectual stimulation later in life, find their places as an integral member of society, and to maintain and to improve their quality of life, and mental and physical health.

The second issue is the challenges due to the ageing of the whole population. In a super-aged society, elderly people should be considered to be a valuable human resource. It is necessary to develop a social system that promotes their active social engagement. In particular, intergenerational exchange and the transfer of knowledge and wisdom to the later generations, which have been lost with the trend toward the nuclear family, are highly important for the development of human and social sensibilities in younger generations who will bear the future of Japan. The Center will actively create a forum where elderly people can directly communicate with younger generations to pass down their knowledge and wisdom. We hope that the Center can contribute to the creation of a bright future through state-of-the-art Smart Ageing research.

What is Smart Ageing?

We define Smart Ageing as "all individuals and the societies are maturing intellectually while effectively dealing with the changes associated with ageing". This concept is a revolutionary paradigm shift away from common negative concepts, such as anti-ageing, that imply an unwillingness to accept or face the later stage of life.

In general, ageing is considered negatively as the loss of something that people have in their youth or a form of regression. As a result, a false image has been formed that ageing is something like an illness or ugly, and that young people are superior to the elderly in many respects. Consequently, an obviously wrong concept of anti-ageing has been developed. However, ageing is a fact of life; in other words, anti-ageing negates life.

"ANTI-AGEING NEGATES LIFE"

Rather, the concept of Smart Ageing advocates a positive acceptance of the later stages of life and a perspective that views ageing as a series of "developmental stages toward intellectual maturity" as one gets older, resulting in a deeper way of looking at things and broadened views, and thus a more enriched life. We think that ageing means people can grow and become wiser as they reach later stages of life, and that society can evolve into a sustainable structure. We call this concept Smart Ageing. We proposed the concept publicly in 2006.

Generally, an individual's quality of life increases as one grows older compared to when they are young: however, many people tend to lose their sense of purpose in their life when they lose their connection with society, triggered by, for example, retirement, leading to a decrease in their quality of life. However, we believe that quality of life can be increased up until the last moment if one pays careful attention to the following four factors, ie cognitive stimulation, regular exercise, balanced nutrition, and relationship with society, and if a social system to realise this for everyone can be established.

The results of the research and development at the Center will lead to the realisation of a society in which people can feel enrichment of life as they become older, and they are connected intellectually and are supportive of each other, regardless of age or gender, through regional personal connection.

"Three-Inter" Activities

There are three major activities promoted by the Center: interdisciplinary cooperative research, international collaborative research projects, and intergenerational exchanges. The Center aims to create an area of integrated research unparalleled in the world on the science of ageing through a unique interdisciplinary research plan. With the beneficial involvement of researchers in neuroscience, gerontology, medicine, medical engineering, bioscience, cognitive psychology, sociology, and philosophy, it will cultivate human resources and uncover ways of coping with the problems faced by super-aged societies. The Center will additionally promote active intergenerational exchanges between young researchers and the elderly participating in the Smart Ageing College, described later.

Organisation

The Center is divided into two divisions: the Division of Research and Development and the Division of Strategic Planning.

Division of Research and Development

This Division consists of three departments with separate research aims.

- The Department of Advanced Brain Science (Prof. Ryuta Kawashima) performs research with the aim of developing techniques for

Smart Ageing International Research Center

Smart Ageing College Lecture (above) and Seminar (below)

Exercise at Smart Ageing Square

maintaining and improving cognitive functions and mental health.

- The aim of the Department of Biomedical Measurements (Prof. Yoshifumi Saijo) is development and validation of both imaging and sensor technologies for measurements of ageing-related physiological, morphological and/or biochemical changes. Such technologies could elucidate the processes and mechanisms of human ageing.
- The aim of the Department of Electromagnetic Neurophysiology (Prof. Nobukazu Nakasato) is to investigate brain physiology through electromagnetic measurement and stimulation. Ultimately, the department's objective is to develop electromagnetic tools for research and medicine and to promote clinical applications for electromagnetic neurophysiology.

Division of Strategic Planning

The Division of Strategic Planning (Prof. Hiroyuki Murata) is responsible for planning and operating the Smart Ageing College and the Smart Ageing Square (see below). It also functions to promote collaborative research with international cutting-edge organisations and interdisciplinary collaboration between industry and academia.

The Division is responsible for planning and promoting projects to spread the concept of Smart Ageing and to apply the research results obtained at the Division of Research and Development to society through (1) collaborative research with leading-edge overseas research institutions, (2) industry-university collaboration with companies in different industries, and (3) intergenerational exchanges between elderly and younger students.

The Center is the first Japanese national university that entered into an academic partnership agreement with AARP, the world's largest nonprofit membership organisation for people aged over 50. We sent a graduate student as the first intern for AARP, and co-hosted an international symposium held in Orlando, Florida, in 2010.

The Center and AARP jointly promoted the "Smart Ageing Initiative," which encourages the Learning Therapy, a non-pharmaceutical method to improve dementia, developed by the Center, to spread out in the U.S. Over 1,400 nursing homes and municipalities in Japan, amounting to over 20,000 people, have tried Learning Therapy and attained

Learning Therapy Practice in the U.S.

Learning Therapy Class at Smart Ageing Square

outstanding results for the improvement and prevention of symptoms of people with dementia. The number of demented people in the U.S. is approximately 5 million, and the demand for the improvement and prevention of dementia is much higher than that in Japan. Therefore, high expectation is placed on Learning Therapy in the U.S.

Smart Ageing Square

The purposes of the Smart Ageing Square are to create a practical healthy ageing system that enables elderly individuals to maintain and improve their mental and physical health and improve the quality of life through industry-university collaborative research, and to propose such a system to society.

The results of the basic research obtained at the Center will be related to industry through liaison activities at the Division of Strategic Planning, and industry-university collaborative research will be carried out to examine the effect of the healthy ageing system on the Smart Ageing of individuals.

In experimental studies, local residents can directly gather in the area for the industry-university collaborative research allocated within the Smart Ageing Square. This will enable the establishment of a research and development environment that is directly related to the local residents. The Smart Ageing Square aims to establish the new style of industry-university collaboration required in a super-aged society for consistent product development from research and development to the commercialisation of products.

Four factors, ie, cognitive stimulation, regular exercise, balanced nutrition, and engagement to the society, are particularly important to maintain and improve the quality of life of elderly people. The Smart Ageing Square provides the opportunity for local residents who participate in the experimental study to develop a relationship with society.

Neurosocial-economics Study

Nursing care prevention currently promoted by the Health, Labor and Welfare Ministry in Japan only focuses on improving the function of locomotorium, balance of nutrition, and function of the oral cavity. This approach lacks viewpoints on prevention of dementia and depression as well as on return on investment of preventive care cost. We are anxious that the current care prevention programme cannot follow the predicted increase of dementia population, which will cause hypanthia increase of social welfare cost.

To avoid this, the Center promotes "neuro-social-economics study", which reduces the cost of medical and care at present and in the future, and stimulates economic demand of individuals by life intervention, such as muscle training and brain training, which enable older adults to improve their brain function and mental health.

Smart Ageing College

The Smart Ageing College provides a forum where elderly people, graduate students, and young faculty members can get together to learn how to achieve Smart Ageing at the campus of Tohoku University. Approximately one hundred members of the general public, including elderly people, are publicly sought; one-year lecture courses and various seminars of different themes are organised by faculty members and young researchers at Tohoku University. We plan to give outstanding participants the chance to serve as mentors to young researchers.

In this super-aged society, how elderly people fulfil their potential and play active roles in society is particularly important. To this end, the Smart Ageing College aims to serve as an academy where social education for young students is combined with the provision of a field for elderly people to fulfil their potential.

In addition, it also aims to serve as a catalyst for the local community to transform into a "Smart Ageing Community" that can effectively deal with the various problems related to ageing. Therefore, the Smart Ageing College is an innovative project in that it provides social education for young students and utilises the abilities of local residents.

Through the Smart Ageing College, we create a forum where elderly people and the general public can engage in direct exchange with young people, and the elderly people can pass on their knowledge and wisdom to younger generations. With these activities, we will propose a social system for promoting the positive social participation of elderly people, considering them as a valuable human resource. ■

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HOSPITALS

FACING AUSTERITY AND AGEING

Eric de Roodenbeke

CEO
International Hospital
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Global Challenges

The major challenges faced by healthcare today are a result of both economic and demographic changes, palpable on a global level. Austerity measures that followed the crisis of 2008 affect all sectors in healthcare, with the exception of long term care (Kumar 2014) (see Figure 1). Future growth in healthcare expenditure will not achieve levels experienced in the past; as a consequence of having to manage fewer resources more attention needs to be given to management.

A recent study links the impact of management to the performance of an organisation, clearly showing just how much management matters. Hospitals in countries with a historically stronger company management culture (such as the United States and the United Kingdom) achieved higher management scores (World Management Survey). There is much room for improvement in healthcare. Hospitals, clinics and other care providers have a critical role to play in pushing forward better management practices. National executive associations have the equally important task of bringing management standards in their respective countries to a higher level.

Silver Tsunami

The world population is ageing fast, representing a wave the world will have to face. The so-called 'Silver Tsunami' has already begun to affect the pattern of care, and will have a dramatic impact on healthcare delivery (see Figure 3).

Closely linked to the ageing population is an increase in multi-chronic conditions. Over the past decade healthcare expenditures have been driven not by the change in the age of the population, but rather by a change in the pattern of care. At high patient age, expenditures have dramatically increased, rendering current healthcare trends unsustainable (Dormont et al. 2005) (see Figure 2).

In developing countries, 83% of the global burden of disease is around chronic and multi-chronic conditions, making them an urgent priority (Institute for Health Metrics and Evaluation). Yet most healthcare organisations are not equipped to address the challenges they represent.
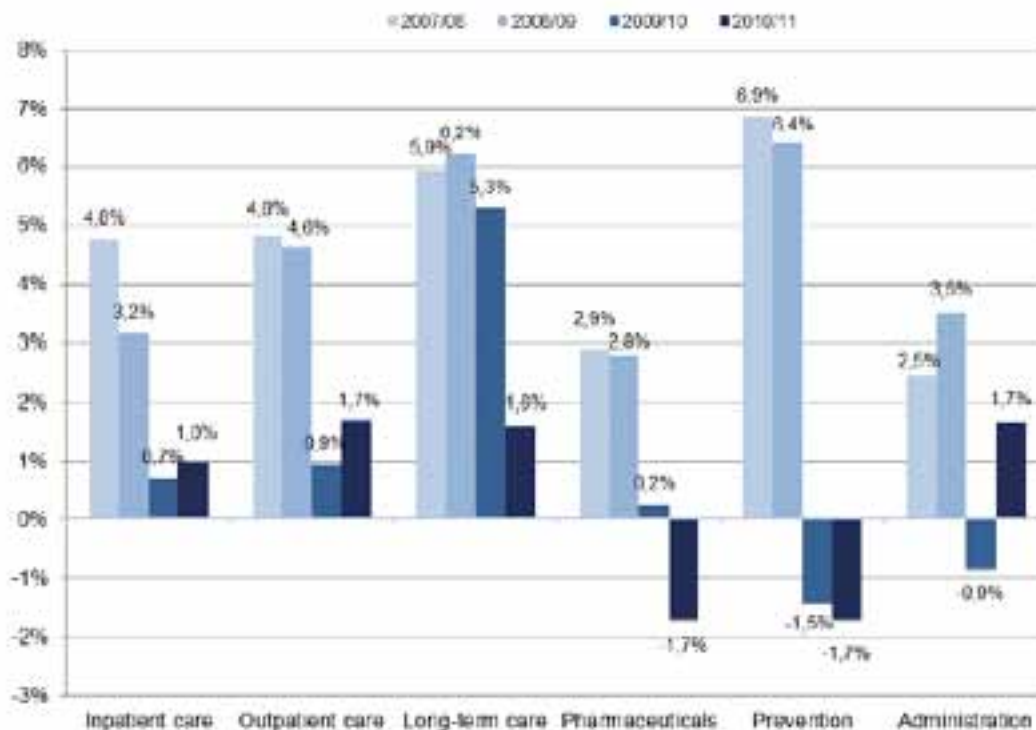
Figure 1. With Limited Growth: cuts are affecting all expenses except long-term care

Role of Hospitals

Many questions need to be asked in order to shape the future role of hospitals in the face of this healthcare evolution. One thing is certain: it cannot be a 'one size fits all' approach, as the role of hospitals is going to be very different from one country to another. Factors such as infrastructure, financing and numerous cultural variables will come into the debate. It is vital that the current role is questioned, and that all those leading the organisations are at the forefront of this questioning.

The World Health Organization (WHO) has developed a model for people-centred and integrated health services (World Health Organization 2015), which is high on their agenda. Member states will be invited to work on key dimensions such as 'Set and Manage Priorities', 'Empower People', 'Engagement and Accountability' and 'Coordinate Services', further defining the role and responsibilities of hospitals (see Figures 4 and 5).
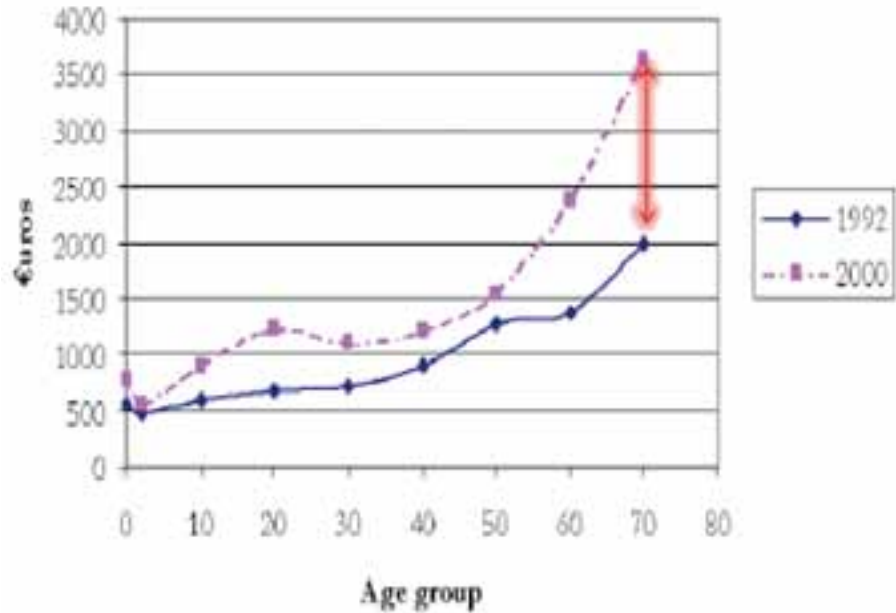
Figure 2. Healthcare Expenditures Profiles by Age - 1992 and 2000
Source: Dormont et al. 2005

"THIS REPRESENTS THE WHOLE PARADIGM SHIFT, THE WHOLE REORGANISATION OF THE HOSPITAL THAT IS AHEAD OF US"

International Hospital Federation Recommendations

International and national organisations need to have very clear priorities, policies and principles in place, which are applicable to hospitals. While hospitals can do their best, there are always factors that make it difficult to improve performance, and hospital managers cannot be expected to perform without a road map and a compass that sets the good direction.

Responsibilities for policymakers

- People-centred integrated care has to be a priority of the health system. Globally, there are major gaps between the payment system and the coverage mechanism that
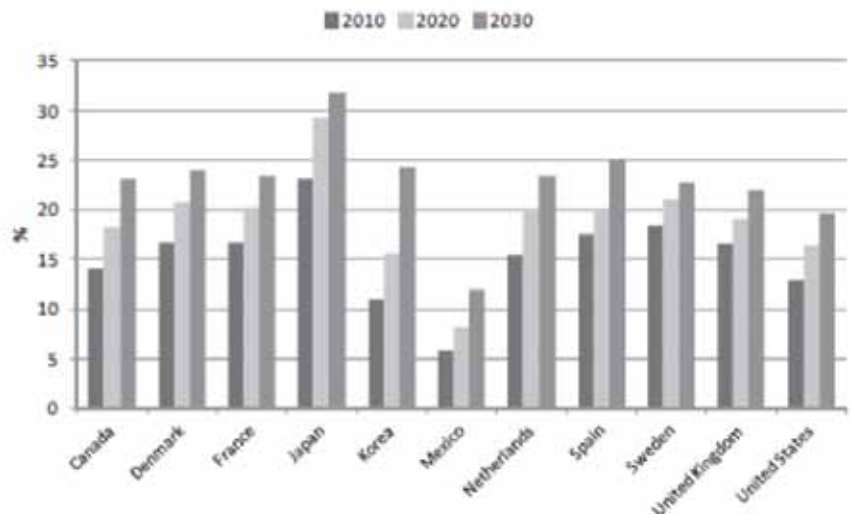
Figure 3. Ratio of Population Aged 65 and Over to the Total Population
Source: OECD 2011

are not incentives for efficiency of the delivery system.
- In order to achieve better results, providers need to have the right level of autonomy. Government decentralisation will lead to good stewardship, and good accountability, monitoring and evaluation

will provide the required framework.
- Any discussion has to be based on data, facts and evidence, and not on ideology and presumption.
- Good practices need to be rewarded, progress celebrated, and, rather than putting blame, it is the great things achieved in the healthcare
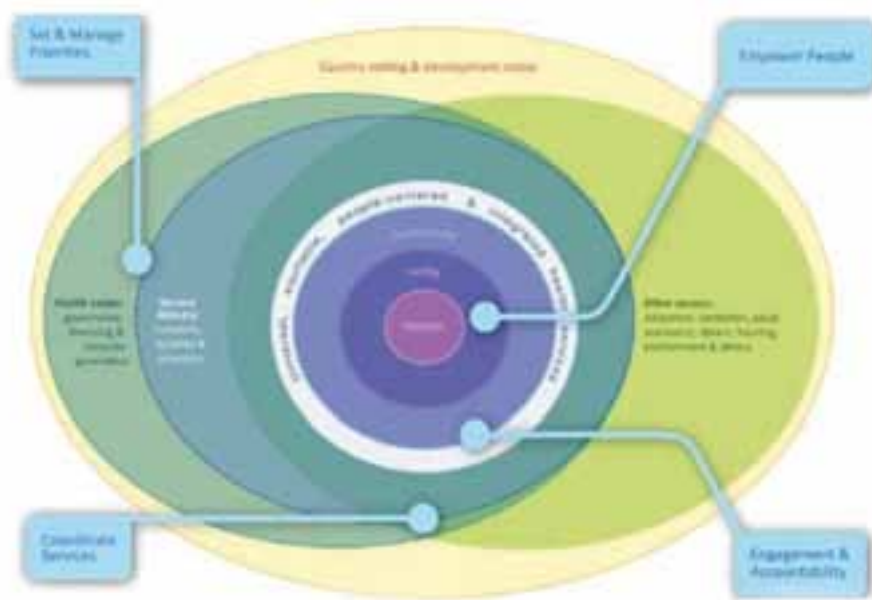
Figure 4. People-Centred & Integrated Health Services
Source: World Health Organization
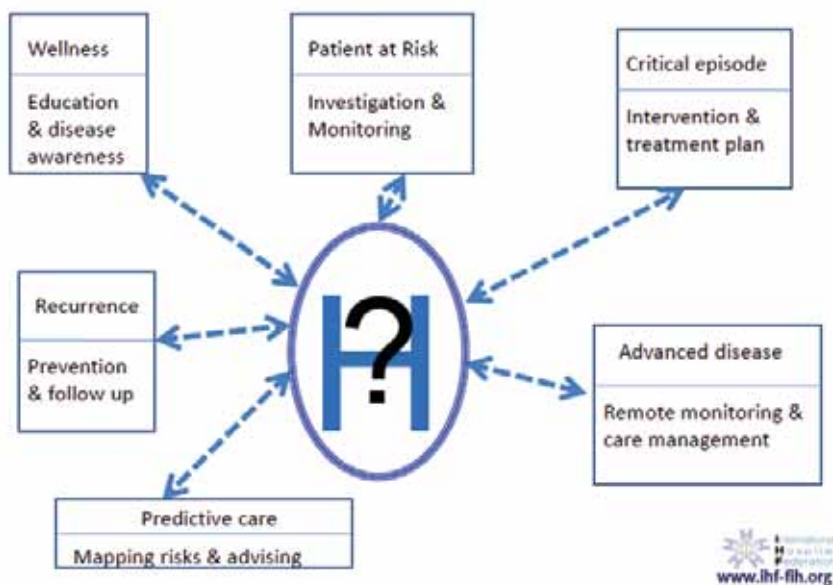
Figure 5. Role of Hospitals for Healthcare
Source: International Hospital Federation

sector which need to be communicated and promoted as part of a government's responsibility.

• Conditions need to be created in order to fully empower people with their health. The debate about chronic conditions includes each and every one of us as a potential patient, and we need to be empowered to deal with our own health.

• This transformation requires investment funds, which will have to be mobilised, also to fund research and dissemination of new effective technologies.

Responsibilities for providers, including hospitals

• Efforts on clinical pathways for multi-chronic conditions need to be made, as they are currently not well organised to deal with the burden they represent.

• A holistic approach to patients should be adopted. Patient conditions need to be dealt with and no longer just the symptoms or causes of a specific disease. This represents a whole paradigm shift, the whole reorganisation of the hospital that is ahead of us.

• There needs to be stronger accountability and transparency. Management matters and no compromises are to be made on quality and patient safety. ■

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DESIGN FOR CARE

THE COLLABORATIVE CHALLENGE OF WELLBEING IN LATER LIFE

Our Shared Challenge

We all know that we need to think differently about the health system in the 21st century if we are to meet the growing needs of the frail elderly. Not only is the demand for care outstripping the capacity of the state, but also the expectations of each new generation massively exceed that of the previous one. Are we thinking radically enough to meet this immense challenge?

Design Council, in partnership with UK health leaders, has for many years focused on creating innovative health and care products, services and models that might demonstrate a way forward. Often these innovations come from collaborations, which invite new players into the world of healthcare – individuals and organisations that bring ideas from other industries and sectors. Collaboration across disciplines, departments or organisations is hard enough, and collaboration across sectors can seem impossible, but open innovation methods are increasingly being employed by governments, corporations and nongovernmental organisations (NGOs) in order to tackle these complex challenges, which no single sector can resolve alone.

1. Think Differently

Design is a practical discipline that aims to reshape and improve the world one product, service or space at a time. But as much as design is about practical action, it starts with reflection. The future is never merely an extrapolation of the present,

> ## "IT IS VALUABLE TO BE OPEN BOTH ABOUT THE PROBLEM STATEMENT AS WELL AS THE COLLABORATORS"

and so carefully framing the opportunity for innovation – to describe how the world ought to be different and why - becomes as important as the act of innovation itself. Design Council developed the 'double diamond' model to illustrate this dual value of design thinking – on the left hand framing what success looks like, on the right hand creating those things that deliver success (see Figure 1).

So often our lack of ability to stand back, reconsider the world and imagine it as it might be means that we end up trying to solve new problems with old ideas. One of the most powerful ways to drive effective innovation, especially in healthcare, is to better understand the end user's point of view. Indeed, whether we label someone a 'patient', 'service user', or 'Mrs Jones' gives a clue as to whether we identify them as a whole human being, or whether we perceive him or her merely as a passive recipient of care. In the world of care, where increasingly we need individuals, their friends and family to take as much responsibility for themselves as possible, we need to remember that people have capabilities, hopes and dreams. This is the starting point of human-centred design.

2. Stay Open

Complex issues can be difficult to frame as simple problems, so linear problem-solving approaches can fail. Attempting to over-specify the problem statement too soon can end up with solutions to the wrong problem. Creative practice, in contrast, is likened to a process of inquiry where the problem statement is refined as it is resolved. Open innovation processes have proved themselves to be useful in this regard. Open innovation is the practice of engaging those outside your organisation to collaborate and bring their knowledge and perspectives to bear. What we have found is that for complex, systemic challenges it is valuable to be open both about the problem statement as well as the collaborators.

For example, when we were looking to generate new products and services that might help those with a diagnosis of dementia to live well, we left quite open the definition of what 'living well'

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Design Council

Double Diamond
Innovating through design

Discover
insight into the problem

Define
the area to focus upon

Develop
potential solutions

Deliver
solutions that work
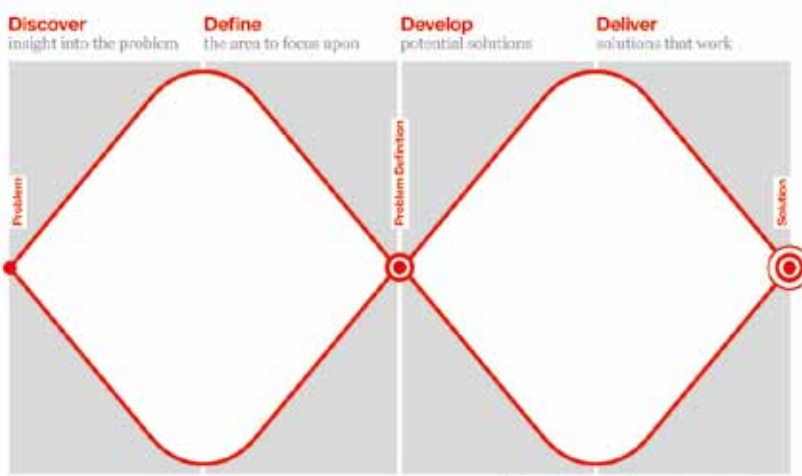
Figure 1
Image Credit: © Design Council
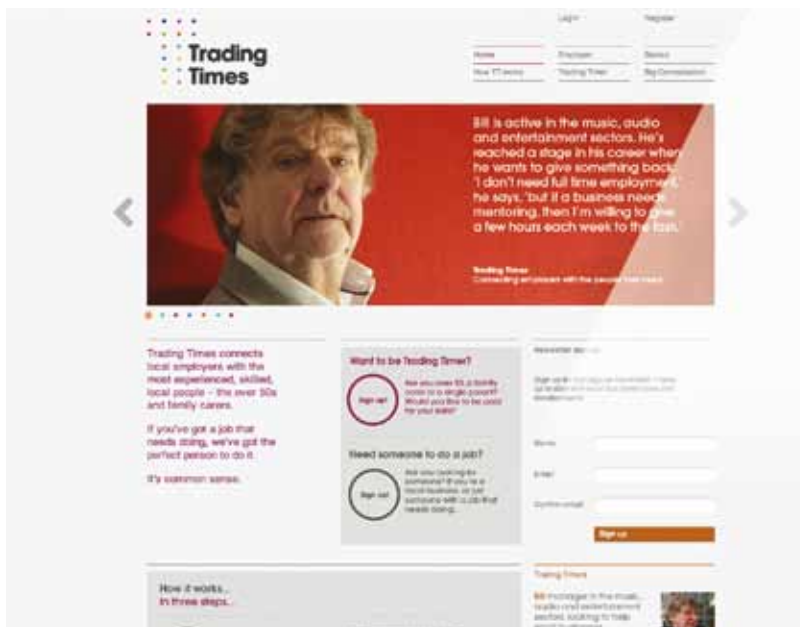
Image 1: Trading Times has now been active for two years and has expanded its role to sup-porting the over 50s whether they are carers or not. They are helping people to find work in 10 local authorities **www.tradingtimes.org.uk Image credit:** (c)Trading Times 2014

Image 2: Dementia Dog is a partnership between Alzheimer Scotland and Dogs for the Disabled and was initiated by Glasgow School of Art. There are three assistance dogs now in active duty with further assistive dog services being developed to meet less intensive need: 'intervention dogs' and 'facility dogs' **www.dementiadog.org. Image Credit:** © Hamilton Kerr 2013

Image 3: While the prototype designs co-created by the team have not yet received implementation funding, the Whittington engaged TILT in co-designing a new ambulatory care facility, which has since been opened to great acclaim by the Minister of State for Care and Support, The Rt Hon Norman Lamb MP **Image Credit:** © Tilt /Jill Tate 2013

meant. Ideas that we received ranged from assistive service 'Dementia Dog' to 'ode', a device that combats malnutrition via the stimulating effects of high-quality food fragrances, to 'Trading Times', a service for part-time carers to remain in formal employment. This variety of ideas is unlikely to emerge from a single organisation with a single mindset (see Image 1 and Image 2).

3. Co-Design
The common perception of design is that it is undertaken by one person,

pencil in hand, sketching on large pieces of paper. In the 21st century this is not how design happens. Design practice is much more likely to involve a room full of disparate talents, with post-it notes, cardboard and sticky tape, generating in real time, with frontline staff, the various artefacts and spaces and scripts that make up a product or service. This is known as co-design.

For instance, when we connected the architectural design practice TILT with the Whittington National Health

Service (NHS) Trust, they redesigned the pharmacy in collaboration with pharma-cists, patients and carers and other healthcare leaders. Why did they design 'with' rather than 'for' the hospital trust? TILT were not pharmacy experts and not responsible for the management and maintenance of the space. At the same time the Whittington staff could not have designed the space without the profes-sionals – those that were experienced in how to design spaces, had knowledge of successful ideas that could be applied from other contexts, such as retail design, and also were usefully naïve about what had gone before. It is this fusion of experience that matters, bringing together expertise and naïvety in order to apply what is known, but also to unlearn what is no longer appropriate to move forward (see Image 3).

4. Iterate Wildly
The process that we then use for helping such novel and risky ideas become reality, has drawn on Californian technology start-up culture. The 'seed accelerator', an innovation in venture capital investment, was built with the view that funding alone was not enough to maximise the chances of success in addition to finance.

For each challenge that we set, be it how to support independent living or how to live well with dementia, we accelerate a cohort of roughly ten ventures. This cohort is then

Image 4: Guidance Solution developed by Pearson Lloyd www.abetteraande.com
Image Credit: © Jill Tate/ Tilt 2013

supported to use creative and experimental methods to rapidly explore their ideas. In the case of 'ode', the fragrance system to combat malnutrition, the team started simply with adapting components available at their local hardware store. By substituting high quality food fragrances for the usual room freshener, and placing the contraption in a care setting, they were able to discover within a few days whether there was any effect at all. After that they could work out where best in the room to place such a device, what food smells worked best and more. This speed of experimentation meant that they learned very quickly what might work, before evaluating with ever larger sample sizes.

Ode was tested with over fifty individuals and families living with dementia. Over an eleven-week period, 50% of participants gained weight at an average of 2kg, and they continue to work with customers to evaluate ode's social impact in dementia (**www. myode.org**).

5. Evaluate Early
Impact evaluation of innovations is important, especially for healthcare, but evaluation so often is attempted only at a pilot stage, once many months have passed and much money has been spent. We collaborated with the NHS in order to

"EMBRACING A WIDE RANGE OF ABILITY IS SOMETHING POSITIVE FOR MAINSTREAM BUSINESS"

help generate a solution to the challenge of violence against staff in Accident & Emergency departments. The signage solution, devised by design consultancy Pearson Lloyd and co-designed with emergency department staff in three hospitals, is relatively low cost to install. It aims to provide everyone with a clearer sense of what to expect. The good news is that controlled evaluation showed a 50% reduction in threatening body language and aggressive behaviour, and 75% of visitors felt that their frustration was reduced during waiting times (ESRO & Frontier Economics 2013) (see Image 4).

Despite the success of this programme, we wondered if we could have evaluated earlier, to better decide what the best interventions might be. Could we have generated even more impact? A more recent innovation in our practice has come through our collaboration with behavioural scientists at Warwick Business School.

By collaborating with experimental psychologists, often running quite small controlled trials in a matter of days, we have brought more rigour to the experimentation than design naturally brings.

Design for Care
Given the development of this collaborative innovation practice over the past seven years, we have decided to put it to the test with a new programme, Design for Care. This programme aims to support the transformation of adult social care so that it is fit for the expectations and demands of the 21st century. The first step in thinking differently about this important challenge is to start by 'asking the right questions'. So far we have identified four areas that, from our conversations with health and care professionals, are ripe for development:

1. Growing Informal Care
How do we increase the care contribution of family, friends and the wider community?
A better integrated health and social care system will be unlikely to possess all of the public resources needed to meet demand. We have to think beyond integration, and look to a more collaborative approach, working with families, friends and the wider community to build sustained relationships. We need to design simpler ways for people to connect and support one another despite their busy lives.

2. Transforming Our Homes
How do we make homes that better support wellbeing?
As our needs change we have to adapt our living spaces, accommodating our changing physical and cognitive abilities. But how exactly do we do that, when there is so little available in the mass market and so little to which to aspire? We need to design better products, services and spaces, and show that embracing a wide range of ability is something positive for mainstream business.

3. Enabling Better Choices
How can we support people to make effective choices for their own care needs or those of a loved one?
More individuals are making care choices than ever before, as they manage personal care budgets or fund their own care. We need to support individuals and their carers to plan ahead as well as to help make

Image Credit: iStock

effective choices when they have a personal or family crisis. We need to design simple tools that make the most of the expert advice and support that is available, but also that help individuals work out what is right for them.

4. Places and Spaces for Care
What are the best environments in which to deliver collaborative care?
The quality of the built environment has a profound influence on our behaviours and experiences. If the expectation is

of a care system more personal, preventative and integrated, then where should care happen and what should it feel like? The GP surgery and hospital are not enough; we need to design new spaces in new places.

Our Shared Challenge
Our goal therefore should be not only to transform health and care sectors, but to galvanise all parts of society to meet our needs as we age, to share a much more rounded view of how to support

living well in later life. So, my challenge to you is simple: are you doing enough to collaborate with those outside the formal health and care system, those people who know what it is to live well and can help bring transformative thinking? ◼

Key Points

Five ways we see traction in stimulating more radical transformation in health and care, through design:

- ✓ Think differently
- ✓ Stay open
- ✓ Co-design
- ✓ Iterate wildly
- ✓ Evaluate early

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Further Information

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Design for Care www.designcouncil.org.uk/projects/design-care.

Guidance Solution developed by Pearson Lloyd www.abetteraande.com.

Ode www.myode.org.

Trading Times www.tradingtimes.org.uk

A LIFE COURSE APPROACH TO CARDIOVASCULAR AGEING

Although cardiovascular disease (CVD) is rare until middle age, it has long been known that the pathophysiological process of atherosclerosis, which ultimately results in disease, is initiated in childhood. In order to identify points of intervention early in the disease development process, well before the clinical manifestation of disease, it is important to understand age-related change in key CV risk factors, such as blood pressure (BP), and to identify exposures across life, which influence disease development. A life course approach provides a framework in which to do this.

Life Course Epidemiology

A life course approach in epidemiology investigates the biological, behavioural and social pathways that link physical and social exposures and experiences during gestation, childhood, adolescence and adult life, and across generations, to later life health, disease risk and ageing (Kuh and Ben-Shlomo 2004). Pioneering studies by David

"IT IS NOT JUST ADIPOSITY THAT IS IMPORTANT FOR CV AGEING"

Barker in the 1980s, which related low birth weight as a proxy marker of poor growth and nutrition in utero to increased rates of CHD, led to the development of the fetal programming or "Barker" hypothesis (Barker 1998). This hypothesis states that exposures during critical developmental periods have long-term consequences for chronic disease. Life course epidemiology emphasises the importance of early social, as well as biological, exposures. The impact of

early life socioeconomic conditions on adult health was initially seen as a competing model to the fetal programming hypothesis. Life course epidemiology also acknowledges the importance of adult lifestyle and risk factors, such as hypertension and inactivity, but recognises their tracking from childhood to adulthood. The life course perspective as outlined by Kuh and Ben-Shlomo thus integrated and extended these three apparently conflicting theories of disease aetiology; fetal programming, social causation and adult lifestyle.

More recently, the importance of age-related change in functional capability, measured with tests of muscle strength and physical performance (such as grip strength and walking speed) and cognitive performance, has been highlighted (Kuh et al. 2014). Functional capability, and the physiological systems (including the CV system) on which they depend, exhibit age-related change across the whole of life. With regards to CV ageing, and rather than simply focusing on disease, measures of cardiometabolic function, such as BP, lipids, and glucose and insulin, allow the full spectrum of function from high to low, to be investigated. Understanding how these markers change across life, identifying underlying 'normal' or 'healthy' trajectories, and the risk factors associated with deviation from these trajectories, are potentially important for fully understanding the development of CVD (Lawlor and Hardy 2014).

Life Course Studies and the MRC National Survey of Health and Development

A life course study may be described as a cohort study that has information from at least one stage of development (gestation, childhood or adolescence) and in adult life. This

distinguishes it from a general cohort or longitudinal study, where individuals may be followed up repeatedly, but over a shorter period of life. The ideal study design for research taking a life course approach is a birth cohort, which follows the same individuals from birth (or pregnancy or even pre-conception). The oldest such cohorts, for example the Medical Research Council (MRC) National Survey of Health and Development (NSHD), are only just now entering older age.

The NSHD, housed in the MRC Unit for Lifelong Health and Ageing at UCL, is based on a nationally representative sample of 5362 births that took place in one week in March 1946 in England, Scotland and Wales (Wadsworth et al. 2006). The study has a wealth of prospective information collected at all stages of life on body size, cognitive tests, and socioeconomic, psychological and lifestyle characteristics. At ages 36, 43 and 53, study members were interviewed in their own homes by a team of trained research nurses, allowing measurements of BP, lung function and cognition to be made. Between 2006 and 2010, when the cohort were aged 60-64, participants were invited to attend one of six clinical research facilities. Detailed vascular measures, such as carotid intima-media thickness (cIMT) and pulse wave velocity (PWV), were undertaken, and measures of cardiac structure and function were obtained through echocardiography (Kuh et al. 2011).

We highlight examples of research from NSHD to illustrate how a cohort study can be used to provide novel insights into CV ageing. First we outline research on BP trajectories, and second describe research relating two life course exposures, body size and socioeconomic conditions, to CV outcomes.

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Life Course Trajectories of Blood Pressure

Even with a measure as common as BP, there is still no single study with BP measured on the same individuals across the whole of life. An improvement over cross-sectional analyses of individuals of different ages, is to compare multiple longitudinal cohorts with repeated measurements that cover different periods of life. We used information on systolic BP (SBP) from seven UK prospective cohort studies, including the NSHD, each with BP measures cov-

> ### "HIGH WEIGHT IN INFANCY WAS FOUND TO BE PROTECTIVE, AND FAST INCREASES IN BMI DURING THE PUBERTAL PERIOD DETRIMENTAL, FOR ADULT BP"

ering different but overlapping periods of life from 7 to 80+ years (Wills et al. 2011). Four life course phases of SBP change were identified: a rapid increase coinciding with peak adolescent growth; a more gentle increase in early adulthood; a midlife acceleration beginning in the fourth decade; a deceleration in late adulthood where increases in SBP slowed and at very old age declined. The extent to which the slowing of the increase, or even decrease, in BP is driven by the survival of those who are most healthy, with lower BP, and less prone to premature mortality, or by effective BP lowering treatment, remains unclear. The decline was less evident in analyses excluding individuals on antihypertensive medication, suggesting treatment may play a role. But age-related weight loss, arterial stiffening and changes in the autonomic control of blood pressure are possible age-related processes, which could explain a decline (Reitz and Luchsinger 2007). An occupational, and thus more healthy, cohort exhibited a SBP trajectory, which did not begin the accelerated rise until a later age when compared with the general population cohorts. This variation, together with evidence of less pronounced age-related rises in

studies from non-industrialised farming populations, suggests the rise in BP is not necessarily part of the physiological ageing process, but is rather a result of western lifestyles.

Evidence is accumulating to suggest that the accelerated midlife rise in BP has implications for subsequent disease development. In NSHD adults belonging to a subgroup with more marked increases in midlife BP were more likely to have undiagnosed angina than other participants (Wills et al. 2012). Greater midlife increases in SBP were also associated with poorer cardiac structure at age 60–64 years (Ghosh et al. 2014). Greater BP increase between 43 and 53 years was a stronger risk factor of higher left ventricular mass index than more recent BP increase. Whether this finding represents a detrimental impact of rate of increase during a particularly sensitive period of adult life, or whether there is a lag effect which is independent of age, or is a result of reverse causality, remains to be seen. These findings raise the possibility, which should be investigated further, of identifying those at risk of future disease according to their rate of change in BP, rather than through a single measurement with a threshold for hypertension.

Life Course Factors Associated with CV Ageing: Examples
Developmental Origins of CVD

Since David Barker's original work, many studies have investigated the relationship between birth weight and CVD. Systematic review of the existing literature has found consistent association of lower birth weight with increasing rates of CHD (Huxley et al. 2007), and of lower birth weight and higher BP in adulthood (Huxley et al. 2002). There is only weak evidence of an association between birth weight and lipids (Huxley et al. 2004). Comparisons of multiple studies with BP measured at different ages suggested that the negative association between birth weight and BP, although initiated in utero, was amplified with age (Law et al. 1993). However, this might be a result of stronger associations in historical, compared to more contemporary, birth cohorts. The idea of amplification is equivalent to hypothesising that those of lower birth weight have faster increases in BP than others. Using the repeated measured of BP in

NSHD suggested that birth weight was associated with the level of BP in early midlife, but inconsistent with amplification, not with the rate of BP increase (Hardy et al. 2003). It should be noted that birth weight has been the most commonly used proxy marker of fetal growth, largely because it is widely available in historical studies. Contemporary cohort studies have collected more sophisticated measures of fetal growth through pregnancy, which should provide new insights into mechanisms, but such cohorts are still young in terms of disease progression.

Life Course Body Size

High body mass index (BMI) in late childhood and adolescence is associated with a higher risk of CHD, but there is less and somewhat conflicting evidence in relation to BMI in early childhood (Owen et al. 2009). The strength and direction of association may thus change with age at BMI measurement. Utilising the unique repeated measures of height and weight in infancy, childhood, adolescence and adulthood in NSHD, high weight in infancy was found to be protective, and fast increases in BMI during the pubertal period detrimental, for adult BP (Hardy et al. 2004). Greater gains in BMI in early adulthood were related to a worse adult lipid profile (Skidmore et al. 2007). A greater accumulation of time spent overweight during adult life was related to higher midlife BP (Wills et al. 2010), and to higher cIMT in early old age (Charakida et al. 2014). Importantly, in relation to cIMT, findings suggested that as well as delaying becoming overweight, loss of weight at any point in adulthood, even if temporary, may be beneficial to vascular health.

It is not just adiposity that is important for CV ageing, as shorter adult height is associated with higher rates of CHD (Paajanen et al. 2010). Adult height, and in particularly leg length, can be considered as a biomarker of early life environmental factors reflecting pre-pubertal growth. This was highlighted in NSHD, where leg length was more strongly related than trunk length to breastfeeding and higher energy diets in early childhood, and more advantaged early life socioeconomic environment (Wadsworth et al. 2002). In subsequent analysis, shorter leg length was related to both BP level and faster age-related increases in BP (Langenberg et al. 2005). This may suggest that detrimental early life influences on vascular structure

and function may increase vulnerability to the effects of ageing on the arterial tree. We have also demonstrated that taller height in early childhood was related to better adult lipid levels (Skidmore et al. 2007) and cIMT (Johnson et al. 2014).

> **"DISADVANTAGED CHILDHOOD SEP WAS ASSOCIATED WITH BOTH HIGHER BP AT AGE 36 AND WITH A FASTER SUBSEQUENT RATE OF INCREASE IN BP"**

Life Course Social Inequalities

Socioeconomic position (SEP) in childhood, as indicated by the father's occupational social class, education, income or living conditions, has been shown in a multitude of studies to be associated with CHD (Galobardes et al. 2006) over and above the influence of adult SEP. In the NSHD, disadvantaged childhood SEP was associated with both higher BP at age 36 and with a faster subsequent rate of increase in BP, such that the association

was stronger by age 53 (Hardy et al. 2003). Such amplification with age could explain why little association has been found in other studies between childhood SEP and BP measured in childhood and early adulthood, but associations between childhood SEP and adult BP have been found. In further NSHD research relating childhood and adult SEP to adult cardio-metabolic outcomes, disadvantaged SEP in childhood was found to be particularly important for men, more important than later life SEP, suggesting a sensitive period for exposure in earlier life (Murray et al. 2011). In contrast, for women, accumulation of

socioeconomic disadvantage over the whole life course predicted poorer cardio-metabolic health.

Conclusion

Evidence from the NSHD and other longitudinal studies suggests that changes in cardiovascular function start early in life, well before the manifestation of disease, and that early life risk factors are involved in initiation of adverse functional change. Understanding the development and progression of disease across the life course is vital to identify potential early interventions to prevent CVD. ■

Key Points

- ✓ Life course epidemiology provides a framework in which to study cardiovascular ageing across the life course.
- ✓ Data from longitudinal cohorts studies following the same individuals throughout life are required to study cardiovascular ageing from a life course perspective.
- ✓ Understanding how markers of cardio-metabolic function (such as blood pressure, lipids and glucose and insulin intolerance) change across life and the characteristics associated with deviation 'normal' age-related change is key to fully understanding disease development
- ✓ Changes in blood pressure in midlife are increasingly being found to be associated with CVD progression and outcomes
- ✓ Factors from across life influence CV ageing; pre-natal and postnatal growth are associated with later CVD and cardio-metabolic risk factor trajectories, and social inequalities in CVD risk are initiated in childhood

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TECHNOLOGY SUPPORTS PATIENTS AT HOME

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The European Union is not alone in facing unprecedented demographic changes (ageing population, low birth rates, changing family structures and migration) that will have an impact on several sectors. The European population is becoming old very quickly, and this situation is leading to a scenario in which support to the elderly will no longer be provided by the active population as it was in the past.

In the past few years, the cost of care provision with respect to the Gross National Product (GNP) has shown a definite boost, due to several factors:

- New medicines or technologies are available on the market.
- The average age of the population and the incidence of chronic diseases have risen and increased the cost of population care provision.
- The economic crisis has impacted all the European Countries, reducing the level of prosperity of this territory.

Projections show that the cost of healthcare provision and the need for long-term care will rise continuously with respect to the GNP of the EU member states.

Making the elderly more active, for example by reducing the need for travelling, or increasing patient engagement, providing more opportunities, decreasing the social exclusion of this part of the population and rationalising costs and resources are the most promising actions that Member States and the European Union can perform in the near future.

The SPES (Supporting Patients through E-services Solutions) project is an initiative co-funded by the Central Europe Programme to implement several pilots based on telemedicine devices, applications and infrastructure, with the aim of improving patient experience and facilitating access to care anytime, anywhere. Even if the pilots involve a small number of people, the real purpose is to prove in a realistic environment that technologies can effectively improve the quality of life of patients.

The project aims also at demonstrating that solutions based on technological innovation offer an attractive way of cutting down expenses in various ways as, for example, by reducing the necessity of going to medical facilities, thus reducing travelling and waiting time, serving remote areas, and generally, the overall cost of medical care. The adoption of these technologies implies a re-organisation

"PARTICIPATION OF OLDER PEOPLE IN EXPERIMENTATION NEEDS TO BE MEDIATED BY TRUSTED INDIVIDUALS"

of the structure of the care system, and re-engineering of the process of supporting patients and providing care services. These are the highest barriers to be overcome.

The technologies used in SPES come from Ambient Assisted Living solutions, telemedicine, e-health devices and social exclusion tools. These are the most promising solutions for implementing healthcare services, with little direct impact on the healthcare system in use.

SPES is making its contribution to the "Internet of Things", which is demanding new application architectures. SPES partners, who became familiar with the integration of diverse technologies and systems, are exploring ways for the connection of SPES "objects" with established e-health systems at a regional level.

SPES worked in 4 different geographical contexts; the cities of Ferrara, Vienna, Kosice and Brno, and faced four different types of chronic diseases or social challenges: respiratory problems, dementia, social exclusion and disabilities.

The Approach

The SPES project aims at transferring the approach and results achieved in the implementation of the VI FP OLDES project (Older People's e-services at home), which developed telemedicine and tele-accompany services, designed to make the life of older people easier at home. For this reason, the aspects of implementing the solutions to provide services and the methodology to approach patients has become more important than the research into technical solutions or the development of new tools. SPES looked at the technologies market, from medical devices to laptops, from GPS trackers to advanced RFID tags, to find the necessary tools to realise new services or to offer improved services to patients.

Patients had the opportunity to experience an easy-to-use telemedicine solution designed to meet the needs identified in each pilot project. For example, in the pilot in Ferrara, one of the objectives was to lower their displacement costs and the time required for going to care providers (hospitals, physicians, medical centres), improving their daily life and general well-being. In Vienna, the support to patients, relatives and caregivers played a relevant role so solutions for patients affected by dementia became one of the central elements of the experiment.

Dealing with real patients and real data in an inter-countries realm, SPES represents

taking, viewing, registering and sending clinical data

communicating with the nurse/specialist

webcam

heart rate measurement

appointment agenda

oxymeter

heart rate measurement

answering clinical questionnaires

communicating with the nurse/specialist

webcam

appointment agenda

taking, viewing, registering and sending clinical data

answering clinical questionnaires

heart rate measurement

one of the most advanced activities in tele-medicine, and faced several constraints originating in the confused legal framework on health data management. Laws on privacy and personal data management vary from country to country, and are often in contrast with each other.

The Methodology
The experiences of the partners in previous projects suggested pairing a partner active in social service provision with a technical one from the same country. This solution impacts on several aspects and improves the quality of the results. Having

a pair of partners working together in the same pilot, speaking the same language, and having the same cultural/social background reduces misunderstandings. It also allows the identification of requirements in a more precise way, allowing the social partner to express its expectations/needs in the same language and with clear examples to the technical partner, who in turn is able to express these needs with more precise technical details. In turn, the technical partner helps the social partner install technical solutions, reducing the time required for testing and effective use of the platform. Strong collaboration

between social and technical partners has led to the creation of new software and the identification of more use cases than planned, increasing the quality of the final results.

**Working With Patients –
The Experience in Ferrara**
The low population density and the high ageing index generated in the Ferrara Province a higher healthcare cost, partly because of the increase in demand, also because of the consistent distance between the patient's home and healthcare services.

The challenge was to assure continuous and integrated high-level healthcare provision to patients suffering from chronic diseases, using telemedicine solutions.

The telemedicine system consisted of sensors for remote monitoring of physiological parameters. The following devices and instruments were selected:

1. A touchscreen tablet for patient interaction with the telemedicine platform - answering clinical questionnaires, taking, viewing, registering and sending clinical data, communicating with the nurse/specialist by mail, webcam and appointment agenda.
2. An oxymeter for blood saturation and heart rate measurement.
3. A spirometer for measuring altered respiratory functions in order to evaluate patient response to therapy and immediate detection of worsening health conditions.
4. A web portal that allows administration of users and devices and the visualisation of direct output of the data collected by the oxymeter, the spirometer and clinical questionnaires.

For the purposes of the project, no specific skill related to the computer and/or medical devices was required from the patients. Patients and their caregivers were taught about the functionalities of the devices and activities they needed to perform.

PATIENT A: "I am satisfied because I have the chance to monitor my health by myself by answering the questionnaires and measuring my blood saturation."

PATIENT B: "I find it very positive to self-monitor my health. It makes me feel more self-confident. I would like to keep using the oxymeter and the tablet. If I cannot keep it I'll buy it."

Patients refer to feeling more self-confident, for three main reasons:

1. They perceive that the specialist constantly monitors their health conditions, at least once a day.
2. They are able to directly check their health parameters themselves also by using the questionnaires.

3. They can better control their lives by having their health parameters monitored by clinicians, and feel empowered by the opportunity to be monitored at home.

The patients have appreciated the possibility to visualise and store clinical data measured with medical devices, discovering the importance of the constant monitoring of their health status.

SPECIALIST: "Telemedicine amplifies the amount of time needed to relate with the patient: this means that the professional needs more time. This requires specific and structured spaces in the organisation of healthcare provision and dedicated and skilled personnel."

"THE EXPERIENCE WITH SPES IS EXTREMELY POSITIVE, DEMONSTRATED BY THE POSITIVE FEEDBACK RECEIVED"

Specialists refer to their satisfaction with the SPES platform because:

1. They are able to remotely and constantly monitor patients' parameters.
2. They are satisfied because patient empowerment is enhanced by self-monitoring.
3. They are more capable to define the medical follow-up agenda according to the health condition, redefining priorities.
4. All patients refer they are willing to continue the experience acquired with SPES.

Working With Patients – The Experience in Vienna

The Vienna pilot in Austria endeavoured to elaborate tailor-made solutions for people with dementia, whose problems ranged from poor memory to complete disorientation. Among other health risks, many of the people tested were prone to accidents because of

their tendency to lose their way in the street, or due to problems organising their everyday life at home.

Discussions with potential users, their families and caregivers, as well as social workers and therapists led to a focus being placed on localisation, orientation and reminder functions in daily life as well as brain stimulation.

Five test cases were derived from the requirements identified:

- The test case 'Orientation support' provided the possibility to support people in case of emergency, with the aid of GSM/GPS localisation devices without restricting their movements;
- The test case 'Preventing dangerous situations' referred to a system expanding the localisation device by including an RFID alarm to be activated when a disoriented individual got into a potentially dangerous situation, eg when he was about to leave his personal safety area' (garden, terrace, daycare centre, flat, house etc.).
- 'Talking Key' meant that with the aid of RFID tags, the individual concerned could be reminded not to forget the keys when leaving the flat.
- 'Finding Things again' described a function which helped people to find lost objects using RFID technology via a touchscreen PC.
- In the test case 'Brain Stimulation' test, the patients used a touchscreen PC to activate recollections from their long-term memory. An individually-combined selection of videoclips, songs, music and photos could be accessed by touching the screen. Other reminders concerned the daily routine of the people participating in the test.

The target group was a heterogeneous user group in terms of diagnoses, phases of dementia and age. This was reflected in a large number of user requirements (intuitive operability, varying reaction time, volumes of acoustic signals and frequencies necessary to be audible, varying reactions to touchscreen PCs etc.) Only six of the people tested had any experience with information technologies prior to the project.

Two test cases ('Brain Stimulation'

and 'Finding Things Again') involved the operation of functions on a touchscreen PC, while three test cases ('Orientation Support', 'Preventing Dangerous Situations' and 'Talking Key') required the test persons' passive utilisation of devices and systems.

The ''wow'' application, continuously developed and designed on the basis of experiences within the test-case 'Brain Stimulation', included a specific user interface designed for older people with dementia. The modules best accepted by the people participating were those for accessing the Internet, personal memory books (termed 'eScrap-Books') and radio.

The applications which were used depended on the tested persons' interests and their current stage of dementia. Individuals with migration backgrounds could easily access programmes in their first language, which helped them reduce stress and feel comfortable with the test settings.

For individuals in advanced stages of dementia, eg in the stage of temporal confusion, it was important to refer to childhood memories. Personal memory books with photographs from early childhood were of greater benefit than listening to songs. For those who liked music, the application of YouTube was very frequently employed. Simplified access to YouTube in the "wow" application made it possible to integrate very different music styles.

Most of the tests were carried out in daycare centres and flat-sharing communities for senior citizens. In the course of two and a half years, a total of 98 persons participated in the test activities, 54 of them women and 44 men.

Conclusions

The experience with SPES is extremely positive, demonstrated by the positive feedback received from all the people involved in the project and in particular from the patients.

The initial patients' diffidence has been overcome with the collaboration and involvement of the caregivers, who work with these patients every day and have gained their confidence.

The participation of older people in experimentation needs to be mediated by trusted individuals, who have to be aware of the potentialities of the technologies. Otherwise, approaching older people may lead to failure, and they may refuse technology.

In the Ferrara pilot, the constant interaction perceived by the patients increased their self-confidence and enhanced their actual health condition on the effective health status. The possibility to read and understand data from devices, to control the evolution in time of critical parameters empowered the patients by offering them new possibilities, like the possibility to daily self-manage their disease and self-administer therapies.

In the Vienna pilot, the experience acquired with patients affected by

"PARTICIPATION OF OLDER PEOPLE IN EXPERIMENTATION NEEDS TO BE MEDIATED BY TRUSTED INDIVIDUALS"

dementia, care providers and families was really positive, enhancing the safety of people inside the day-care centre or flats and outside. GPS solutions provided real support to families, reducing the risk associated with disorientation in these patients. Finally, the enhanced brain stimulation

performed with the aid of images or multimedia from the patients' youth, had a stronger impact on those individuals and on the results of rehabilitating therapies.

The barriers preventing the widespread adoption of telemedicine involve change management and human resources in addition to technological, financial and legal issues. A clear strategy and strong organisational support are essential to any telemedicine initiative. Without them, telemedicine efforts often fail to become institutionalised and a part of healthcare routines.

Even if the feedback from patients, doctors and caregivers is good in almost all the initiatives similar to SPES, the awareness of telemedicine possibilities in decision-making groups and in the population is very low and influenced by other factors than results. The use of telemedicine in real contexts and, why not, in inter-country realms is contained in the framework of personal data management and healthcare system organisation on a single-country level.

SPES partners will continue the experience gained with the actual project, trying to enhance the general awareness of the opportunities that ICT offers in the provision of healthcare services to European people.

This project is implemented through the CENTRAL EUROPE Programme co-financed by the ERDF.

For more information on the SPES project
http://www.spes-project.eu ■

Key Points

✓ SPES is a telemedicine project fostering the use of ICT solutions at people's home;

✓ SPES has involved more than 160 patients in testing solutions to improve their quality of life;

✓ SPES has not increased the cost of care provision;

✓ SPES is not a medical trial and does not aim at modifying therapies.

ORGANISATIONAL DEVELOPMENT

ACHIEVING CHANGE

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A wanderer asks a woodcutter in the forest the way. The woodcutter says that he has so much to do that he has practically no time for explanations. The wanderer then asks him if he has ever thought to sharpen his axe. To which the woodcutter says that he has so much to do that he has absolutely no time for that sort of thing. (Anon.)

A typical situation associated with the optimisation of processes in a hospital or a practice is as follows: *Staff members are asked whether they would like to take part in a working group / workshop. Everyone knows that this will be in addition to daily tasks. The answer is: "Can't do that now — too much pressure of work — later, perhaps". If the employee is nevertheless selected for the task, he or she will try to 'survive' this working group or workshop with the least possible effort, or cause it to fail by increasing the degree of complexity. If such employees are also senior managers of staff, this has an especially limiting effect on the organisation's development potential.*

Attempts to achieve successful organisational development often fail. Anyone who has held workshops with unprepared and unwilling participants, complaining that they are losing time they need for their 'real' work, will already know some of the causes.

Reasons for Failure

1. Not 'tried and tested', doubting Thomases: Senior managers cannot be persuaded of the need to depart from 'tried and tested' procedures and privileges. Everything seems fine on their 'island' (eg full complement of staff, an acceptable balance between pressure of work and salaries, sufficient (private) patient numbers). Then there are strategies and concepts for change that are presented by senior managers, who do not believe that they can be implemented. The defenders of vested interests, the doubting Thomases and the pessimists take the helm!

2. Always done this way: New challenges require new processes, structures and modes of thought. However, senior managers try to solve today's problems by using yesterday's methods ("We've always done it that way.") The old way, with well-known structures and procedures, achieves more individual performance while maintaining quality and using existing equipment and rooms, but fewer staff. Generally, this 'prescription' leads to failure and frustration. The old structures are already at their limits; all room to manoeuvre has long since been used up.

3. Stick to specialty: Top level and senior staff often seek refuge in operative activities related to their specialities ('safe ground' — That's what we have been trained to do, that's why we became doctors, administrators etc.), either because they are afraid of the strategic challenges involved in developing processes, structures and staff, or they do not like that kind of work. Organisation of procedures and structures in hospitals and practices is accompanied by unrest and scepticism, and invites resistance: not many people wish to take such things upon themselves.

4. Social and leadership skills not integrated into change strategy: There is no systematic and sustainable process for developing the social and leadership skills of present and future senior managers. For example, a 'Leadership Workshop' organised by the human resources department and presented by external experts ("You'd better go along, too"), is not backed up by a sustainable change strategy (monitoring, systematic refresher courses) with an assessment of results. Isolated courses for senior managers that are not integrated into a change strategy for existing processes and structures (eg for reporting

structures and hierarchies) are pointless and useless, as what is allowed is not in line with the knowledge that has been amassed and the will to implement it. It is often not clear where responsibility for senior staff development lies.

5. Change management is an 'add-on': There is no professional, systematic change management. Change management is not an 'add-on' task to be addressed at the end of a busy daily routine, but the main task for qualified, specialised, additional staff. Often, the way things develop and the results achieved are not properly monitored and weak points in management remain unaddressed. This is when the PDCA cycle (plan-do check-act) has no effect outside management seminars. If these issues are not addressed professionally, sustainability falls by the wayside, and in a short space of time things are back to square one.

6. Information dissemination is poor: The medium and long-term targets of the hospital may be discussed at great length by senior management. However, this does not trickle down to other employees, despite general statements distributed via newsletters, information meetings etc. (Lack of feedback on the quality of the information management.)

7. Stick to the familiar: Where defenders of privilege and doubters rule, there is no room for clear decisions that lead to definite consequences — rather stick to the familiar (and hopefully improve it a little).

8. External consultants are hired: When things have to change, external consultants are called in to supply the missing competence in an environment they do not know well, and for which they

cannot be well prepared. Someone who does not have the capacity to introduce and implement change generally also has no capacity to put systematic monitoring in place to ensure sustainability (processes, structures, persons), and does not have to communicate uncomfortable news personally.

9. New processes and structures slotted in: Persons have to adapt to (be selected to fit in with) the necessary (new) processes and structures. Often, processes and structures (and implicitly the patients) are adapted to the people who are there already.

Successful optimisation takes place in the following order: first the processes, then the structures, then the staff need to adapt/develop.

Following a laborious learning curve consisting of the failed experiments of the old guard of senior managers, leading to no change in the processes, structures and staffing, new senior managers are appointed. They put everything that has been learned into question, and the cycle begins anew. New senior managers are given the brief to improve what is already there. However, when one turns 180°, and does the same thing again, one ends up pointing in the original direction.

Examples for this are:

- The introduction of treatment paths (no sustainability);
- The introduction of new, interdisciplinary and autonomous centres with the aim of optimising overall processes across departments (new name in old responsibility structures);
- Certification (everything gets described, nothing gets done);
- Systematic, multi-project management, transparent for all employees (soon forgotten after the end of a workshop);
- Internal cost allocation for performance items (brief attempt to optimise costs without evidence of sustainability);
- Budgeting on diagnosis-related group (DRG) shares (short-term attempt at implementation after a workshop);
- Systematic personnel development (uncoordinated individual measures without overall plan).

If you enquire into the result of a workshop not only immediately afterwards, but a year later, often nobody can remember the workshop and the results have been forgotten. However, nobody has noticed this, because by good luck the economic results have improved again, so there is no more pressure to act. When strategies that have been agreed fade from memory without consequences, this represents a poor basis on which to build future developments.

"CHANGE MANAGEMENT IS NOT AN 'ADD-ON' TASK"

Within existing structures, the 'energy' of a hospital is still sufficient for individual measures (workshops, seminars). However, sustainability can only be guaranteed through integration into a long-term concept with regular monitoring and refreshment, as well as personal responsibility. Optimisation of processes and structures must be carried out on time and with considerable organisational effort.

Tips for Success

- As a manager, clarify how things stand with your capacities, your wishes and what you are allowed to do before starting a task! When senior managers are commissioned to undertake tasks and projects, often the framework conditions are not sufficiently defined and discussed, perhaps because they are not clear to whoever issues the commission. No project work can be successful where the prerequisites and framework conditions are unclear and insufficient time is allocated.
- Where strategic thinking is missing, workshops with external experts are rarely useful. Workshops are a (useful) part of operative business, not of strategic planning.
- Working in projects requires future project leaders to go through a learning and practice phase. Successful project managers must have methodological, subject-specific authority and maturity of outlook. in order to inspire confidence in the participants.
- Project managers should be versed in the 'art of red lights' - with experienced project managers, these light up at a very early stage when there is a danger of things going off course. Then, it will be necessary to conduct time-consuming personal individual interviews, perhaps to pinpoint personal points of sensitivity. This requires experienced
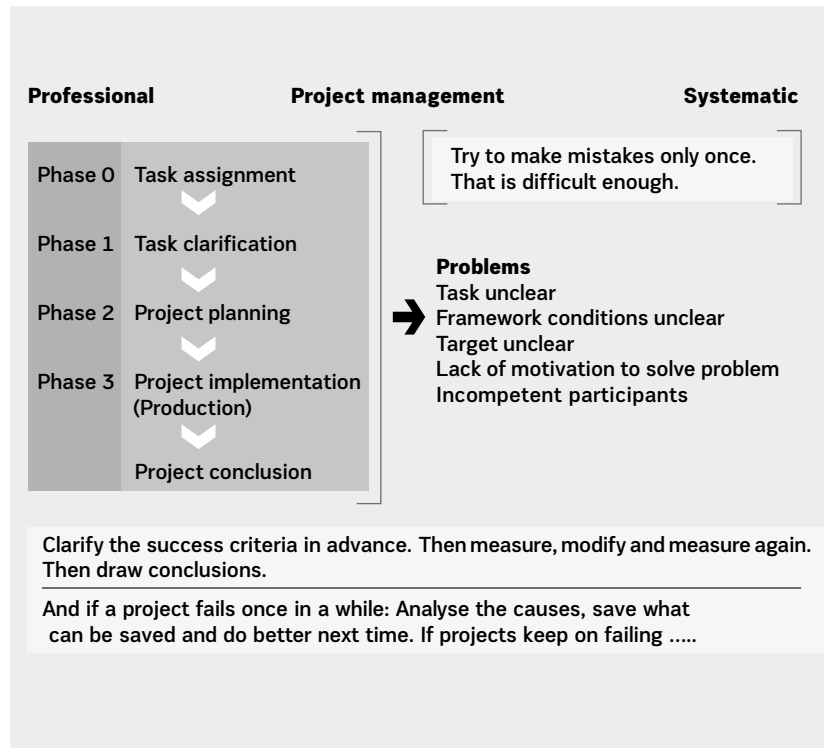
Figure 1. Problems and Hazards of Project Management

project managers with authority.

- It is better to pass up a task at an early stage rather than try to execute it when one already knows that it will not succeed.

In poorly managed organisations it is still possible to get away with: "Say yes and do nothing — sooner or later it will be forgotten." That does not work in a well-run organisation. Another tactic used by unwilling participants is to engineer a rapid increase in the degree of complexity involved so as to render the project task impossible. In such cases the project manager should concentrate efforts strictly on what is essential if necessary using a dose of authority.

Tips for Project Managers

To conclude, the author would like to present examples, hints and tricks gathered over 25 years of personal experience for discussion and as a stimulus.

- Address employees in their (mental) situation as it actually is, not as it should be.
- Don't overestimate the available social and managerial competence.
- Take account of individual egoism on the part of the participants ("What's in it for me?").
- Don't rely on information being passed on properly (use smaller information units). You can only rely on rumours and scandals being passed on faithfully!
- Without systematic repetition (practice) and regular monitoring information is quickly forgotten. If there is not enough energy

available to push things through (processes, structures, staff), then don't even start!
- Take a lot of time for personal conversations.
- Make sure that a positive climate of change is there before the workshop starts.
- Try to make sure that nobody is seen to be the 'loser' of a conflict.
- The 'face-saving' part of the task is often the most difficult, but it ensures that there are no open sores and enmities afterwards.
- Never take important decisions spontaneously (think it over first — sleep over it at least once).
- Before drawing conclusions and making decisions, first check the quality of the available information.

"CHANGE MANAGEMENT IS NOT AN 'ADD-ON' TASK"

- When a problem presents itself, make an assessment of its significance and effects. When assessing problems, be aware of the difference between the volume of the cheese and the volume of the holes between! Don't spend disproportionate amounts of your time on organisational rarities (first draw up a statistic — and remember the Pareto principle). Then either solve the problem or ignore it steadfastly.

- Don't allow every problem to find its niche on your back!
- Delegate and monitor — although the responsibility remains yours.
- Don't forget anything (use IT tools or at least a note on your desk).
- Don't start a working group for reasons based on your own strategic and operative helplessness. Talk to each participant in advance (and privately) and make sure of his or her competence and motivation.
- Formulate initial, clear targets and framework conditions in writing that are not subject to debate.
- Bring order into your dealings that is visible to others. (Sometimes a desk is a mirror of the head that owns it.) Senior managers are responsible for the way the department and the staff present themselves to the world. Quality must be made visible through an attractive ambience.
- A key organisational factor is a visually appealing reception area staffed by very competent people and always 'open for business'. This makes for a good atmosphere prior to diagnosis/therapy, and represents a useful pre-emptive defence against complaints and legal disputes.
- Live out what you demand of others! ■

Key Points

- ✓ Organisational development in hospitals and practices often fails.
- ✓ Explores the human factors behind this failure.
- ✓ Tips for success and tips for managers in project management.

AUTHOR'S NOTE:

This paper is intended to encourage critical reflection. It reflects to a small degree personal experience gained in the Hospital Krankenhaus der Barmherzigen Brüder, but it is based on many of my own management conferences and management training sessions, advice provided to other hospitals and practices, regular exchange of information with management consultants, readers' responses to my books and publications and frequent requests for help that I have received from fellow senior consultant and doctors. From the perspective of one's own, well-directed hospital, in which it is a pleasure to work, this contrast appears especially stark, perhaps a little overstated. For a number of successful hospitals and practices, the content of this contribution will apply only in part or not at all. It is the aim of this contribution to increase that proportion.

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CREATING STRONGER BONDS BETWEEN HEALTH MANAGERS AND CLINICIANS

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Managers and clinicians in health and social care are committed professionals working towards a common goal - achieving better patient outcomes - but tensions in the relationship can risk getting in the way of driving forward service improvement.

Managers and clinicians, in whatever area of health and social care they work, are on the same side. Both strive to provide the best possible patient experience of care in an increasingly challenging environment, bringing to their roles enormous professionalism, experience and commitment. However, as in all relationships, unhelpful tensions between the two can - and do - arise, not least because within the overriding desire to improve services, conflicting priorities sometimes emerge.

So what of the history of this relationship? The Griffiths report (1983) heralded the age of general management in the NHS. A move towards managers having operational control at every level of the organisation and relieving clinicians of strategic responsibility was seen as the way to transform healthcare to resemble successful private and commercial organisations.

Clinicians may not have agreed. Literature confirms that non-engagement between themselves and managers is a long-standing, multi-factorial and international problem. A 2007 review from the Health Foundation noted:

"Different health professional groups largely inhabit separate hierarchies and networks, often with surprisingly little inter-communication. Thus, different professional groups often do not define quality in the same way. Moreover, the processes of determining what constitutes good or quality practice within an individual profession are complex and sometimes divergent between different professional groups." (Davies et al. 2007).

Change is a constant in health and social care. In more recent years there has been an increasing importance placed on clinicians working in multidisciplinary teams and across professional and organisational boundaries. Indeed the High Quality Care for All report from Lord Darzi put clinical leadership at the heart of improving the National Health Service (NHS) (Department of Health 2008). In some cases, such as at Hinchingbrooke Hospital, Cambridgeshire,

"CHANGE IS A CONSTANT IN HEALTH AND SOCIAL CARE"

clinicians were put in charge, as it was deemed that they understood what worked best, and that giving power back to them was the way to drive up productivity.

This change in emphasis is supported by a growing body of evidence, which shows that clinical leadership improves quality and outcomes for patients (Mountford and Webb 2009). Kirkpatrick and Veronesi (2012) found that those NHS hospital trusts with larger proportions of doctors on their boards were more likely to achieve high quality ratings, lower morbidity rates and higher patient satisfaction.

The evidence also shows a clear link between an organisation's performance and a good level of engagement between clinicians and managers (Spurgeon et al. 2011).

Where are we in 2015? The endless cycle of reform in the NHS has not been helpful. Structural change within any organisation almost invariably leads to tensions, and one of these strains has been on the relationship between clinicians and managers, which has been described as 'fraught' and 'tense' (Mountoute 2012).

A small survey of just over 200 managers, carried out by IHM recently, confirms this. Nearly three-quarters of managers (73%) said they thought the relationship between the two groups of professionals could be defined as "a partnership with areas of tension" or "a relationship of tolerance with frequent tensions". A similar number (73%) thought the relationship would stay the same or get worse over the next five years (Institute of Healthcare Management 2014).

Isolated versus Powerless

The differing ways in which the two professions approach the challenge to improving health contribute to the tensions between them. Clinicians focus on the patient in front of them, aiming to offer that individual the best healthcare they can. But they can be frustrated by, among other things, financial constraints.

Being a doctor often does not feel powerful, as the 2012 King's Fund report *Leadership and engagement for improvement in the NHS: together we can* noted:

"They may have no budget, no status to make demands on the administration, no power to hire and fire, and little influence over the organisation's goals. Yet the decisions they take not only have a profound impact on patients, but on the quality of care, productivity and reputation of their employer."

The strains on managers are different, but no fewer. Their focus is on broader patient populations and allocating resources within a budget at organisation level to maximise health outcomes. It is a huge job, and, although the days of

the 'heroic leader' are clearly numbered or even over, sometimes isolating. They are often caught in tensions between financial, safety and quality requirements and, although they may share the same goal as clinicians, the context and structure they work in may have a set of parameters and limitations that the clinicians do not fully appreciate.

Clinicians and managers have both highlighted a number of facilitators to fostering a positive relationship. They include trust, mutual respect, support, accessibility, visibility, good communication, close proximity, mutual interdependence and friendship (Mountoute 2012). Identifying and listing positive facilitators is easy. However, successfully implementing them in a working environment is much more difficult.

Calls to Action
Without the engagement of clinicians, it is clear that managers may find themselves fighting a losing battle to implement the required changes to address the improvement agenda. With this in mind, the IHM is making a number of calls to action.

One way for clinicians and managers to explore each other's roles and responsibilities is through paired learning and shadowing initiatives. Paired learning initiatives, such as those piloted at Imperial College Healthcare NHS Trust during 2010-11, invite both clinicians and managers to spend time learning about each other's roles and responsibilities (Imperial College Healthcare 2015). By spending time training with and shadowing those in different roles, clinicians and managers can better understand one another's viewpoint when making important decisions.

IHM believes that joint management training programmes and events should support these initiatives. Clinicians,

like managers, need development and support. The IHM survey suggested that they would benefit, in particular, from training in managing staff and budgets, business planning and organisational change (Institute of Healthcare Management 2014).

It will also be important to create working environments that encourage informal interactions between clinicians and managers to help build trust and interdependence between the two professions.

Small, informal changes in the working environment have the potential to improve the clinician-manager relationship. Close proximity to one another can lead to relaxed, spontaneous contacts outside of the formal working setting. Sharing an office, being down the corridor or sharing a kitchen area have all been cited as possible ways to enhance accessibility and cultivate strong relations (Mountoute 2012).

In the past, doctors have been accused of cynicism and suspicion regarding managerial motives (Wilkinson et al. 2011). Frequent informal interactions can help alleviate these uncertainties and build trust between professions who are ultimately striving to achieve the same goals.

IHM believes that the involvement of doctors, nurses and other clinicians in leadership roles, working closely alongside their managerial colleagues, must also be a priority for the current and successive governments in the UK. An organisation as large and complex as the NHS cannot be run without high-quality management and leadership. People in those roles must be trained, empowered and valued whatever their background.

It should also be recognised that individual clinicians and managers bear some responsibility for deciding on the changes they can make to improve their relationships with one another. ■

Key Points

✓ Despite working towards a common goal, managers and clinicians frequently experience unhelpful tensions in their relationship as a result of conflicting priorities.
✓ The Institute of Healthcare Management investigates causes and offers solutions to address these issues and enhance communication between managers and clinicians.

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PUTTING QUALITY AND SAFETY FOR PATIENTS FIRST

ESR EUROSAFE IMAGING

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The demand for medical imaging examinations is constantly growing, and safety and quality in radiological practice are more important than ever. The European Society of Radiology (ESR) has taken a major step in raising awareness of the importance of radiation protection with the launch of EuroSafe Imaging at the European Congress of Radiology (ECR) in March 2014.

With the establishment of this radiation protection initiative, the ESR has created a new and comprehensive framework for its efforts to improve quality and safety in medical imaging in Europe. The initiative is led by the EuroSafe Imaging Steering Committee, whose composition reflects the ESR's multidisciplinary approach. Charged with setting the campaign's strategy and overseeing its implementation, the steering committee is chaired by ESR Past President Prof. Guy Frija, and consists of representatives from the ESR, the European Federation of Organisations for Medical Physics (EFOMP), the European Federation of Radiographer Societies (EFRS), the patient organisation European Federation of Neurological Associations (EFNA) on behalf of the ESR Patient Advisory Group, industry group COCIR and an observer from the European Commission. Outreach to other professions including cardiologists, orthopaedists and general practitioners is planned for 2015.

EuroSafe Imaging's mission to support and strengthen medical radiation protection across Europe following a holistic, inclusive approach has been translated into the following main objectives:

- promoting appropriateness and justification of radiological procedures;
- maintaining radiation doses within diagnostic reference levels (DRLs);
- promoting the application of the 'as-low-as-reasonably-achievable' (ALARA) principle;
- the use of up-to-date imaging equipment;
- developing a strategic research agenda in radiation protection
- empowering patients through better information and communication;
- joining forces by bringing together a variety of stakeholders.

In 2014, EuroSafe Imaging started implementing measures to deliver its mission by developing a comprehensive strategy in the form of the EuroSafe Imaging Call for Action, which was launched in September 2014. The EuroSafe Imaging Call for Action is designed to support the

> ## "EUROSAFE IMAGING'S MISSION IS TO SUPPORT AND STRENGTHEN MEDICAL RADIATION PROTECTION ACROSS EUROPE"

International Atomic Energy Agency and World Health Organization's 2012 Bonn Call for Action, which identifies responsibilities and proposes priorities for stakeholders regarding radiation protection in medicine (International Atomic Energy Authority and World Health Organization 2013).

EuroSafe Imaging's 12-point action plan will make a significant contribution to each of the ten priority areas in the Bonn Call for Action, and it is also geared towards realising the campaign's own objectives regarding appropriateness, DRLs, the ALARA principle, high quality equipment, as well as cooperation with patients and other stakeholders.

In the months following the publication of the Call for Action, considerable progress has been achieved on several fronts.

Implementation of Actions 1 and 9 started in November 2014, as an ESR expert group initiated the development process of European imaging referral guidelines, which will be adapted from criteria developed by the American College of Radiology (ACR). These guidelines will form the content for ESR iGuide (http://www.eurosafeimaging.org/information-for-referring-professionals-2/clinical-decision-support), a Clinical Decision Support platform for distribution in Europe to be developed in cooperation between the ESR, ACR and National Decision Support Company. A prototype of this system will be launched during ECR 2015.

The development of the ESR's clinical audit tool also progressed in 2014, as the level 1 clinical audit templates were finalised by the ESR Audit and Standards Subcommittee in early 2015. The official launch of the ESR's audit tool itself is slated for ECR 2015.

In assuming the lead of a European Commission project on paediatric diagnostic reference levels (DRLs) entitled 'PiDRL' (www.eurosafeimaging.org/pidrl), the ESR also contributed towards implementing measures to maintain radiation doses within DRLs (Action 3).

EUROSAFE IMAGING CALL FOR ACTION

Action 1: Develop a clinical decision support system for imaging referral guidelines in Europe
Implementing Bonn Call for Action 1: Enhance the implementation of the principle of justification

Action 2: Develop and promote a clinical audit tool for imaging to increase the quality of patient care and improve justification
Implementing Bonn Call for Action 1: Enhance the implementation of the principle of justification

Action 3: Implement measures to maintain radiation doses within diagnostic reference levels (DRLs)
Implementing Bonn Call for Action 2: Enhance the implementation of the principle of optimisation of protection and safety

Action 4: Promote the use of up-to-date equipment and provide guidance on how to further reduce doses while maintaining image quality
Implementing Bonn Call for Action 2: Enhance the implementation of the principle of optimisation of protection and safety

Action 5: Establish a dialogue with industry regarding improvement of radiological equipment, the use of up-to-date equipment and the harmonisation of exposure indicators
Implementing Bonn Call for Action 3: Strengthen manufacturers' role in contributing to the overall safety regime

Action 6: Organise radiation protection training courses and develop e-learning material to promote a safety culture and raise awareness of radiation protection
Implementing Bonn Call for Action 4: Strengthen radiation protection education and training of health professionals

Action 7: Collaborate with research platforms and other medical professions to develop a strategic research agenda for medical radiation protection
Implementing Bonn Call for Action 5: Shape and promote a strategic research agenda for radiation protection in medicine

Action 8: Develop data collection project "Is your imaging EuroSafe?" and educational project on guidelines "Are you imaging appropriately?"
Implementing Bonn Call for Action 6: Increase availability of improved global information on medical exposures and occupational exposures in medicine

Action 9: Develop criteria for imaging procedures that use ionising radiation in specific exams and anatomical regions
Implementing Bonn Call for Action 7: Improve prevention of medical radiation incidents and accidents and Action 8: Strengthen radiation safety culture in healthcare

Action 10: Improve communication with health professionals through EuroSafe Imaging Steering Committee, website, newsletters, conferences, training material and social media
Implementing Bonn Call for Action 8: Strengthen radiation safety culture in healthcare

Action 11: Improve information for and communication with patients regarding radiological procedures and related risks in order to ensure empowerment of patients
Implementing Bonn Call for Action 9: Foster an improved radiation benefit-risk-dialogue

Action 12: Engage with other stakeholders and collaboration with related initiatives and regulatory authorities in Europe and beyond to contribute to a global safety culture in medical imaging
Implementing Bonn Call for Action 10: Strengthen the implementation of safety requirements globally

Education and training to improve radiation protection is of particular importance to the ESR, and the inclusion of 12 modules on radiation protection in its e-learning platform 'Education on Demand' as well as the EuroSafe Imaging radiation protection orientation session held at the MIR 2014 Annual Meeting in Bologna, Italy in October 2014 were part of the implementation of Action 6 of EuroSafe Imaging's strategy.

With the launch of the cooperation with the research platform MELODI (Multidisciplinary European Low Dose Initiative) and the European Association of Nuclear Medicine, European Society for Radiotherapy and Oncology, EFRS, and EFOMP in 2014, the ESR showed its commitment to Action 7 of the Call for Action. Implementation of Action 8 was also started, as the 'Is your Imaging EuroSafe?' survey series was launched in the November 2014 edition of ESR News **(http://esr. frauida.at/gui/newsletter/newsletter.asp?languageId=1&newsletterId=26)**. The aim of these surveys is to build a European repository based on DRLs for those clinical indications most helpful for self-benchmarking, thereby also contributing to Action 3.

Conceived as an awareness campaign, communicating EuroSafe Imaging's efforts to improve quality and safety in medical imaging (Action 10) is essential. EuroSafe Imaging has published articles in journals and newsletters, issued press releases, and created a promotional video in 2014 (Available from: **https://www.youtube.com/ watch?v=jinJ3nwYDCU)**.

The ESR also enhanced its cooperation with patients (Action 11), as its Patient Advisory Group for Medical Imaging, founded in 2013, developed a 'driver diagram of patient-centred care'. Other patient-related activities included the publication of an article on EuroSafe Imaging in the European Patients' Forum's newsletter **(http://www.eu-patient.eu/ News/News/EuroSafe-Imaging-Campaign-Towards-Patient-Safety/)** and preparations to add more patient-centred information to the EuroSafe Imaging website.

Joining forces with a variety of stakeholders (Action 12) is an essential part of the structure of EuroSafe Imaging. Not only does the campaign directly incorporate external stakeholders in the EuroSafe Imaging Steering Committee, the ESR also utilises EuroSafe Imaging as a framework to actively engage with decision makers at the national, European and international level to effectively represent radiologists' interests. This includes relations with EU institutions, IAEA, WHO and Heads of the Radiological Protection Competent Authorities (HERCA), the association of regulatory authorities for radiation protection in Europe.

EuroSafe Imaging also aims to foster global cooperation on radiation protection by working with ini-

"THE ESR ALSO ENHANCED ITS COOPERATION WITH PATIENTS"

tiatives outside of Europe. A first meeting with the American campaigns Image Wisely® and Image Gently® was held in December 2014 to establish a basis for future collaboration; a follow-up meeting has been set for ECR 2015. Furthermore, EuroSafe Imaging supports the AFROSAFE project, an African radiation protection initiative to be launched in February at the 2015 Pan African Congress on Radiology (PACORI) in Nairobi.

EuroSafe Imaging will also feature prominently again at ECR 2015, where planned activities include a dedicated poster exhibition, six scientific sessions and an information booth.

The ESR invites individuals and organisations to support EuroSafe Imaging's mission of improving quality and safety in medical imaging by signing up to become Friends of EuroSafe Imaging at **www.eurosafeimaging.org**. ∎

ABOUT THE ESR

The ESR is the world's largest radiological society with more than 60,000 individual members from 155 countries, 43 institutional member societies across Europe, 15 European subspecialty & allied sciences member societies and 43 non-European associate institutional members. The ESR's mission is to serve the healthcare needs of the general public by supporting science, education, research, and quality of service in the field of radiology.

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BREAST MRI

THE NEW STANDARD IN BREAST IMAGING?

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Breast MRI is standard practice in all major breast imaging clinics worldwide. This is due to the unrivalled sensitivity of breast MRI, reported to be between 90 and 95% (Peters et al. 2008; Phi et al. 2014). Moreover, the three-dimensional nature of the examination allows a much better understanding of the spread of eventual disease throughout the breast (see Figure 1). Detailed guidelines on techniques and indications have been published that allow state-of-art practice in virtually any clinic (Mann et al. 2008; Sardanelli et al. 2010). In fact, every new modality on the market is nowadays compared to breast MRI to assess its clinical value. However, breast MRI is also viewed as a very expensive modality that, while presenting beautiful images, does more harm than good. In this article the reasons for these sharp contrasts are discussed, as well as the need for further investigations in the field of breast MRI specifically and breast cancer treatment in general.

Preoperative MRI

From the introduction of contrast-enhanced breast MRI in the mid-1980s (Kaiser 1985; Heywang et al. 1986), it was clear that a new era in breast imaging had started. It became possible to assess breast cancers in three dimensions, and detect many tumour foci that were completely occult at mammography or ultrasound. In recent years, despite the large improvement in the quality of conventional methods, the additional gain of breast MRI in women with breast cancer remains impressive. Additional tumour localisations, often changing the therapeutic management of the affected breast, are detected in, on average, 20% of patients. Moreover, otherwise undetected second cancers in the other breast are found in up to 5.5% of women (Plana et al. 2012).

Transition of these findings to therapeutic protocols and operating theatres is slow. This has several major reasons: the first is that from pathology studies it has always been clear that not all cancer present in the breast is visible in imaging studies. In fact this has been exploited, as tumour resections are nowadays aimed at removing the palpable or visible tumour and not so much at complete excision of all cancer present in the breast. After surgical debulking, radiotherapy and adjuvant chemo- and hormonal therapies are supposed to treat the remaining cancer cells. Considering the relatively low recurrence rate of between 2 and 8% in 10 years, this apparently works, thus an additional imaging test that shows more cancer in the affected breast may only increase the surgical volume, decrease the cosmetic outcome and thus negatively impact on the overall quality of life of women with breast cancer (Morrow 2004).

However, leaving large amounts of residual cancer within the breast is still detrimental for the overall outcome, and consequently margin assessment is performed on all surgical resections. In case of tumour infiltration of the margins re-excisions are performed, thus exposing women to repeat operations that could have been prevented by adequate use of the information in a decently performed breast MRI. This brings us, however, to the second reason that adaptation of clinical protocols and surgical procedures is slow: translating the information from MRI to the operating room (OR) is difficult. Women are positioned in a completely different position in the two situations, and since the breast is pliable the relative position of the cancer to major landmarks such as the nipple and the sternum shifts substantially. This likely explains also why the first large study on the effect of breast MRI on re-excision rates failed to show any benefit from MRI (Turnbull et al. 2010), while some single centre investigations document a strong impact (Mann et al. 2010; Sung et al. 2014). The three-dimensional appreciation of this shift demands extensive practice. Nevertheless, experienced surgeons will nowadays, based on the MRI findings, attempt lumpectomies in patients, who would definitively have undergone mastectomies without this additional information, and will reduce the volume of tissue removed in many others.

While it is evident that tumours that appear much larger on MRI than on conventional imaging techniques must

> ## "UNDERSTANDING BREAST-CONSERVING THERAPY IS ESSENTIAL FOR ADEQUATE USE OF BREAST MRI IN THE PREOPERATIVE SETTING"

be excised in toto, it is unclear how to deal with incidentally discovered additional tumour foci away from the primary tumour. In the early days of breast MRI such findings would invariably lead to mastectomy and hence a more extensive operation than was actually needed. Only now is it admitted that treating those foci in some women might only negatively impact the outcome, and it might be wiser to follow such findings. Unfortunately, there are no clear cut-offs to determine which lesions should, and which lesions should not, be surgically treated. This is a clear field for further multidisciplinary investigations. It also demands a different approach to informing women with breast cancer. Too often the fact that surgery is commonly not curative in itself is ignored, and women are being told that adjuvant therapies are mainly a safeguard and not part of the primary therapy. Understanding the real meaning of breast-conserving therapy is essential for the adequate use of breast MRI in the preoperative setting, and guidelines for women's information are currently in press.
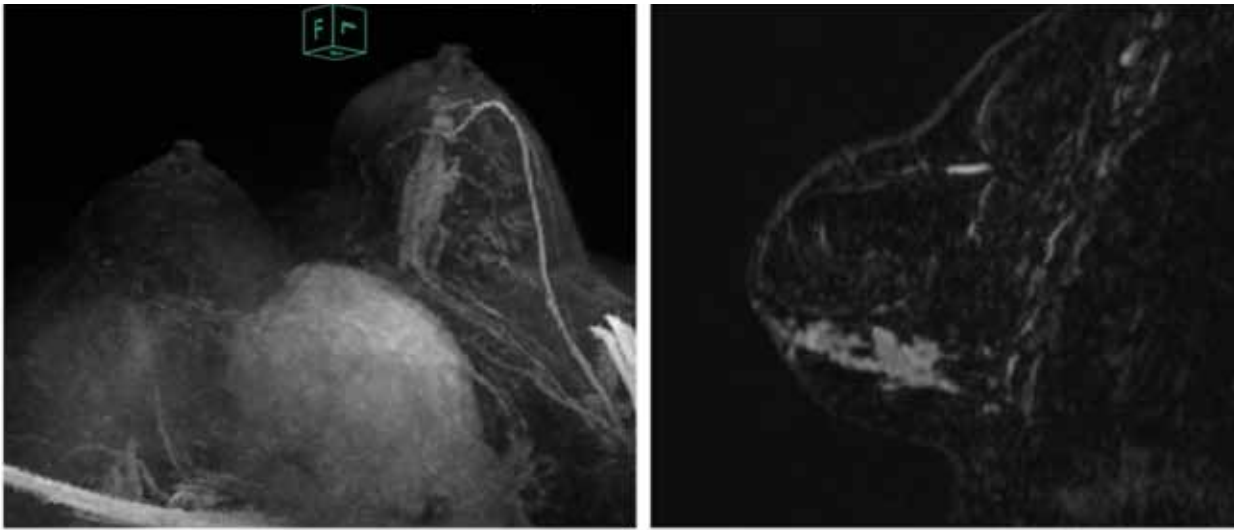
Figure 1. Large segmental DCIS lesion in the lower outer quadrant of the left breast. In the left frame a slightly rotated maximum intensity projection is depicted that shows the total lesion clearly. The right frame shows a sagital reconstructed subtraction image documenting the extent of this lesion from the nipple, almost to the thoracic wall.

Further clinical indications for breast MRI are less disputed. Breast MRI is clearly the most effective method for the monitoring of patients treated with neoadjuvant chemotherapy, and is undoubtedly valuable in women with metastasis from an unknown primary cancer. Its high negative predictive value (NPV) can also be exploited in problem cases where biopsy is not possible (Mann et al. 2008).

Screening

The high sensitivity of breast MRI has sparked a strong interest in the technique as a screening modality. At first, some reservations were in place, because of the presumably somewhat lower sensitivity of MRI for ductal carcinoma in situ (DCIS), the non-invasive precursor of breast cancer. This was due to the fact that breast MRI only detects approximately 85% of calcified DCIS lesions discovered by mammography (Bazzochi et al. 2006). However, it is now evident that DCIS does only calcify in approximately half of the cases. In fact, if all lesions are considered and not only those that calcify, the sensitivity of breast MRI for DCIS is much higher than that of mammography (Kuhl et al. 2007). From the start of this century, and now backed by these findings, multiple studies have evaluated the added cancer detection rate of breast MRI in women at intermediate and high risk. Each of these studies showed that breast MRI virtually doubles

breast cancer detection when compared to a screening regimen based on mammography only. In an early meta-analysis a sensitivity of 77% was documented for MRI, compared to 39% for mammography (Warner et al. 2008). While the MRI sensitivity is clearly much higher than that of mammography, this figure still appears poor compared to the results in staging MRI. This is explained by the fact that screening breast MRI is different from MRI as a staging modality. Lesions are often smaller (and thus still occult on mammography), and have fewer classic features of malignancy. Consequently, a learning process had to be observed. This likely explains why the reported sensitivities of newer studies that were not included in the initial meta-analyses are, at respectively 93% (Kuhl et al. 2010) and 91% (Sardanelli et al. 2011), much higher than in earlier studies. It is also backed by the fact that recent reports from groups that performed early screening studies now also report an equally high sensitivity (Obdeijn et al. 2014).

A common objection to breast MRI as a screening tool is that the specificity is lower than that of mammography. Breast MRI does detect many more lesions, both benign and malignant, and separation based upon imaging characteristics is not always possible. However, care must be taken not to confuse the specificity of mammography screening with that of MRI in clinical cases. In screening most cases are normal.

Consequently, the specificity of any screening test is very high. For mammography the specificity is reported to be in the order of 99%; this only drops slightly to approximately 96% with MRI screening (Morrow et al. 2011). It is likely more important to evaluate the positive predictive value (PPV) of screening-induced biopsies, as unneeded biopsies for benign abnormalities are among the most unwanted side effects of screening. This figure ranges between 25 and 48%, and is in general terms virtually equal to the PPV of mammography-induced biopsies (Saslow et al. 2007;

"BREAST MRI VIRTUALLY DOUBLES BREAST CANCER DETECTION COMPARED TO SCREENING BASED ON MAMMOGRAPHY ONLY"

Warner et al. 2008; Morrow et al. 2011), and much higher than the 10% or less that is normally reported for ultrasound screening (Berg et al. 2012; Brem et al. 2014). Since radiologists will always include a range of error in their indication for breast biopsies (1 in 3 biopsies positive for cancer is quite acceptable for most radiologists), it is unlikely that the PPV for MRI-detected lesions will increase much. It is therefore essential

to inform women screened with MRI that the likelihood of biopsy due to MR screening increases as more cancers are detected, but in an equal fraction also more benign lesions. In the end, women should evaluate whether or not they find for themselves this increased risk of a negative breast biopsy worth the chance of earlier cancer detection.

The success of MRI screening in the high-risk population has induced further screening studies in women at average risk in whom mammographic breast screening fails. Especially in women with dense breasts the sensitivity of mammography is reduced. Based upon mammographic literature, this sensitivity is approximately 50 to 60% at a detection rate of around 4 cancers per 1000 screens. However, supplemental MRI screening subsequently detects a staggering 14.7 cancers per 1000 screens that were not observed on mammography (Berg et al. 2012), hence reducing the actual mammographic sensitivity to less than 25%. Naturally, this is a prevalence screen and it is unlikely (and unwanted) that in subsequent rounds equally high detection rates will be observed, but it

Key Points

✓ Breast MRI is the current gold standard in breast imaging in terms of cancer detection.

✓ Breast MRI largely changes the oncologic profile of breast cancer and has a major influence on treatment.

✓ Breast MRI is a vital part of current day-to-day breast imaging and has great potential for screening.

clearly shows the potential of breast MRI to detect breast cancers earlier and hence improve the overall prognosis. Moreover the exceptionally high NPV of breast MRI in this setting allows honest reassurance of anxious women after a negative scan.

Cost Issues

That breast MRI is still not widely adopted as a screening modality is largely a cost issue. The costs of a single MRI scan are at least 4 to 5 times higher than that of a mammogram and, since the actual gain in quality-adjusted life years based upon the earlier detection of breast cancers with MRI is not known, estimates on cost-effectiveness vary widely (Taneja 2009). Cost-effectiveness is questioned for all women, except those at the highest risk, mainly women with BRCA 1 and BRCA 2 mutations. The task for the radiological scientific community is thus to reduce the costs to an acceptable level for mass screening. One approach is to largely reduce the scan protocol to the most basic sequences only. The scan length is than reduced to one-fifth of the full protocol, while the sensitivity is approximately 90% of the full scan and the NPV is hardly affected (Kuhl et al. 2014). This reduces the costs to approximately one-third of the full scan, since patient positioning remains the same and reporting costs are only slightly reduced. To preserve specificity in such a shortened scan protocol ultrafast dynamic sequences can be employed that provide information to increase specificity that actually outperform the conventional dynamic approach, while reducing the scan time even further

"CARE MUST BE TAKEN NOT TO CONFUSE THE SPECIFICITY OF MAMMOGRAPHY SCREENING WITH THAT OF MRI IN CLINICAL CASES"

(Mann et al. 2014). A further option would be to abandon mammography in women screened with MRI, since the added detection of mammography after a negative MRI is very low (Kuhl et al. 2010; Obdeijn et al. 2014), while women are still exposed to discomfort and ionising radiation. These new approaches have not yet been validated in prospective screening trials, and are hence not yet applied in clinical practice. Designing large multi-institutional and preferably multinational screening studies is thus of utmost importance to exploit breast MRI to its full potential.

Conclusion

Breast MRI is in fact the new standard in breast imaging. However, it is unsure how to use this new standard for optimisation of treatment protocols that are still based upon findings from conventional imaging studies. Furthermore, bringing the costs of breast MRI under control is essential for its future as a screening tool. Multicentre and multidisciplinary investigations are essential to alleviate these issues in the near future. ■

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BREAST IMAGING

WHICH VENDOR?

The breast screening landscape is changing rapidly as providers seek to increase cancer detection and decrease screening recalls. Tomosynthesis is increasing its uptake in the USA, and breast density legislation is increasing awareness and use of breast ultrasound. KLAS Research surveyed providers on their choice of vendor currently and in the future, in *Breast Imaging 2014: Finding a Partner for the Future*.

The KLAS report is based on the opinions of 183 healthcare providers, who were asked about digital mammography, mammography information systems (MIS), whole breast ultrasound and future plans for MIS and tomosynthesis.

Digital Mammography

At the time of the survey, Hologic was the only vendor in the U.S. offering tomosynthesis, and for Hologic customers upgrading is based on the Selenia Dimensions 2D platform. GE has recently been FDA approved. Costs for upgrading and the need to pay for a special reading workstation would be applicable to some providers. Despite these extra costs, providers were content with the return on investment, and felt they were getting their money's worth. 100% of Hologic customers would choose Hologic again, reporting that Hologic is a true breast imaging partner and also that it is the technology leader in tomosynthesis.

Siemens and Fujifilm, while not yet offering tomosynthesis in the U.S., will have an upgrade path to tomosynthesis when the technology is FDA approved. 81% of Siemens customers chose Siemens as their top choice. Several providers said they were looking forward to Siemens' new tomosynthesis unit and would choose that machine when it came to purchase.

Fujifilm customers were surveyed, but the limited numbers did not meet KLAS Konfidence levels.

Whole Breast Ultrasound

21% of the providers KLAS interviewed said they planned to purchase whole-breast ultrasound. Only 8% said they were already using it. However, those using it cited the benefits of no radiation dose, consistency of scans and ease of training staff to use it.

Mammography Information Systems

Providers were more satisfied with specialist MIS vendors over using their RIS. Providers reported that MRS and PenRad offer better mammography functionality overall than RIS vendors.

The full report *Breast Imaging 2014: Finding a Partner for the Future* is available from KLAS Research, **www.klasresearch.com**

About KLAS Research

KLAS works with over 30,000 people in 5,000 hospitals and nearly 3,000 ambulatory organisations. KLAS sources its information predominantly from the United States. KLAS data and reports represent the combined opinions of actual people from provider organizations comparing how their vendors, products, and/or services performed when measured against participants' objectives and expectations.

KLAS findings are a unique compilation of candid opinions and are real measurements representing those individuals interviewed. ■

PERFORMANCE REPORT

MAY 2014

Tariq Gill, MD | AFRICA - RADIOLOGY WITHOUT BORDERS

Breast Imaging
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DANGEROUS BOOBS TOUR TARGETS DENSE-BREAST TISSUE AWARENESS

Heather Reimer

Chief Visionary Officer
Each One. Tell One.

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Breast density was a hot topic at the Radiological Society of North America (RSNA) Annual Scientific Meeting in Chicago in December. A new grassroots initiative, "Each One. Tell One.", also known as the Dangerous Boobs Tour, made its debut through the sponsorship of SonoCiné AWBUS™, an Automated Whole Breast Ultrasound technology that provides a supplementary examination for women whose mammograms are inconclusive.

Heather Reimer, Chief Visionary Officer of Each One, Tell One and Co-Founder of the Dangerous Boobs Tour took time to speak with *HealthManagement* about their mission.

Why Dangerous Boobs Tour?

First of all, because it gets your attention. Boobs ARE dangerous if you don't know how to take care of them. "Each One. Tell One." is a movement to raise dense-breast tissue awareness for early breast cancer detection. We want each person who learns this information to tell another until every woman in the U.S. understands what she needs to do about her own breast health. The Tour is the presentation arm of the "Each One. Tell One." movement. It consists of the three co-founders, Wendy Damonte, Chiqeeta Jameson and me. We have all been devastated by breast cancer because of dense-breast tissue and have discovered a powerful way to combine our unique stories that move women to take action about their own breast health. Our tour is an educational, medically based, inspirational presentation. We travel the country with a tailored performance to fit each audience who hears our message. It may be one of us, two of us or all three. Regardless, if you are a woman that hears our message, you will leave with information that you probably have never been told. You will want to share this information with your friends and loved ones and you will be empowered to call your doctor to find out if you have dense-breast tissue and what you need to do about it. And THAT is the purpose of our "Each One. Tell One." movement.

My cancer was missed by the mammogram because I had dense-breast tissue. It was later discovered through an Automated Whole Breast Ultrasound examination as a fast growing triple negative invasive cancer. A year after I finished treatment, a friend of mine called to tell me that she too had dense-breast tissue and her cancer was also missed by the mammogram. It was then that I founded "Each One. Tell One." I realised that my story isn't unique. I now know that 40% of women have dense-breast tissue and about 85% of them have no idea that they have it. Why? Because, until recently it has not been the medical standard to inform women of their breast density. So, the standard of breast health care has got to change and our mission is to spread awareness so it will change and therefore save lives. Mammography is not enough of an examination to see through dense-breast tissue. An additional exam such as an ultrasound, automated whole breast ultrasound or MRI, along with the mammogram, is what is needed for women with dense-breast tissue.

Our mantra is "Until there's a CURE, find it SMALL. It's the new BIG". Today, there is technology that will find breast cancer when it is small, easier to treat and therefore, in most situations, eliminates the need for chemotherapy.

Have the radiologists at the RSNA conference been receptive to your message?

The reaction has been across the board. There have been radiologists who have told us, "I agree with your message. Keep up the good work!" Others have said, "There is still no clinical evidence to support your messaging." All I could say was, "Look at our website under the "Clinical Data" tab and see if that doesn't change your tune." One told me that, "I don't like the idea of alarming my patient with extra information." I responded by saying, "What is more alarming, not informing a woman that she may have cancer that can't be detected by the mammogram or, telling a woman that she has cancer and it is so advanced, that she needs a mastectomy…. as was my case?" On another positive note, we have been asked to have our site translated into Spanish, French, Italian and Portuguese. These doctors are grateful for the support and we want to provide it.

What is the role of the technologist concerning the dense-breast tissue message?

Other than the referring physician, the technologist is the most important person, who is in a direct position to educate women about breast density. Every breast centre is different. Some technologists are allowed to let a patient know her density at the time she is getting her mammogram and others will only allow a radiologist to inform her. Or, she needs to ask for her report from the radiologist. Regardless, the technologist can take less than two minutes to show her stock mammogram images that clearly show the difference between fatty tissue (clear, like a cloudless blue sky) and dense tissue (like a white cloudy sky) and how cancer (which always shows up as "white" on a mammogram) is easy to see in fatty tissue but in dense tissue, a white cancer, on a white background, is extremely difficult to see. The technologist can let the patient know that for dense-breasted women, there are additional exams such as ultrasound, automated whole breast ultrasound and MRI that can see more than the mammogram. The technologist is not her doctor so it is important that she inform the patient to have a conversation with her referring physician to determine what additional exam may be right for her. Mammography may still be the standard of breast care, but studies show that it misses over 50% of all breast cancers in women with dense-breast tissue. Women

(L-R) Wendy Damonte, Heather Reimer, Chiqeeta Jameson

still need to have a mammogram, because it can detect calcifications that are not as well imaged on other modalities such as with ultrasound. However, studies also indicate that ultrasound, automated whole breast ultrasound and MRI find more cancers, and at a smaller size, than mammography. We have talked to a lot of technologists here and, overall they know that the standard needs to change to incorporate other technologies that will complement the mammogram and find what mammography doesn't.

How are you planning to spread your message to all women in the country?

In 2015 we are launching a national campaign, starting in the state of Nevada. The campaign focuses on being a support system for all facilities, centres and hospitals that offer mammography. To do this, our goal is to provide breast density education to referring physicians, who send their patients to these facilities, centres and hospitals, and to the patients themselves. If the patient has learned about breast density she will know to ask her doctor about her own breast density. If the referring physician understands the need for an additional examination, for the 40% of his patient clientele, he will then focus on the clinical data and prescribe the

most appropriate additional examination for each of his dense-breasted patients. In turn, the imaging entities will change their standard of care and begin offering these exams. Thus, the standard of care will change. Our desire is to be help and not a hindrance. Our goal is change from the cookie-cutter-one-size-fits-all status quo.

What is your view concerning the progress of breast density legislation in the United States?

It's working! We completely support Nancy Cappello, PhD, who has now brought Breast Density Inform laws into twenty states. Because of Nancy's efforts, two new insurance codes for additional breast ultrasound examinations (CPT 76641 and CPT 76642) when the mammogram is inconclusive, will go into effect in January 2015. A mammogram is inconclusive in such cases as with dense-breast tissue and implants. This

is a huge step forward because there has not been insurance coverage in the past. We also know that legislation alone will not change the standard of care. That is why we want to support Nancy's efforts through education at the level of physician, staff and patient.

What education materials do you offer?

Our website www.eachonetellone.com is a wonderful, easy to understand resource. It is loaded with information and the clinical data that supports it, that everyone needs to know about breast density. In 2015 we will have educational packages available for all breast imaging facilities, hospitals and centres. We also are available to provide a live presentation. We tailor our presentation to our audience. It's educational, medically based and designed to empower.

Do you have a favourite quote?

"Never doubt that a small group of thoughtful committed citizens can change the world. Indeed, it's the only thing that ever has." – Margaret Mead. This quote defines who we are and how we will accomplish our goal of changing the standard of breast healthcare in this country. We will do it, one woman at a time. ∎

NUCLEAR MEDICINE AND PROSTATE CANCER

INTERVIEW WITH PROF. UWE HABERKORN

Prof. Uwe Haberkorn

Director, Clinical Cooperation Unit Nuclear Medicine

Medical Director Department of Nuclear Medicine German Cancer Research Center (DKFZ)

Professor of Nuclear Medicine, University of Heidelberg Heidelberg, Germany

What are the issues with imaging of prostate cancer when it comes to early detection, tracking and management?

In recent years there has been a significant decrease in mortality, which is mainly due to early detection. However, early detection may lead to overdiagnosis and overtreatment with resultant impact on the quality of life of men with prostate cancer (PCa). These problems are due to the variability of the clinical course of the disease and the high prevalence of microscopic disease. Therefore, a risk-adapted strategy is needed to choose among a wide variety of treatment options: from active surveillance to aggressive treatment. In the face of such broadly differing options that impact survival and quality of life it follows that patient-specific staging is essential for optimising individual outcomes. This creates a demand for sensitive and specific imaging of prostate cancer for local and metastatic disease. Furthermore, as active surveillance becomes a more widely considered management option in low-grade disease a sensitive method of monitoring changes in the extent of disease would potentially eliminate the need for repetitive biopsies and enable a more advanced temporal evaluation. This is in principle an ideal field for imaging. However, especially in the situation of biochemical recurrence lesion detection is desired at low PSA values (below 1) to start early treatment. This is very difficult with existing methods.

What role does prostate-specific membrane antigen (PSMA) play in imaging and therapy of prostate cancer? Why is it a suitable target for nuclear medicine?

There are several biological characteristics making prostate-specific membrane antigen (PSMA) an outstanding target for nuclear medicine. As a type II transmembrane protein with glutamate-carboxypeptidase activity and a known substrate, PSMA represents an ideal target for developing small molecule radiopharmaceuticals, which typically show fast blood clearance and low background activity. Furthermore, after binding of the ligand to its target, PSMA is inter-

> ## "PSMA REPRESENTS AN IDEAL TARGET FOR DEVELOPING SMALL MOLECULE RADIOPHARMACEU-TICALS"

nalised via clathrin-coated pits and subsequent endocytosis resulting in an effective trapping of the bound molecule in the cells. Since internalisation leads to enhanced tumour uptake and retention, targeting PSMA is expected to result in high image quality. Finally, PSMA is a cell surface protein that shows a significant over-expression on prostatic cancer cells and especially in advanced stage prostate carcinomas with low expression in normal human tissue. There are several studies reporting that PSMA expression levels increase with stage and grade of the tumour (Silver et al. 1997; Chang 2004; Bostwick et al. 1998). Moreover, nearly all prostate adenocarcinomas show PSMA expression in the majority of primary and metastatic lesions. Taken together, PSMA seems to be an ideal target for high contrast nuclear

(PET-CT and SPECT-CT) imaging, and, therefore, has high potential to improve patient management at every stage of the disease. The fact that the ligand is rapidly internalised makes it also an excellent target for endoradiotherapy. Using a I-131 labelled PSMA ligand obtained from John Babich we were able to show in a population of final stage patients that this approach is not only feasible but highly promising (Zechmann et al. 2014). As a further improvement a PSMA ligand was coupled with the chelator DOTA (work done together with Matthias Eder, Michael Eisenhut, Martina Benesova and Klaus Kopka) and has been used since December 2013 for therapy with Lu-177 and Ac-225.

Please tell us more about (68) Ga-labelled PSMA ligand that your research team has developed and trialled.

The tracer was designed by Michael Eisenhut and Matthias Eder, Department of Radiopharmaceutical Chemistry at the DKFZ, using a urea-based inhibitor of PSMA. These urea-based inhibitors represent low molecular weight pepidomimetic structures and show the ability to image PSMA-expressing prostate tumour xenografts. N,N′-bis [2-hydroxy-5-(carboxyethyl)benzyl] ethylenediamine-N,N′- diacetic acid (HBED-CC) is an efficient 68Ga chelator with fast complexing kinetics even at room temperature and a high in vitro as well as in vivo complex stability. Besides the efficient Ga(III) complexing characteristics, HBED-CC was chosen because of the potentially beneficial properties in respect to its lipophilicity. The PSMA "active binding site" is composed of a structural motif interacting with urea-based inhibitors and a lipophilic pocket. The chelator-related hydrophobicity of Glu-NH-CO-NH-Lys(Ahx)-HBED-CC may be responsible for fulfilling a bi-functional

interaction including inhibitory enzyme binding and interaction with the lipophilic pocket of the enzyme. After the design of the tracer preclinical studies in cell culture and tumour–bearing animals were done by Michael Eisenhut's group and my group at the DKFZ. Clinical translation was started in May 2011 where the first patient was studied.

This tracer has already compared well with choline in your study published in EJNMMI (European Journal of Nuclear Medicine and Molecular Imaging). What is the next step? Will this be used in patient-specific imaging and surveillance?
The better performance in comparison to choline-based tracers has now been confirmed by other groups. For the next step an academically-driven multicentre study with 11 centres in high-risk patients prior to prostatectomy is planned. This will ensure that we have a pathological evaluation for all patients. One important feature of that study is the design of standardised tissue sampling and standardised pathological evaluation. This will give us important data about the sensitivity and specificity of the tracer. I see the major future use of the tracer for therapy planning and detection of tumour lesions in the situation of biochemical relapse, maybe also in the primary situation in high-risk patients. Whether it can be used for therapy monitoring remains to be determined.

You hypothesise that detection rates in 68Ga-PSMA PET/CT will increase with rising PSA levels and tumour size. Is that the case?
We have published a study with 319 patients (Afshar-Oromieh et al. 2015), showing that there is an increase of the detection rate with increasing PSA levels. Similar data have been obtained by other institutions with a comparably large population studied by the group of Markus Schwaiger at the Technical University of Munich (Eiber et al. 2014).

An editorial in EJNMMI, "Writing PET into existence" suggested that "a strong behavioural change is needed…let us delay publication until we have data on outcome or on surrogate markers of outcome." Is this a fair suggestion in your opinion?
It is not a question of fairness, but rather of relevance. Is that editorial relevant or is there a useful message? Do we have to perform multicentre studies to bring promising tracers into the clinic? Of course we need such studies, so this point is trivial. The authors state "let us delay

"HIGH POTENTIAL TO IMPROVE PATIENT MANAGEMENT"

publication until we have data on outcome or on surrogate markers of outcome". This is a weird conception of how science works. Are recommendations for oncological guidelines really the goal of first scientific reports? Surely not. These first reports of new radiopharmaceuticals have to be seen as initiation of scientific discourse and stimulation for further studies. How else could we identify a tracer which is worth studying in a costly multicentre trial. Proof-of-principle studies have to be done first and, of course, published. Thereafter the scientific community has to decide which tracer has to

be followed further. Only at these later stages of scientific evaluation do recommendations for oncological guidelines make sense.

This same editorial also says, "A major problem commonly encountered in clinical studies employing new diagnostic modalities, such as PET/CT radiopharmaceuticals, lies in the difficulty of assessing the accuracy of the technique." Why is this the case?
The problem especially in the setting of biochemical relapse lies in the difficulty to obtain tissue samples as a gold standard. This is often related to ethical concerns or problems to obtain tissue samples using a standardised procedure especially in metastatic disease. In our experience in approximately 10% of these cases a biopsy or surgery is possible but not with a standardised procedure. Therefore, the accuracy is hard to evaluate and analyses in these patients often have to rely on other imaging methods and clinical follow-up. ∎

IMPORTANT

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CONTROLLING PATIENT WORKFLOW IN A RADIOLOGY DEPARTMENT

DIGITAL SIGNAGE, TICKETING AND ELECTRONIC DASHBOARDS

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For the purpose of protecting patient safety and upholding quality standards in hospitals and healthcare facilities, governments and authorities have been implementing stricter rules and healthcare regulations. In order to meet these requirements, hospitals face a pressing need to improve their organisational structure. This is one of the greatest challenges facing the healthcare community in the near future.

A department of radiology or medical imaging is a service-oriented department, which provides very important, if not crucial, added value for diagnosis and patient management. In a modern healthcare environment, almost all in- and outpatients are likely to undergo one or more radiological studies. This implies a constant stream of patients. Managing waiting times and optimising patient workflows are the key elements for the successful and efficient organisation of a radiology department.

Thanks to digitalisation we have access to electronic patient-related data. Sadly, however, there are little or no integrated software solutions available to manage this data flow and support the organisation of the department. Using up-to-date software it is now possible to query waiting times through the database of the Radiology Information System (RIS). Unfortunately, this process provides historical information and is not a representation of the actual workflow processes, thus making it impossible to take action when needed. Moreover RIS data do not take into account staffing problems, patient load, x-ray device failure etc.

"INVOLVE TECHNOLOGISTS IN THE WORKFLOW PROCESS… MAKE THEM OWNERS"

A possible solution to this problem could be to have a "guard" in the department. By this we mean a physical person, working as a waiting room manager, who checks waiting room occupancy, interacts with patients, and inquires how long they have been waiting for already, and who is able to redirect patient flows in case of an x-ray device failure, or reallocate technologists depending on the workload. Such a solution would be expensive and is not foolproof. We are convinced that it would be preferable to involve technologists in the workflow process, to empower them and make them "owners" of the production process. For such a solution to succeed, it is essential to share current and up-to-date information with the technologists (eg the number of patients in each waiting room, waiting times, number of expected patients etc.). This implies that there is a need for supporting software tools to collect the facts, and to integrate these data with scheduling software, RIS and PACS (Picture Archiving and Communication System). We are certain that visual reproduction of these data in a user-friendly setup would provide an additional benefit.

In our study, we started from the patient's point of view. Upon entering the radiology department, the first step for every outpatient is to register for his or her examination(s). After registration, the patient is then directed towards a specific waiting room depending on the type of scheduled examination (chest x-ray, CT scan etc.). Even though this process is relatively straightforward, we are all aware that things can go wrong. Some outpatients do not understand the instructions they are given, or forget to which waiting room they have been assigned. As a result, some patients take a seat in a waiting area without knowing that they have made a mistake. They just wait until the technologist or nurse comes to escort them to the examination, and they are not aware that they will have to move to another waiting area.

Our purpose is to improve this process, and to that end we have explored three possible avenues:

1. Help (guide) patients to find their way by using ticketing and digital signage screens.
2. Visualise the occupancy of the different x-ray rooms by making use of digital dashboards.
3. Our global aim is to render patient throughput and production processes visible to management.

We decided to solve this problem by implementing a three stage solution:

1. Digital signage;
2. Ticketing;
3. Creation of digital dashboards and management statistics.

At present, stage one is fully operational in our department. Every waiting area is equipped with a digital signage screen, which displays a video loop containing specific examination-related information for the patient as well as more general information about the radiology department and the medical staff (see Figure 1).

Stage two (ticketing) is partially implemented. Upon arrival at the reception desk,

patients take a numbered ticket from a dispenser. They are called in a sequential order for registration in the RIS (by ticket number). Currently these numbered tickets are thrown away after the patient has been registered. For the future it is our goal to include the ticket number in the RIS at procedure level. Procedures in RIS are linked to an examination room, and each examination room is allocated to a waiting area. After registration the ticket numbers appear on the digital signage screen in the allocated waiting area. In this way, patients have a visual confirmation of being in the correct waiting area. All the ticket numbers are displayed in a sequential order, which makes it possible to estimate waiting times.

Finally, in the third stage of the process, we need to create a waiting room dashboard, which will provide an overview of the different waiting areas, and allow the staff to evaluate patient throughput and workflow (see Figure 2). This third step will be implemented together with the RIS vendor.

The first horizontal line of numbers on the dashboard represents the different waiting rooms (1 to 6). The two-digit numbers beneath every waiting room number represent the ticket identifiers of the waiting patients. For example, in waiting room 2 there are three patients waiting for their procedure. These patients are identified by ticket number #31, #36 and #39. The partial circles, colour-coded from green to red, indicate how long each patient has been waiting. A full circle indicates a waiting time of one hour. So the patient with ticket number #31 in waiting area 2 has been waiting for approximately fifty-six minutes. The indication "Expected" at the bottom of the dashboard indicates how many patients are still expected in that particular waiting room; WT indicates the average waiting time.

This process can only become successful if positively received by patients and staff. In order to assess patient acceptance, we performed a pilot study through an online questionnaire via email after implementation of step 1 and partial implementation of step 2. A total of 1,002 patients were invited to supply feedback via e-mail; 122 emails bounced. Of the remaining 880 patients, 566 respondents completed the questionnaire (64.3%), 31 patients started the questionnaire, but did not finish it, and 314 patients did not reply. For the setup of the waiting areas and digital signage, respondents assigned an approval score of 92.1%. Patients greatly appreciated

Figure 1. Example of a Digital Signage Screen Providing Instructions for Patients in Waiting Room 3

Figure 2. Proposed Layout for a Waiting Room Dashboard

the examination-related information on the digital screens. Questions related to the reception desk welcome, ticketing and privacy received an approval score of 92.8%.

Conclusion

Controlling and improving patient workflow in a radiology department represents a formidable challenge. We conceived a project using digital signage, ticketing and electronic dashboards to improve patient throughput and workflow management. Even though our project has only been partially implemented, we are very happy to see the positive feedback from our patients. Further improvements can be achieved by fully integrating numbered ticketing within RIS, in order to guide patient flow. The creation of digital electronic dashboards is the next step, and it will be mandatory to integrate this process

with existing software. We feel that the proposed three-step process is beneficial to our patients, and it also helps to render production processes visible to management. ■

Key Points

✓ Patients can be helped to find their way in a radiology department by using numbered ticketing and digital signage.

✓ Shared information about patient workflow, through electronic dashboards, helps to involve radiographers and to empower them as "owners" of the workflow processes.

✓ Digital dashboards, indicating waiting times and waiting room occupancy, give managers a tool to gain information "at a glance" of the production process in the radiology department.

REAL-TIME MONITORING IN RADIOLOGY

THE KEY TO OPTIMISING REPORT TURNAROUND TIMES

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In healthcare today control is mainly based on retrospective analysis of business data, usually financial key performance indicators (KPIs) or performance KPIs such as utilisation or number of examinations. Control is often misinterpreted as an instrument of scrutiny, a misconception that is particularly common in the German-speaking world. However, control should be more than just that; it should rather be a management tool that considers all aspects of business needs and gives a push in the right direction. In service-oriented business there are four relevant aspects: customer, finance, employees and process (Gocke et al. 2002).

This article focuses on a process-oriented approach to workflow control. According to Zapp and Oswald (2010), efficient processes are the foundation of customers' (and even employees') satisfaction and thus also of economic success. How can efficiency and effectiveness of typical radiologic processes be defined and measured? While processes are dynamic, static and retrospective analysis of data is still possible and oftentimes helpful. However, the extraction and analysis of data in real time as it is implemented in the Department of Radiology at University Hospital Basel seems even more interesting. This approach allows in-time intervention instead of delayed damage control. The aim is to actively visualise the status quo of workflow, and to recognise possible hazards or even unexpected cessation, eg it is preferable to recognise a patient waiting for more than an hour than to realise that the average waiting time increased five minutes over the last month.

The solution for effective process control is real-time monitoring. This has been successfully applied to other non-medical industries for a long time. Especially in manufacturing industries such as automotive production or chemistry, real-time monitoring is essential. No chemical manufacturing process will run properly without permanently measuring process KPIs such as pressure, flow or temperature. Unfortunately, medical procedures are less predictable than those in other sectors. Additionally, there may also be downsides to measuring outcome and processes in healthcare (Lilford et al. 2004). However, there is also evidence that processes can be optimised by defining process KPIs (Halsted and Froehle 2008). Diagnostic radiology in particular is suitable for this kind of process optimisation. Radiology workflows are characterised by a high degree of standardisation (Teichgraeber et al. 2003). Nowadays most processes are computer-based, utilising Radiology Information Systems (RIS), Hospital Information Systems (HIS) and Picture Archiving and Communication Systems (PACS). This allows extraction of a huge variety of data for use in process control.

Process and KPI Definition

Main processes in diagnostic radiology are highly structured. In the beginning an examination is ordered by a referring physician; the final report of the process usually represents the end. Figure 1 shows the simplified overall process. Of note only part of all these process steps are visible for the referring physician. In regards to a high level of service quality, it is therefore important to remember that customer satisfaction is mainly determined by these visible process steps. While other process steps are relevant only within the radiology department, these steps still have a substantial impact on processing times of the overall process, and thus also affect customer satisfaction.

According to this process definition, the following internal KPIs are derived:

- T_{i1}: time period from order entry to defining the examination protocol
- T_{i2}: time period from protocolling to scheduling the examination
- T_{i3}: time period from the end of the examination to signing-off the finalised report

At least for these KPIs, process control should be implemented in a radiologic department. Depending on the specific reporting workflow (eg additional read-out of the resident/fellow by the attending in teaching hospitals) it might be appropriate to split T_{i3} in two separate steps.

Before implementing a measurement system of KPIs and processing times, specific targets need to be defined. What are the mean goals, what is the 95% confidence interval, eg what is the maximum permissible time between order-entry and protocolling by the radiologist; what is the maximum permissible report turnaround time? Without defining specific goals it will be impossible to assess whether the desired service quality (ie these goals) has been achieved.

In order to control this process, it is essential to collect these KPIs in real time and visualise them permanently. A simple example for real-time monitoring is the visualisation of all pending results, their status and the time remaining until the predefined goal occurs. This information should be displayed and be clearly visible to all radiologists involved in these specific examinations (see Figure 2). An additional colour-coded alarm system of time-critical reports is also deemed helpful. This type of monitoring allows not only the identification of potential problems, but also to take action in a timely fashion.
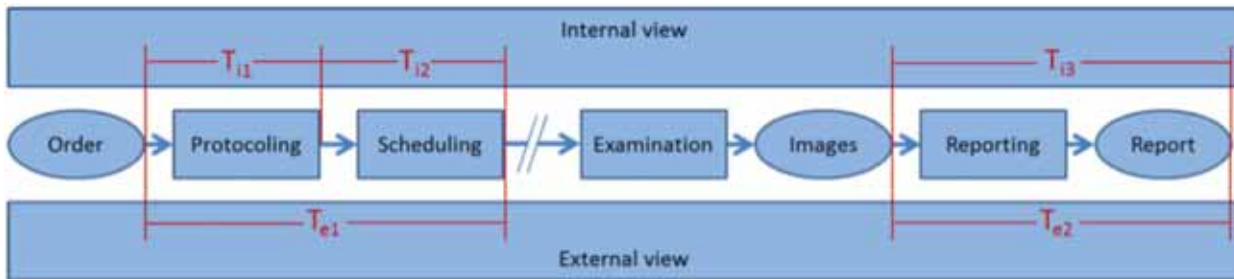
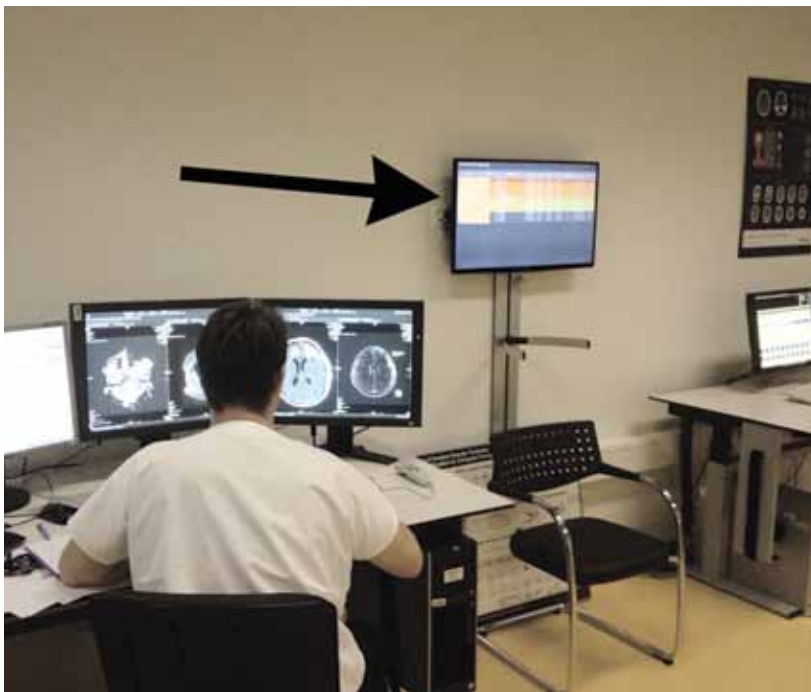**Figure 1.** Simplified Main Process of Radiology

Figure 2: Monitoring Display Installed in a Reading Room

The internal KPIs within the main process listed above can and should be complemented by external KPIs that also determine service quality. As shown in Figure 1 the following KPIs are defined as:
- T_{e1}: time period from order entry to receiving the date/time of the examination
- T_{e2}: time period from the end of the examination to signing-off the finalised report

These KPIs mainly determine customer satisfaction, and may be included in contracted Service Level Agreements. However, a retrospective survey of these KPIs seems acceptable as long as these processes are controlled by the internal KPIs as defined above.

Benefits of Real-Time Monitoring
What are the benefits of real-time monitoring? First, it helps to coordinate processes within the radiology department. Nowadays staff requirements are so complex that it is difficult for the individual employee to keep on track. A common reason for delayed turnaround times simply is that pending reports or important process steps will not progress, and nobody is aware of this problem. Oftentimes reports are forwarded for co-signature to a staff radiologist, who will be out of office the next few days. This is avoidable by implementing a monitoring system that indicates time-critical issues, based on a departmental/sectional rather than personal perspective. Following the implementation of real-time monitoring in the Department of Radiology the median report turnaround time improved from 7 hours 50 minutes to 3 hours 14 minutes, with more than 90% of all reports being finalised within 24 hours.

Additionally such a monitoring approach increases transparency. This applies to both internal processes as well as external communication. A similar approach of real-time monitoring is also used to display information about the status of patients from the emergency room (ER) in the radiology department. Thus every ER physician is informed about what is going on with his/her patient. They know when the examination will take place, when the images will be available and when the report is finalised. This can help to increase customer satisfaction simply by avoiding countless status update requests over the phone. This is a benefit for both the ER and radiology department, as these unnecessary phone calls are eliminated.

However, the single most important benefit of real-time monitoring is the fact that it enables management and staff to react to critical issues before "damage" has occurred.

Challenges and Limitations
Although it may appear rather simple, the implementation of real-time monitoring can be quite challenging. On a level as described above, it is easy to define KPIs for report turnaround times and monitor these constantly. For instance, an overall maximum permissible time of 24 hours for report finalisation is a first step only. Unfortunately, reality is much more complicated. Depending on the clinical context of the examination eg life-threatening motor vehicle accident or follow-up exam on an outpatient basis, 24 hours can be either much too long or unnecessarily short. Thus real-time monitoring reflecting the complexity of medical procedures quickly becomes very complex. The challenge now is to visualise these complex issues in a simple way.

The implementation of effective process monitoring is not possible without substantial effort. It requires human resources with appropriate knowledge of business processes and IT systems. The mapping and documentation of business processes using IT systems is not trivial. Reflecting all processes with corresponding data-based KPIs may not always be possible. Data inconsistencies through suboptimal data acquisition can additionally limit the validity of results. Erroneous data will inevitably lead to a low acceptance of such measures. Therefore process control has to be tested properly before deployment. In addition to the human resources (capacity and knowledge), the technical environment has to be implemented. While many core systems such as RIS or HIS provide simple control modules these days, they are often not sufficient to match management requirements. Therefore it may be necessary to add better suited IT solutions.

Another challenge is the acceptance of such a monitoring process by staff. There may be a misconception by some staff members, who conceive the monitoring process as surveillance of their individual performance. It is highly recommended to involve all the various employees early on to achieve broad-based support. This works best if the benefits to the individual employee are highlighted, with the two most important ones being the avoidance of unnecessary interruptions and the optimisation of internal processes. Nevertheless, the need for a high quality service should also be emphasised. Overall, it is recommended to introduce process control incrementally. It should start with activities that provide tangible and visible results. This leads to a positive association, and promotes acceptance by all coworkers.

Conclusion

Today good clinical quality is no longer the single decisive factor for the success of a radiology department. Rapid availability of examinations, quick delivery of the results and maximum transparency of the current workflow and patient status to the referring physician and the patient are prerequisites for high customer satis-

"IN-TIME INTERVENTION INSTEAD OF DELAYED DAMAGE CONTROL"

faction and business success. Moreover the economic circumstances, eg rising costs and decreasing reimbursement, provide a demanding environment when striving for a higher efficiency of service. This can only be achieved if a radiology department has control over its internal processes. Well-designed processes are an essential prerequisite. Subsequently these processes must be controlled and monitored continuously. For this purpose, real-time monitoring is essential according to the catchphrase "You cannot manage what you cannot measure." Even though the introduction

of such process control requires effort and may meet initial resistance by staff, it will be essential for continuous economic success.

However, optimisation of the internal processes within a radiologic department may be considered a starting point only. The overall goal is to use such indicators to monitor the entire patient pathway within the hospital. This will not only improve internal processes within radiology, but also increase transparency to customers and patients. It is quite conceivable to show each patient their individual expected waiting time.

Another benefit may be computer-aided documentation of the communication of critical findings. The system cannot and must not release the radiologist of his medico-legal responsibility to discuss critical findings directly with the referring physician. However, an electronic system can support the documentation of this communication, eg it can track acknowledgments and remember periodically if no feedback has been received. Finally, subsequent activities such as recommended follow-up examinations can be monitored.

In summary, the benefit of process control is the opportunity to achieve control over increasingly complex processes that are out of the scope of an individual. It creates transparency, security and relieves the employees of frequent interruptions and unpopular activities. ■

Key Points

- ✓ Process control can help optimise workflows in radiology.
- ✓ Real-time monitoring enables action before damage has occurred, helps to organise workflows and increases transparency.
- ✓ Implementation of real-time monitoring is challenging, requires expertise and resources, but has a measurable effect on service quality.

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MEDICAL DEVICE INTEGRATION IN THE OR

INTEROPERABILITY STANDARDS AND ISSUES RELATING TO INTERNATIONAL APPROVAL PROCEDURES

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The Digital Operating Room

Advances in medical technology, specifically information technology (IT), in the last quarter of the 20th Century have produced extraordinary changes in the way medicine, and in particular surgery, is practised. These advances have not been without certain drawbacks and shortcomings, including escalating healthcare costs and the challenge of handling the complexity of these technologies.

It has been challenging to cost-justify many of the new technological and system advances, associated interventional procedures and the corresponding redesign of healthcare infrastructures, for example, for the Operating Room (OR). The development and dissemination of these technologies have become central issues in the debate over healthcare reform and healthcare finance.

In particular, a number of major technical and organisational challenges are being faced in the attempt to improve the safety and effectiveness of connectivity/interoperability for the diverse array of medical devices and information technology that proliferates in the OR environments today. These have been clearly identified in recent years, for example by J. M. Goldman, MD, (Director, CIMIT Program on Interoperability, and Medical Device "Plug-and-Play" Interoperability Program), as challenges in their MD PnP Program (Goldman 2007):

- Proprietary medical device systems; long capital equipment cycles (12 years!);
- Limited comprehensive, vetted user requirements (clinically/safety-based);
- Absence of proven standards matched to clinical requirements;
- Tendency to silo standards that would limit interoperability across continuum of care;
- Limited funding for development;
- Limited recognition of complexity of challenges in IT-BME convergence and lack of system; integrators to build the middleware;
- Legal (liability) concerns;
- Regulatory pathway questions.

In the current MD PnP Program (MD PnP Program 2014) it is interesting to note, that user requirements in the program are established by means of explicit clinical scenarios – i.e. workflow analysis of clinical scenarios at a level of detail needed to create the basis of interoperability solutions and to derive engineering requirements.

In the context of international approval procedures and, relating to the challenge of "Regulatory Pathway" transparency and reduced complexity, the MD PnP Program is leading a working group of companies, academics, and hospitals that are developing a prototype regulatory submission to help refine the FDA clearance process (see FDA workshop content (U.S. Food and Drug Administration; Continua Health Alliance; Center For Integration Of Medicine & Innovative Technology (CIMIT); Medical Device "Plug-and-Play" Interoperability Program (MD PnP) 2010)).

To move beyond conceptual demonstrations of new interventional systems and towards the systematic assessment and employment in interventional settings, an understanding of the expected maturity levels of the Digital Operating Room (DOR) at present and in the foreseeable future is helpful (Lemke and Berliner 2011).

Figure 1 provides an estimated timetable for the past, present and future developments of the DOR over a 25-year period including:

- its development up to the present time as well as its continued development and implementation
- the political, economic, and industrial issues that may be encountered (Lemke and Berliner 2011).

Four main areas of technology development for the DOR can be identified:

1. Devices, including signal detection and recording, robotics, guidance systems, simulation technologies, which allow precision in the delivery of personalised operative healthcare;
2. IT Infrastructure, including DICOM, IHE, EMR, Therapy Imaging and Model Management System (TIMMS) infrastructure for the storage, integration, processing and transmission of patient specific data;
3. Functionalities, including specific interventional processes, patient-specific modelling, optimisation of surgical workflow, TIMMS engines and;
4. Visualisation, including the processing, transmission, display and storage of radiographic images, video, and physiologic signals (e.g. a type of surgical PACS).

Each of these areas is following its own characteristic development, validation and approval cycle and methods. In (Lemke and Berliner 2011), five stages of maturity for the various technical areas have been identified in the development of the Digital Operating Room for the first quarter of the 21st century:

2005+: Maturity level 1

Characterised by the vendor-specific integration of technologies. The critical feature of this stage is considered to be the development of integrated device control. Additional technologies include high definition (HD) video and digital image acquisition and processing, boom-mounted devices, automatic reporting.

2010+: Maturity level 2

Characterised by perioperative processes optimisation. The two critical features of this stage are considered to be the development of preoperative image integration and navigated control. Additional technologies include basic DICOM in surgery, intraoperative image acquisition, modelling and simulation and intelligent cameras.

2015+: Maturity level 3

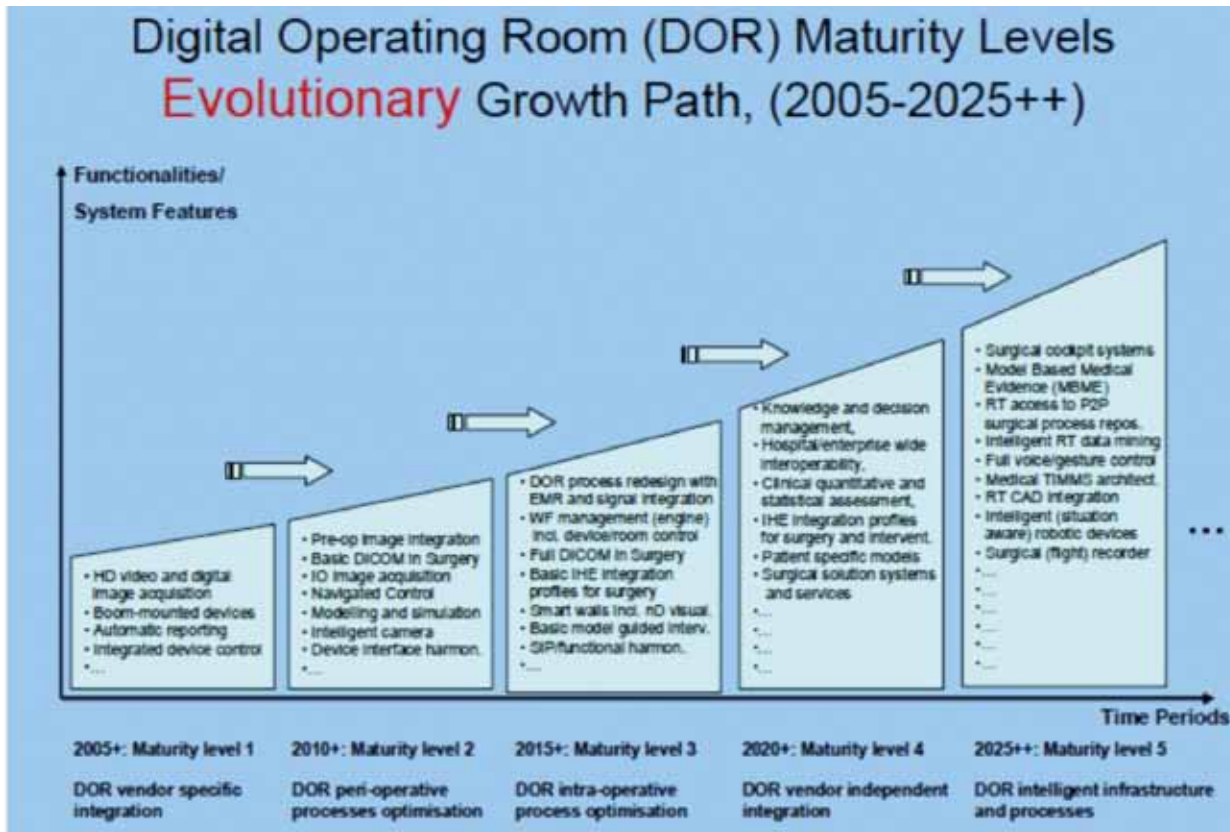Characterised by intraoperative process

Figure 1. DOR Maturity Levels

optimisation. The two critical features of this stage are considered to be the development of a workflow management (TIMMS) engine and full DICOM in surgery. Additional technologies include DOR process redesign with EMR and signal integration, basic IHE integration profiles for surgery, smart walls including n-dimensional visualisation, and basic model-guided intervention.

2020+: Maturity level 4

Characterised by vendor-independent integration of technologies. The critical features of this stage are considered to be the development of hospital/enterprise wide interoperability and patient-specific models. Additional technologies include knowledge and decision management, clinical quantitative and statistical assessment, and IHE integration profiles for surgery, pathology and interventional procedures generally.

2025+: Maturity level 5

Characterised by intelligent infrastructure and processes. The critical feature of this stage is considered to be the development of surgical cockpit systems and Medical TIMMS architecture. Additional technologies include real-time access to peer-to-peer surgical process repositories,

intelligent real-time data mining, full voice/gesture control, real-time CAD integration, and intelligent (situation aware) robotic devices.

A glimpse of what may be ahead in the OR and predicted in (Lemke and Berliner 2011) is provided by an interesting example of a surgical workflow management system, which includes a Surgical Procedure Manager (SPM), already in clinical use at the International Development Reference Centre (IRDC) in Leipzig (Strauß et al. 2013).

First experiences with this system show that this type of knowledge-based system in the OR can improve efficiency of the interventional processes. It may, however, induce the surgeon to rely excessively on the "intelligence" of the machine to provide the "right" information on patient and processes at the right place, at the right time and to the right person in the OR.

Trust in this form of "intelligence" and in the right record-keeping and subsequent management of interventional process information for patient outcome evaluation, are new dimensions of concern when machine intelligence moves into therapeutic activities within the context of a digital OR.

Important aspects of these dramatically evolving ICT based methodologies and tools are new requirements for:

1. DOR IT architectures providing the right basis for enabling a higher quality of therapeutic interventions by means of interoperability features, for example, real-time integration of information in patient-related data structures and therapeutic processes through computer-assisted workflow, knowledge and decision management (see also section 2 below).

2. Standards that take account of the specific requirements for surgical/interventional workflows, devices and systems. Examples are DICOM in Surgery and IHE Surgery (see also section 3 below).

3. Methods and tools for supporting approval procedures on an international level, for example, device/systems classification, clinical and non-clinical testing for safety, high confidence medical device software and systems through appropriate modelling and simulation, etc. (see also section 4 below).

Figure 2. ENT surgical workstation supported by a surgical procedure manager

2. DOR IT architectures for interoperability

Architectural features, for example, as part of an intelligent infrastructure of an OR have only recently become a focus in discussions relating to interventional settings (Goldman 2007; Lemke and Vannier 2006). Such an IT reference architecture may be referred to as a Therapy Imaging and Model Management System (TIMMS) (Lemke and Vannier 2006).

A TIMMS-like architecture and its application for achieving image and model-guided therapy has been the subject of discussions in the DICOM and IHE standard activities. An implementation of a prototype based on open standards of the modular TIMMS-like architecture is in progress at the Innovation Centre Computer Assisted Surgery (ICCAS) in Leipzig, Germany. TIMMS is a comprehensive medical-surgical communication and assistance system (see Figure 3), which is composed of interconnected computer hardware and software components (such as engines, repositories and an IT infrastructure).

There are seven TIMMS engines, which may be defined as software modules which can be executed on an appropriate computing machine in order to provide interventional functionalities. These engines relate to imaging and biosensor data acquisition, modeling, simulation, workflow and knowledge and decision management, visualisation, intervention and validation. Some of these engines are already present and used in modern OR systems.

The Kernel for workflow and knowledge and decision management provides the strategic intelligence for therapeutic planning and workflow execution. Often this module (or parts thereof) is integrated into some of the other engines, as need may demand. This important computing kernel (or "brain") of the system may use different forms of logic, different database structuring, agents and other forms of artificial intelligence, depending on the specific applications of the performed procedure.

In a full realisation, a TIMMS may provide the following features and functions throughout the course of a medical and surgical treatment:

1. Standardised interfaces for communication and mechatronics, thereby creating a unified environment for the input and output of data (including the representation of and display of information and images, as well as the electromechanical control of surgical and navigational devices);
2. Creation and maintenance of a patient-specific model (PSM), thereby providing a multi-scalar, comprehensive, precise, personalised representation of the patient;
3. Creation and maintenance of a system for process modelling (PM) of all aspects of the surgical workflow, to ensure efficiency, learning and safety throughout operative procedures;
4. Real-time knowledge management and decision support system thereby promoting optimised diagnostic, prognostic and therapeutic decisions throughout the treatment workflow;

5. Validation and approval procedures, thereby providing quality assurance, patient safety, system security and processing of medical evidence towards securing better patient outcome.

Features 1, 2, 3 and 4 are the prerequisite of an intelligent infrastructure of an OR. A full realisation of these functions is still a long way away. In practice, however, some small subsets of patient models, process models and/or real time knowledge management have been implemented and clinically tested. Feature 5 can begin to be properly addressed when features 1-4 have reached a tangible stage of implementation from which one can derive appropriate requirements for safety testing and feature/(usage) classification for devices and systems approval.

Feature 2 is subject to standard activities in working groups in DICOM and IHE in surgery. Feature 5 is of major concern in a number of regulation agencies such as FDA, PMDA, CEN and DIN. FDA and PMDA will be discussed further in section 4 below.

One of the architectures proposed in OR:NET (OR.NET 2014) is somewhat different in appearance with respect to the TIMMS architecture, but conceptually contains an equivalent base structure (see Figure 4).

3. DOR standards

Since 2003/2004 it was recognised (Lemke et al. 2005; CAR/CMI 2004), that the realisation of the "OR of the Future" or DOR, will be a comprehensive undertaking, requiring, among others, the development of standards for achieving interoperability of medical devices and systems in the OR. Since then, DICOM and IHE have been considered, in principle, as enablers for fulfilling these requirements.

3.1 DICOM in Surgery

DICOM in Surgery, i.e. the DICOM Working Group 24 was founded in 2005 with the aim of developing DICOM objects and services related to image-guided surgery (IGS) and related interventions. Its initial roadmap included:

- Select and define a user community of IGS disciplines in WG24. Initially five surgical disciplines (Neuro, ENT, orthopedics, cardiovascular, thoracoabdominal) and interventional radiology have been selected. Anaesthesia is included as long as surgery is affected.
- Compile a representative set of surgical workflows (with a suitable
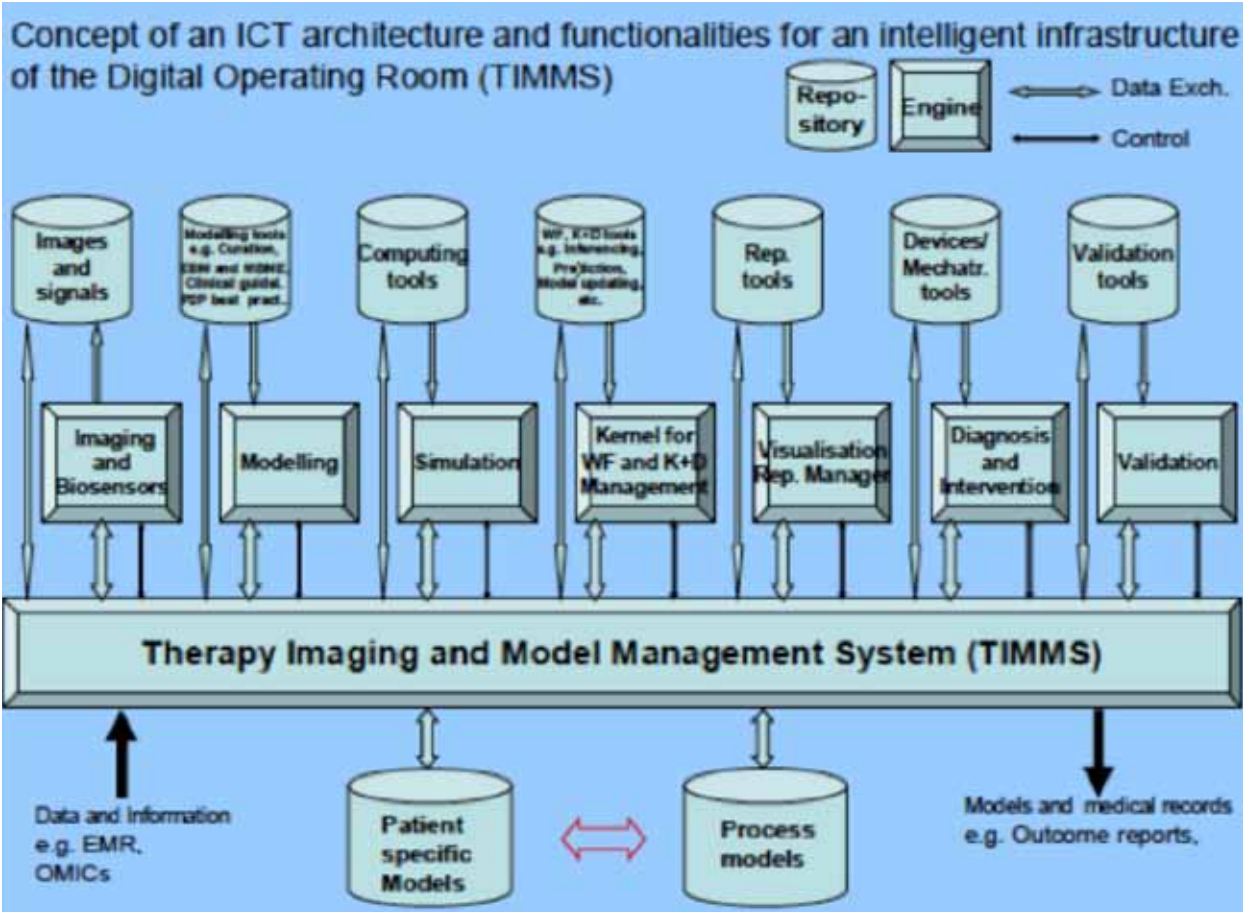
Figure 3. TIMMS: an informatics platform/structure for model-guided therapy including the engine and repositories for machine intelligence (marked with ellipsoids)

Figure 4. Proposal for IHE surgical domain architecture (Source: Jörg-Uwe Meyer, MT2IT GmbH & Co)

high level of granularity and appropriate workflow modelling standards and surgical ontologies) as a work reference for the scope of WG24. Initially, 3-5 workflows, characteristic for each discipline, should be recorded with sufficient level of detail.

● Derive potential DICOM services from these surgical workflows and identify appropriate use cases.

● Design an information model based on electronic medical record (EMR) and related work on patient modelling to identify IOD (Information Object Definition) extensions for DICOM.

● Take account of the special image communication (1D - 5D) requirements for surgery and mechatronic devices. A close cooperation with other Working Groups should be pursued.

● Connect to integration profiles specified in existing IHE domains.
In close cooperation with industry a number of DICOM supplements have been realised in recent years.

Supplement 132- Surface Segmentation

This IOD can be used to encode tissue segmentation, functional segmentation, and artefact identification for quantification or visualisation.

Supplement 131- Implant Template

This supplement describes storage, query and retrieval of implant templates (generally non-patient-specific) as they are used in implantation planning.

Supplement 134 - Implantation Plan

The aim of this supplement is to communicate implantation planning information from the planning workstation to the operating room.

Supplement 154 - Optical Surface Scanner

This supplement introduces a modality for optical surface scanners. This allows storage and retrieval of scanned surfaces to and from a PACS.

Some IGS and DOR related problems are currently under discussion in WG 24 that could lead to work items.

● A Universal Reference Coordinate Standard which helps to freely transfer spatial information between involved devices and systems pre- and intraoperatively;

● A standardised way to communicate patient identity to participating devices in the OR. WG 24 is open for discussion for other potential work items, in particular those which may be indentified, for example, in projects such as OR.NET and MD PnP.

3.2 IHE Surgery

IHE Surgery was founded in 2012 as a provisional IHE domain (IHE International Board 2012) after a long preparatory phase by the sponsoring organisations, the International Foundation of CARS and the International Society for Computer Aided Surgery. The scope and rationality of the domain include:

• The IHE Surgery domain addresses the problems of interoperability, information sharing, and model sharing to improve the quality of care in surgery and related interventional therapies. It focuses on the needs for Image and Model Guided Therapy (IMGT) Systems.

• The solutions for the interoperability problems in the field of surgery and related interventional therapies are not yet on the level of the solutions presented in the IHE profiles of other IHE domains. Since surgery is one of the core units in a clinical setting, it

is therefore important that it is represented as an IHE Domain.

Some of the needs in the context of the DOR that are currently being addressed are:

• Distribution of implant templates for surgeons, applications, and surgical devices

• Distribution of implantation plan through the preoperative, intraoperative, and postoperative phase.

• Creating, storing, and retrieval of surface segmentations.

• Creating, storing, and retrieval of surface scanner objects.

• Intra- and inter-institutional distribution of surgical process models.

• Intra- and inter-institutional distribution of digital patient models.

Of particular interest for IHE Surgery are the potential integration profiles or clinical story boards from the clinical domains of ENT, laparoscopic, spinal surgery and anaesthesia currently being investigated for the OR.NET Demonstrators and which are expected to be implemented in the last phase of the OR.NET project.

This would support the recommendation expressed in (Moser et al. 2013), which envisages a strong role for IHE Surgery in transcribing OR.NET use cases (after they have been prioritised and consolidated) into IHE use cases / Integration Profiles (IP) in a move towards a closer cooperation between OR.NET and IHE Surgery, generally.

4. International approval issues

A critical question for the development of IT architectures and standards which support interoperability in the OR, relates to the issues they raise in risk assessment and the appropriate classification by the international approval processes for medical devices and systems.

In the following, the current situation of approval procedures in the USA and Japan will be briefly outlined (in a follow-up publication they will be compared to regulatory developments in Europe). Most of these observations are based on presentation and discussions in the course of a CARS 2014 DICOM in Surgery and IHE Surgery Workshop on "DICOM Supplements and IHE Integration Profiles, Implementation and Approval Issues", which took place in Fukuoka, Japan on June 28, 2014.

4.1 FDA (USA)

It appears that the FDA is taking an active role in the discussion relating to interoperability and corresponding issues in approval regulations by also being a member of the MD PnP project (Goldman 2007).

Support for MD PnP program work has come from DoD/TATRC, NSF, NIST, CIMIT, and NIH/NIBIB, which awarded a $10M Quantum grant in October 2010 to develop a healthcare intranet based on integrated medical device systems.

An important part of the key MD PnP Program projects is (MD PnP Program 2014) "Defining a safe regulatory pathway for patient-centric networked medical devices." Carried out in close partnership with the FDA, progress so far includes a co-sponsored workshop held by FDA in January 2010 on medical device interoperability, followed by a working group of companies, academics, and hospitals that have developed and submitted a pre IDE (Investigational Device Exemption) regulatory submission to help refine the FDA clearance process.

Some of the questions posed by representatives from FDA include (U.S. Food and Drug Administration; Continua Health Alliance; Center For Integration Of Medicine & Innovative Technology (CIMIT); Medical Device "Plug-and-Play" Interoperability Program (MD PnP) 2010):

Clinical issues

What clinical scenarios could make use of medical device interoperability? Are there clinical scenarios that would not be appropriate?

Engineering issues

How should medical device interoperability be defined in terms of architecture, components, interfaces, functional requirements and performance requirements?

Risk issues

What are the risks associated with medical device interoperability and systems of systems composing medical devices? Use of risk models for interoperable systems.

Management issues

Who are the responsible parties and what is their role in design, building, maintenance, improvement as well as development and dissemination of standards and best practices?

It is interesting to note, that the FDA is responding positively to 510(k) applications, which include in their device description compliance to IHE, DICOM and

HL7. For an example see (U.S. Food and Drug Administration (2011), which refers to a recent PACS approval procedure by a major manufacturer who included in its device description:

"Centricity PACS is a standards-based, customisable, and scalable solution supporting several of the Integrating the Healthcare Enterprise (IHE) profiles, Digital Imaging and Communications in Medicine (DICOM), and the Health Level Seven (HL7) protocol standards for managing digital medical images and patient data. Centricity PACS supports radiographic imaging-as in clinical radiography, cardiology, dentistry, and mammography and non-radiologic imaging, including video support".

Also in the area of PACS components or devices it can be observed that compliance to IHE integration profiles is thought to be a significant advantage in FDA approval procedures. For example, Three Palm Software, LLC stated in their application (U.S. Food and Drug Administration 2007):

"The enterprise workflow of the workstation (WorkstationOne™ Breast Imaging Workstation) follows IHE integration profiles, specifically, MAMMO (Mammography Image Profile) and RWP (Reporting Workflow Profile)".

Another example of FDA approval applications with IHE integration profiles is in the area of digital radiography software tools for Quality Assessment (QA), in particular "Standardised Dose Reporting for QA" (Don 2012). The Alliance for Radiation Safety in Pediatric Imaging recommends the IHE Radiation Exposure Monitoring (REM) profiles and DICOM Structured Reports (SR) to be applied in this context.

For approval purposes, medical devices and systems, such as given above need to be grouped into one of three FDA regulatory classes: Class I, II or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness.

The three device classes are defined as follows (U.S. Food and Drug Administration 2014):

Class I: Devices are subject to a comprehensive set of regulatory authorities called general controls that are applicable to all classes of devices.

Class II: Devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device,

and for which there is sufficient information to establish special controls to provide such assurance.

Class III: Devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require premarket approval.

Most medical devices can be classified by finding the matching description of the device in Title 21 of the Code of Federal Regulations (CFR), Parts 862-892. FDA has classified and described over 1,700 distinct types of devices and organised them in the CFR into medical specialty panels such as Cardiovascular devices or Ear, Nose, and Throat devices. The devices most relevant for the OR can be found in Part 878 entitled General and Plastic Surgery, Part 876 entitled Gastroenterology-Urology Devices and in Part 892 entitled Radiology.

There is a comprehensive set of guidelines on how to apply for FDA Premarket Approval (PMA) or premarket notification (often referred to as a 510(k). This is particularly the case also when there is software contained in medical devices (U.S. Food and Drug Administration 2002).

An approval application is usually supported by a list of standards, which the medical device/system has been shown in tests to be in compliance with. Most of the well-known national and international standard bodies are explicitly recognised by the FDA. This list does not include IHE (as IHE is not a standardisation organisation)

but examples of FDA approval application demonstrate that IHE compliance is being used in the device descriptions as a marker for quality. How the importance of compliance with IHE integration profiles is being rated in the approval process, however, is not made clear by the FDA guidelines for Industry or by Food and Drug Administration Staff.

A very special situation exists for an approval application for an IDE, relating to clinical trial approval by foreign companies. In this case, the sponsor of the clinical trial is responsible for submitting the IDE application to the FDA (§812.40) and obtaining Institutional Review Board (IRB) approval before the study can begin. Foreign companies wanting to conduct a clinical study in the U.S. MUST have a U.S. sponsor (§812.18).

4.2 PMDA (JAPAN)

The Pharmaceuticals and Medical Devices Agency (PMDA) is the FDA equivalent agency for approval procedures for medical and surgical devices and systems in Japan. In principle, it can be observed, that the medical device approval procedure is harmonised with those of other advanced countries.

Figure 5 shows the classification used by PMDA, in principle derived from activities of the GHTF (Global Harmonisation Task Force) (USA, EU, Australia, Canada, and Japan). It is (almost) in line with respect to the FDA classification, except that an extra Class IV has been added for highly risky devices. For Class II devices, third-party certifiers (in EU terminology: notified

Figure 5. Regulation and classification of medical devices in Japan (Pharmaceuticals and Medical Devices Agency, Japan 2013)

bodies) are approved by the Minister of Health, Labor and Welfare (MHLW). The approval criteria, however, are defined by MHLW. It is expected that after November 26, 2014 third-party certifiers will also be permitted to review and approve Class III devices.

As regards approval for software, it is important to note that high-risk health software running on non medical devices will be regulated after Autumn 2014. Specifically, software operated in non-medical devices (such as PC and tablet) used for high-risk applications will be reviewed by PMDA also after autumn, 2014. It can be expected, that the safety requirement defined in international standards will be referred to. Surgical navigation software running on conventional PC will also be regulated.

An important point of discussion in Japan relates also to the question whether the clinical data obtained in foreign countries is applicable to the review process in Japan. Specific issues are:

- clinical environment,
- differences in anatomy, pathology, depending on race, etc.,
- comparison with standard care.

In general, the PMDA profile of services as indicated in the 6 phases (top of Fig. 6), i.e. Research and development, Non-clinical tests, Clinical Test, Filing of application, Approval and Marketing, are similar to the FDA and European approval services. It is important to note that standards development is considered to be a continuous activity in the PMDA profile of services.

It is also recognised by PMDA that, in order to improve on the profile of services (Pharmaceuticals and Medical Devices Agency, Japan 2013), a promotion of regulatory sciences is important to accelerate R&D of medical devices as well as an enhanced international cooperation. PMDA, therefore actively promotes international activities in line with the PMDA International Strategic Plan and the International Vision formulated in 2009 and 2011, and as well as a road map for more specific action plans defined in 2013.

In order to build closer relationships with the EU and the US, PMDA has dispatched its staff members to regulatory agencies abroad including the European Medicines Agency. Moreover, PMDA's ties with other regulators from the US, Europe, and Asia have been reinforced by means of holding PMDA training seminars and the exchange of trainees.

5. Conclusion
5.1 OBSERVATIONS AND QUESTIONS

A significant number of functionalities in the Operating Room require (real-time) exchange of data and control information. Based on the IT architectures discussed above and generic standard issues outlined in a Weissbuch on "Sichere Dynamische Vernetzung in Operationssaal und Klinik" (Moser et al. 2013), these functionalities may best be understood by means of clinical scenarios or use cases which address real clinical requirements for interoperability. Approval of devices and systems, which claim to have features to support such interoperability should be based on tests, which include compliance to standards. This, however, poses a number of questions which need to be addressed in the development of the DOR

These include:

1. What functionality/feature changes to an already approved device distinguishes a predicate device 510(k) procedure from a new or post-predicate device (for example, augmented with new interoperability features), ie when and when not is a device substantially equivalent to a predicate device and does it need to be classified as Class 3 requiring something similar to a Premarket Approval?

2. How will specific software (including for example, new Apps) for "intelligent" or web-enabled interoperability be classified in Japan, USA or Europe (taking into account the differences in device classification systems)?

3. What strategic steps in national and international approval organisations and technical and legal developments are necessary to raise the importance of IHE Connectathon and certification, as a basis for safety assessment in the approval process?

4. What strategic steps in national and international approval organisations and technical and legal developments are necessary to raise the importance of a scientific approach, as a basis for safety assessment in the approval process?

Another interesting observation relates to the classification of medical devices, which perhaps will become a major issue comparing FDA, PMDA and corresponding EU Directives. The latter states (Council directive 2007):

"Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it may submit a duly substantiated request to the Commission and ask it to take the necessary measures for adaptation of classification rules. The measures designed to amend non-essential elements of this Directive relating to adaptation of classification rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3)."

The question here to be addressed in the future relates to whether devices augmented with (intelligent) software for interoperability qualify for the label "technical progress" and may therefore require, for an appropriate classification, an adaptation of the classification rules as given by the regulatory agencies. It remains to be seen, whether the new drafts for Amendments of the EU Directives concerning medical devices or the expected new PMDA regulations will take account of these new technological challenges.

5.2 Recommendations

It can be expected, that the complexity of the clinical and non-clinical tests for safety is very high, and a solid scientific foundation (Pace 2004) is necessary to show that a safe interoperability has been achieved. The PMDA drive to promote regulatory sciences is important in this context and may be of particular significance when devices and systems are planned to be employed in an international environment. From this and the observations made above, a number of recommendations can be derived:

1. In the middle or long term a Centre for interoperability in the OR with a strong focus on scientific methods and tools may have to be established on an international level, not least to establish completeness and reproducibility of testing procedures for clinical and non-clinical tests for interoperability of medical devices and systems for the OR, thereby enabling a higher confidence level for safety of medical device software and systems in the OR (Lee et al. 2006).

2. As it is expected that the role of IHE integration profiles will increase in importance for approval agencies in the future, IHE generally and IHE Surgery Connectathons specifically,
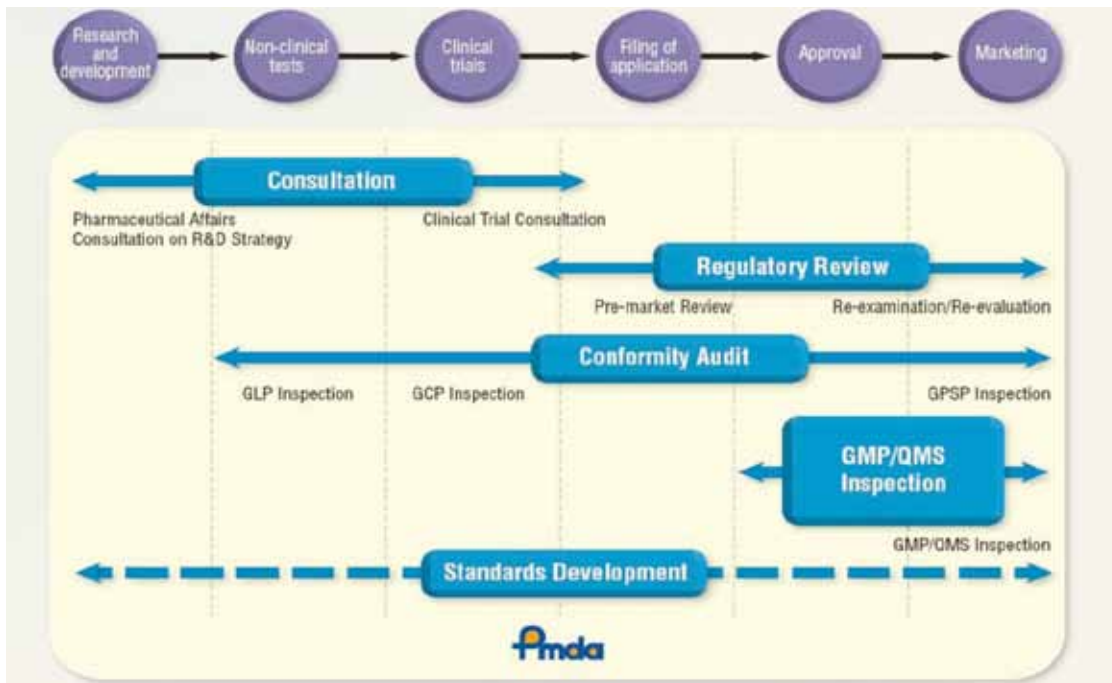
Figure 6. PMDA profile of services 2013-2014 (Pharmaceuticals and Medical Devices Agency, Japan 2013)

can be considered to be the first steps in this direction and should become a focus of OR.NET, MD PnP and similar (follow-up) projects in the near future.

3. Leading industry for integrated ORs should be encouraged to take an active role in promoting activities towards recommendations 1 and 2. This does imply In particular, taking steps towards the definition of a set of promising IHE integration profiles, which may then provide the basis for work items in the appropriate IHE domains.

4. A regular annual international OR interoperability forum for the exchange of views, concepts, R&D results, clinical and non-clinical safety testing, classification standards to facilitate conformity and predicate device testing, technical documentation, quality assessment and control of notified bodies, regulatory developments, etc. should be established. This forum should be of particular interest to SMEs engaging in the development of medical devices, in order to obtain a better understanding of resources required to achieve medical device approval on a national and international level.

The CARS 2014 Workshop on "IHE Integration Profiles, Implementation and Approval Issues" (CARS 2014) may serve as a template for such a forum. ∎

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TELECARDIOLOGY IN THE NETHERLANDS

RESULTS OF A HIGHLY SUCCESSFUL SERVICE

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Telemedicine

Telemedicine is the delivery of healthcare and sharing of medical knowledge by use of information and communication technology (ICT), enabling caregivers and caretakers to work together independently of place and time for the purpose of consultation, examinations or medical procedures, and education (Strode et al. 1999). Telemedicine has been considered an organisational answer to keeping healthcare accessible for the general population. It has become one of the solutions for the restructuring of healthcare systems in the developed world and the progression towards better healthcare in developing countries in coming decades.

Due to its visual character, dermatology was one of the first specialties to adopt telemedicine, preferably in store-and-forward sessions (Wurm et al 2008). Telemedicine has also been widely introduced in other specialisms like cardiology, ophthalmology and pulmonology (Hailey et al. 2004; Lamminen et al. 2003; Thrall 2007).

Telecardiology, the application of telemedicine in the field of cardiology, has applications in diagnosis and management of hypertension, implantable electronic devices, echocardiology and coronary CT scans, reduction of sudden cardiac death, diagnosing acute ST elevation myocardial infarction, the treatment of heart failure and diagnosis and treatment of arrhythmias. Studies have shown telecardiology services to substantially reduce the number of hospitalisations of patients with a wide range of heart diseases and conditions, and to lower mortality after myocardial infarction, compared to the general acute myocardial infarction population (Birati and Roth 2011).

Teledermatology has been fully integrated in the Netherlands and has been extensively described (van der Heijden et al. 2011). Comparable results to teledermatology are reached in telecardiology.

This paper describes results regarding implementation, efficiency and quality of telecardiology in regular care, performed by GPs and medical specialists that work with KSYOS TeleMedical Centre, an institution for specialist medical care engaged in developing, researching and introducing telemedicine services in regular healthcare.

Health Management Research Model

With the use of the Health Management Research Model (Witkamp and van der Heijden 2012), private and public parties and independent knowledge institutes can jointly develop telemedicine tools, study their effect on efficiency increase of the primary healthcare process, and enable their modular introduction and upscaling

"TELECARDIOLOGY STRENGTHENS THE HEALTH CHAIN"

in regular care through 4 phases (see Table 1). It entails usability, feasibility, efficacy and (cost-)efficiency research aimed at professionalising new telemedicine tools in a phased way, obtaining support, proving the effect on the improvement of efficiency, and after that studying the user and reimbursement model. Independent scientific parties protocol the various stages of the research and monitor its quality and independence.

Telemedicine Development (phase 1 and 2)

Partners construct a telemedicine tool and develop it to an integrated service that incorporates most aspects of ICT security, safety, software, hardware, hosting, infrastructure, logistics and, if needed, certification.

Health Management Research (phase 3)

Health Management Research aims to prove that the use of telemedicine services increases efficiency on several levels: bringing more work satisfaction at the user level, increasing production volume and providing better healthcare quality at equal or lower costs.

Health Management Implementation (phase 4)

All stakeholders – manufacturers, users, policymakers and health insurers – are involved in the design of practice and reimbursement research. The starting points here are significant reductions in costs on a macro level and a sustainable business case, with surplus reimbursement per use for manufacturers, users and policymakers. The interested parties together establish a price for the use of the telemedicine tool, and predefine performance indicators that are conditional for reimbursement. These performance indicators may entail health outcomes as well as logistic outcomes. In order to guarantee successful upscaling in regular care, the benefits of the telemedicine instrument for, and its synergy with, regular care are actively marketed and communicated.

KSYOS TeleMedical Centre: the First Virtual Hospital in The Netherlands

Safe, prosperous and socioeconomic balanced introduction of telemedicine services demands its provision by certified centres that meet minimal quality requirements: a care institution (or commercial company) that acts as a dedicated telemedicine provider, thus providing a single organisation that manages all these issues and is also the point of contact for patients, care professionals and other actors such as government and supervisory bodies. The responsibilities and tasks that a telemedicine provider can (and perhaps should) incorporate to set up a telemedicine service are:

• Administration, registration and storage of clinical records;

- Negotiating sustainable reimbursement with healthcare insurers;
- Handling claims and crediting incorrect claims;
- Payment of involved actors (eg dermatologist, general practitioner (GP) and telemedicine provider staff);
- Providing clinical liability insurance specifically tailored to telemedicine procedures;
- Providing a telemedicine software platform and keeping it up-to-date in concordance with the latest security standards, legislation and regulations;
- Providing suitable hardware for telemedicine procedures (eg ECG recorders, cameras, dermoscopes);
- Providing CME-accredited training programmes for the medical staff (eg taking clinical pictures, using the telemedicine platform, assessment of skin lesions via telemedicine);
- Providing on-site training in the use of the telemedicine system to all users;
- Providing project management for telemedicine implementation in a region;
- Providing a helpdesk service for technical and administrative issues;
- Providing yearly reports on performance indicators (eg per clinic);
- Providing integration with Electronic Health Records (EHRs) for both GPs and specialists;
- Negotiating and developing communications standards together with EHR providers and other (governmental) actors;
- Adhering to the latest quality standards and certifications where and when applicable (eg ISO, CE).

KSYOS TeleMedical Centre was officially recognised as a healthcare organisation in December 2005. KSYOS contracts health insurance companies and care groups that pay for each tele-examination and teleconsultation that is performed. KSYOS in return provides a complete service integrating all the items mentioned above.

TeleCardiology Results in The Netherlands
Process
KSYOS Telecardiology consists of two types of diagnostic tele-examinations (TeleCardiology Rest ECG (TCER) and TeleCardiology Event ECG (TCEE)) and teleconsultations (TCC) with the regional cardiologist.

Depending on the clinical context, a GP can give patients a TCER on the spot, or the GP can provide a recorder and the cardiac rhythm can be recorded continuously for 24, 48 or 72 hours, or even up to 7 days or 14 days in a TCEE. Unlike conventional event diagnostics, the advantage of continuous recording is that asymptomatic clinically relevant arrhythmias are indeed registered (for example, paroxysmal atrial fibrillation).

All ECGs (biometry) are stored as a PDF file. This PDF can be accessed online through the secured online KSYOS Electronic Patient Record and are assessed by a grader. This can be a cardiologist but also analysts trained specifically for this task. The results (biometry and grading) are presented to the GP who ordered the tele-examination.

If an abnormality is found, the GP can decide to refer the patient physically, or send a TCC to the regional cardiologist using the data received from the tele-examination, all from within the KSYOS Electronic Patient Record. Additionally, the system selects about 10% of the tele-examinations at random for auditing, where a cardiologist reviews the quality of the biometry and grading anonymously. The biometrist and grader thus receive feedback on their work.

TeleCardiology Examination
Since May 2011, KSYOS has performed 14,687 TCERs and since August 2013 2,195 TCEEs together with 557 GPs. 14% and 43% of TCERs and TCEEs respectively were converted to a telecardiology consultation.

TeleCardiology Consultation
Since 2006 there have been 170,189 teleconsultations performed through KSYOS, of which the most used services are

Phase 1	A specific Telemedicine service is developed, which is tested internally for usability in practice.
Phase 2	10 to 20 future users test this Telemedicine service for usability in practice.
Phase 3	50 to 100 future users test whether the Telemedicine service actually contributes to improved efficiency in the healthcare process: a higher production volume and/or better quality at lower or the same costs.
Phase 4	Many users in a full implementation of the Telemedicine service generate data in real life experiment. These are used to investigate large scale cost efficiency. Results can be used in developing sustainable business cases.

Table 1. Health Management Research Model phases
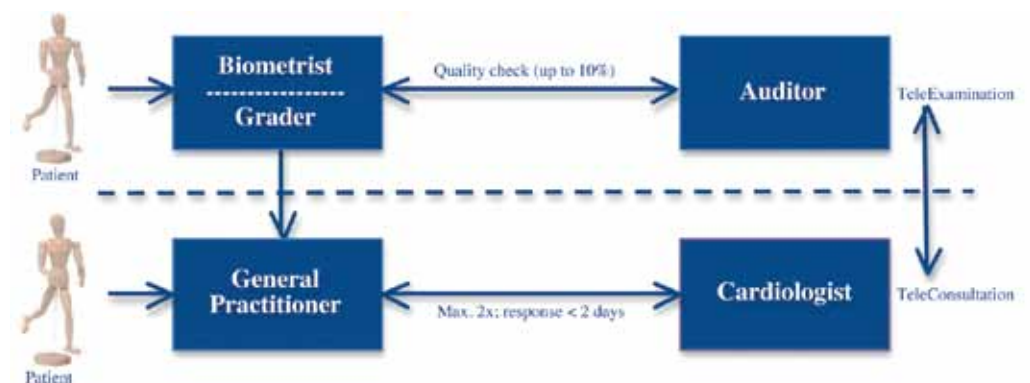
Figure 1. TheTeleCardiology Process

	male	female	avg. age	median age	max age	min age
TeleDermatology	44%	56%	44	45	104	6 days
TeleCardiology	50%	50%	59	61	111	2
TeleOphthalmology	51%	49%	66	68	110	1

Table 2. Teleconsultation Demographics

teledermatology (TDC) (111,597), telecardiology (TCC) (24,924) and tele-ophthalmology (TOC) (18,646). These teleconsultations were sent and answered by 884 GPs and 256 cardiologists in TCC, 1,003 GPs and 98 ophthalmologists in TOC and 3,232 GPs and 348 dermatologists in TDC.

Reduction of Physical Referrals
In 46% of all TCCs (n=11,483), the GP intended to refer the patient physically to the cardiologist if teleconsultations were not available. In this group, 59% of the patients (n=6,736) were not physically referred after TCC.

Quality of Care
In total 13,441 patients (54% of all TCCs) were selected for advice via TCC only. In this group, 2,579 patients were referred to the cardiologist as a result of early diagnosis in the TCC. These additional referrals lowered the overall reduction of physical referrals from 59% to 36%.

The mean interval for answering by the cardiologist was 5.4 working hours. The GPs indicated in 80% of all TCCs that the answer of the cardiologist was useful. In 70% of all TCCs, the GP perceived a learning effect from TCC (see Figure 2).

With advances of technological medical possibilities and the ageing and more demanding population, healthcare organisation and delivery need to undergo drastic changes. At regional, national and international level, health workers, policymakers and health insurance organisations are addressing these issues. Efficiency increase of healthcare delivery and the role

of ICT in this process is a recurrent issue in policy documents and grant descriptions. Instead of piling on new telemedicine services on top of existing conventional healthcare services, at the base of this efficiency increase is the replacing of the bulk of the work from higher to lower in the health knowledge hierarchy – from

"TELECONSULTATION LEADS TO QUALITY INCREASE"

medical specialist to general practitioner, from general practitioner to nurse practitioners or from nurse practitioner to the patient – under supervision of the person higher in the hierarchy.

Telemedicine is perceived as an excellent tool to achieve this goal, combining innovative technology, changed working conditions, prevention and education. With the use of telemedicine, conventional general hospitals are able to elaborate on their role as a centre of excellence on the top of the knowledge hierarchy in healthcare. On the one hand, it enables these hospitals to further focus on highly specialised care as with the help of telemedicine less routine care will pass through their doors. On the other hand, telemedicine enables these hospitals to maintain their supervising role in this routine care.

Apart from the fact that telemedicine in general prepares hospitals for future changes in healthcare delivery, telecardiology has proved to have various immediate positive effects.

The results of this evaluative study show that KSYOS TeleCardiology Consultation leads to a 59% reduction of physical referrals in the group that the GP intends to refer physically to the cardiologist. The overall reduction rate was lower (36%) because of TCs for advice that led to additional referrals occasionally.

Teleconsultation leads to quality increase as a vast proportion of all TCs are performed for advice only (54%) and without intending to refer physically. In addition to that, some TCs for advice are leading to a physical referral (19%). Both parameters can be seen as quality improvement. Without telecardiology these patients would have had no supervision by of or referral to the cardiologist. The response time of 5.4 working hours is in sharp contrast to usual waiting times of 4 – 6 weeks for physical referrals. Finally, the learning effect of TC will in the long term lead to better care, as all healthcare providers down the hierarchy chain are learning through using telemedicine.

Telecardiology enables hospitals and cardiologists to influence their waiting lists. By doing so, the hospital delivers quicker and better care to general practitioners and patients without cannibalising on their own production. If telecardiology is delivered on a regional basis, general practitioners and cardiologists are excited about telecardiology. Telecardiology strengthens the health chain and contacts between general practitioners and cardiologists. Offering telecardiology, the hospital firmly strengthens and enlarges its catchment area of general practitioners that refer to it. ∎

Key Points
- Using the Health Management Research Model, private and public parties and independent knowledge institutes can jointly develop telemedicine tools.
- Safe, prosperous and socioeconomic balanced introduction of telemedicine services demands its provision by certified centres that meet minimal quality requirements.
- In this study 59% of the patients the GP intended to refer were not physically referred after teleconsultation.
- Telecardiology enables hospitals to deliver quicker and better care to general practitioners and patients without cannibalising their own production.
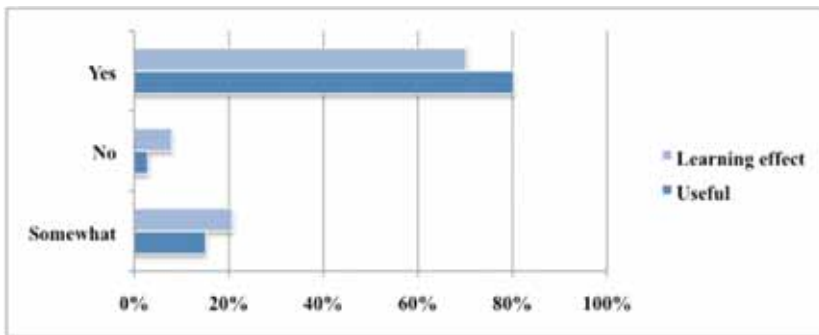
Figure 2. Perceived Learning Effect

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GERIATRICS IN TURKEY

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In 2013 the elderly population in Turkey was 7.7% of the total. Population projections predict a rise to 10.2% in 2023, 20.8% in 2050 and 27.7% in 2075. As at 2013 Turkey already had one of the highest proportion of elderly according to the United Nation's definition of 60+ (TUIK 2014).

In addition, the elderly population has the highest level of growth compared to other age groups. Although the total population growth in Turkey was 13.7% in 2013, the elderly population growth stood at 36.2%, roughly three times higher (TUIK 2014).

Migration from rural areas to the city started in the 1950s, and has rapidly increased in the last 30 years, due to the enhancement of the health condition of mothers and children, the increase in education levels and the rate of women's involvement in socio-economic life. After the 1980s the birth rate decreased, and as a result the total fertility rate regressed to 2.16 children from 5. Life expectancy in Turkey has increased over the years due to the decrease in infant deaths. Although life expectancy was 30 for men and 33 for women in the 1940s, now it has risen to 71 for men and 76 for women. The Turkish Statistical Agency (TUIK) predicts that life expectancy will be 73.1 for men and 78.9 for women in 2025. This shows that Turkey's population will continue to get older, and women will be predominant amongst the geriatric population (Tezcan 2012).

Turkish society has a history of caring for its elders. As the bond between family members is still strong, elders prefer to live with their children or close to them. This preference is thought to be really advantageous for the elders, and also for their children socially and economically.

The education level of the elderly population is rather low. 84% of women and 70% of men appear to be barely literate or illiterate. 56% of the elderly population earn any kind of income. Only 75% of men have a reasonable income, while for women this rate decreases to 38%.

While 10% of elderly men work, only 1% of women do (DPT 2007).

Although geriatrics is a new field in our country, studies continue to develop fast and sharpen awareness of elderly care. The geriatric disciplines studied at our universities, the geriatric centres in our hospitals and foundations, which carry out the relevant research studies, are the best evidence of improvement. The geriatric disciplines and centres were first established in Turkey in the 1980s with the Cerrahpaﬄa Medical Faculty, and became popular in other faculties beginning in the mid 1990s. By 2015 the geriatric discipline was established at 13 medical faculties.

Geriatrics is a subdivision of internal medicine, and four years of training is required to become an internist. Three further years of training in caring for patients both on wards and in outpatient services are crucial in order to

> **" GERIATRIC NURSING IS NOT A SEPARATE SECTION IN TURKEY, ELDERLY PATIENTS ARE CARED FOR BY INTERNAL MEDICINE NURSES"**

become a geriatrician. There is also a compulsory service that has to be completed after completing the geriatrics residency, the duration of which varies between 300 and 600 days, depending on the region of the country. In Turkey there are 35 lecturers, six specialists and 19 residents working in the field

Turkey Statistics (2013)	
Total population	74,993,000
Gross national income per capita (PPP international $)	18,760
Life expectancy at birth m/f (years, 2012)	72/78
Probability of dying under five (per 1,000 live births)	19
Probability of dying between 15 and 60 years m/f (per 1,000 population, 2012)	150/75
Total expenditure on health per capita (Intl $, 2012)	1,144
Total expenditure on health as a percentage of GDP (2012)	6.3

Sources
World Health Organization (2013) Turkey-Country Statistics http://www.who.int/countries/tur/en/
World Bank (2013) Turkey Death Rate http://data.worldbank.org/indicator/SH.DYN.MORT

of geriatrics. Geriatric nursing is not a separate section in Turkey; elderly patients are cared for by internal medicine nurses.

The Darülaceze Foundation is the oldest establishment of elderly nursing with a tradition of 150 years. Such foundations for the elderly continue to provide important services and studies (Arıoğul 2009).

The major panels, symposia, congresses and courses on geriatrics are the National Geriatrics Congress, the Academical Geriatrics Congress, the Rational Drug Symposium, the National Elderly Health Congress, the Geriatric Haematology Congress, the Geriatric Oncology Congress, and the list may continue.

Besides Ege University Medical Faculty, which has an elderly health postgraduate programme and holds a geriatrics nursing licence, Adnan Menderes University Medical Faculty has an elderly health and nursing postgraduate programme.

Conclusion

Geriatric services are still primarily provided in medical institutions. Although civil and official foundations' efforts have increased, a widespread and systematic service regarding the provision of medical care at home has not been implemented yet. ■

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"...it's the person that makes the place"

PROFESSOR LORENZO BONOMO
ESR PRESIDENT

1. What are your key areas of interest and research?
The chest was my first professional passion and continues to be so. My early research focused on the possibilities of the chest x-ray in the evaluation of changes in the pulmonary circulation in various lung and heart pathological conditions. CT allowed me to further develop my interest in thoracic radiology, focusing on imaging of lung tumors, and deepening research on pulmonary circulation with CT.

2. What are the major challenges in your field?
There are many: some internal to our discipline and others external. Among the first, to emphasise the need to be increasingly clinical radiologists, competent and updated, capable of being valid consultants for our clinical colleagues and specialists helping in patient management, providing more accurate diagnosis and able to make accurate therapeutic decisions. Among the external challenges are the development of molecular imaging and personalised medicine.

3. What is your top management tip?
It is very important to have a vision and share it in order to develop a strategy and motivate people.

4. Your career highlight?
The current position of Professor of Radiology of one of the most prestigious Italian Medical schools and President of the largest Radiological Society of the world are certainly my career highlights.

5. If you had not chosen this career path you would have become a...?
I love music and I wanted to be a singer, but I sing so out of tune that I don't dare sing in the shower.

6. Your leisure interests?
Music, going to movies, long mountain walks and (knees permitting), skiing.

7. Your favourite quote?
There are two quotes:
• "It's not the place that make the person, it's the person that makes the place."
• "People come and go, but institutions stay."

"At the crossroads of life there are no signposts"

PROFESSOR BERND HAMM
ECR PRESIDENT

1. What are your key areas of interest and research?
Supporting and promoting radiology at a European level, including defining the changing role of radiology and shaping its position in the interaction of the different clinical specialties. My key scientific interests are abdominal and genitourinary imaging, in particular the detection and characterisation of liver tumour, the diagnosis of malignant uterine tumours, and MR diagnosis of prostate cancer.

2. What are the major challenges in your field?
Radiology is one of the medical specialties with the most dynamic development and the most breathtaking innovations. I hope that different subspecialties continue under the common roof of radiology. We must not slacken in our efforts to further improve and advance radiological diagnosis and patient treatment.

3. What is your top management tip?
To have motivated staff willing to provide empathetic medical care to the benefit of our patients and continuing to be curious to do good research. My guiding motto is "You must succeed at home first before you can start dreaming about playing Champions League". So one must first show a good performance in organising one's own department and other local activities before one can get involved in international professional activities and expect to succeed there.

4. Your career highlight?
Small and bigger accomplishments, which provide support and motivation to carry on. One must not get discouraged when things do not turn out as expected, but take a defeat as an additional incentive to carry on, develop new ideas, and start other projects.

5. If you had not chosen this career path you would have become a...?
I wanted to become a radiologist in private practice. I did not imagine that I would one day be a Professor and Chair of a large University Department of Radiology.

6. Your leisure interests?
Skiing, sailing and the cultural life of Berlin.

7. Your favourite quote?
"At the crossroads of life there are no signposts" (Charlie Chaplin).

"Potentiality has a shelf life"

SHIRLEY CRAMER
ROYAL SOCIETY FOR PUBLIC HEALTH CEO

1. What are your key areas of interest and research?
Finding innovative ways to improve the public's health by building the capacity and capability of the wider workforce and measuring the impact of community-based preventative work so that the best practice can be easily disseminated.

2. What are the major challenges in your field?
a) Getting prevention to the the top of the healthcare policy agenda; until we do life will only get more challenging for those in healthcare management.
b) Developing a holistic healthcare system which is patient-centric.
c) Motivating and supporting the healthcare workforce.

3. What is your top management tip?
Always ask the frontline workforce what works and what doesn't; too often they are left out of the decision-making process with resulting poor outcomes.

4. Your career highlight?
Initiating a national US Summit on Learning Disabilities in Washington DC, which led to positive long term effects for vulnerable children (the No Child Left Behind Act).

5. If you had not chosen this career path you would have become a...?
I was always interested in people and issues so possibly politics.

6. Your leisure interests?
Hiking, skiing, theatre, spending time with friends, which usually involves good food.

7. What is your favourite quote?
Margaret Atwood, the Canadian writer, said in one of her books that 'potentiality has a shelf life'; this always reminds me of the urgent need to make sure that all our young people are given the education, help and support that they need to succeed.

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REPRESENTING HOSPITAL PHARMACISTS AT EUROPEAN AND INTERNATIONAL LEVELS

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Everything EAHP wishes to achieve for hospital pharmacy is underpinned by the principle of working in a multidisciplinary team.

Joan Peppard is President-Elect of the European Association of Hospital Pharmacists (EAHP). She commences her term of office in June 2015.

Joan Peppard is Chief Pharmacist at the Midland Regional Hospital Tullamore, Co. Offaly, Ireland, and serves on the EAHP Board as Director of Professional Development.She has been the head of the Hospital Pharmacists Association of Ireland twice.

In an exclusive interview with *HealthManagement*, Joan Peppard shared her thoughts about the goals of EAHP, the challenges facing pharmacists and the role they play in the healthcare system.

EAHP promotes the best and safest use of medicines and medical devices. At the same time, it is often said that pharmacists use their own systems rather than use a uniform process in providing patient care. Could you comment?

I would actually question the evidence for the assertion that hospital pharmacists like to use their own systems in preference to accepting more uniform processes. As part of the multidisciplinary team, I believe hospital pharmacists are open to, and welcome evidence-based guidelines.

EAHP's perception is, at least from our member associations, that common protocols and guidelines are often welcomed and indeed requested by the profession, albeit with an obvious need to reflect and respect certain local or national realities. This perception was most recently confirmed by the enthusiastic input into and positive reception about the 44 European Statements of Hospital Pharmacy published in May 2014 (**http://ejhp.bmj.com/content/21/5/256.full.pdf+html**).

However, in any guideline or protocol development there is also a need to allow both local innovations as well as permit a sense of local ownership. It's a balancing act, but overall I do not recognise the suggestion that hospital pharmacists are difficult in terms of adopting uniform systems. Indeed, it is the opposite criticism I sometimes hear – that hospital pharmacy is a profession with a great love for standard procedures! Indeed, to ensure the safe use of medicines, our profession could not be anything other than orientated in this way.

As prescription drugs move to non-prescription status and more drugs become available to consumers through self-selection, how can pharmacists effectively monitor which drugs patients are taking and record this? Is drug interaction a cause for concern, especially when it comes to elderly patients?

Medicines reconciliation by pharmacists is one of the key ways in which health systems can tackle this particular issue. In an ageing society, and with an ever expanding number of new medicines to treat the growing incidence rate of chronic disease, the need for medication reconciliation services will only increase. It seems to EAHP that every European health system needs to immediately implement greater use of the hospital pharmacist expertise in this area to address the risks presented by polypharmacy, both prescribed and self-selected.

Underlying this, a statement strongly endorsed not only by the hospital pharmacy profession, but also European patient groups and other healthcare professionals at our 2014 Summit was "All the medicines used by patients should be entered on the patient's medical record and reconciled by the hospital pharmacist on admission. Hospital pharmacists should assess the appropriateness of all patients' medicines, including herbal and dietary supplements."(**http://ejhp.bmj.com/content/21/5/256.full**).

Antibiotic resistance has been in the news a lot lately, and the World Health Organization feels that pharmacists are in the best position to promote the appropriate use of antibiotics. Does EAHP have a position on this issue?

Yes, EAHP has a strong position on this issue set out in a recent policy statement agreed at our last General Assembly of member countries in June 2014. Antimicrobial resistance is one of the biggest health challenges that European and global governments currently face, and, alongside improving the research environment for new agents, serious policy is required in relation to improving antimicrobial stewardship. This means leveraging the full potential of the hospital pharmacy profession in relation to the conduct and management of stewardship activities in the hospital setting (**http://www.eahp.eu/press-room/new-year-appeal-europe-make-2015-year-action-amr**). These stewardship activities are evidence-based and translate across different health systems. EAHP also believes that we need constant policy vigilance in respect of how to improve the managed use of antimicrobials not only in human medicines, but also in other sectors such as agriculture, veterinary and aquaculture settings.

The use of electronic prescribing has been increasing in recent years. What are the major pros and cons of it in your opinion? Does the EAHP have any set goals in this regard?

Yes, electronic prescribing is a real area of potential gain for health services in the years ahead, and in a recent policy statement from our member associations EAHP has made a call for its uptake to become universal across Europe (**http://www.eahp.eu/practice-and-policy/EAHP-statements**)The gains of electronic prescribing are many, but above all it has a major part to play in improving patient safety through improved communication and reducing medication error.

Ideally we'd like to see such systems supported by additional e-health utilisations such as bedside scanning of medicines to reduce errors at the point of administration. This requires changes to the way medicines are bar-coded, and we are working with European pharmaceutical company associations to investigate the possibility of making such changes in the years ahead.

The European Statements of Hospital Pharmacy, supported and endorsed by European patient groups and other healthcare professional associations state "Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes. This will ensure that pharmacy services are integrated within the general Information and Communication Technology (ICT) framework of the hospital including electronic health (eHealth) and mobile health (mHealth) procedures."(**http://ejhp.bmj.com/content/21/5/256.full**)

"EVERYTHING EAHP WISHES TO ACHIEVE FOR HOSPITAL PHARMACY IS UNDERPINNED BY THE PRINCIPLE OF WORKING IN A MULTIDISCIPLINARY TEAM."

In your opinion, how can pharmacists contribute to the drug development process?
Pharmacists have a very important role to play in drug development processes, including contributing to the management of clinical trials in the hospital environment. After all, it is the hospital pharmacist who is the resident expert on medicines in the secondary care sector.

However, to be able to conduct this role to the full it is critical that the hospital pharmacist has access to all relevant information for decision-making. This relates not only to the patient's medical record, but also to the entire information about past clinical trials. Sadly, in both respects we are still battling to improve the national and European legal landscape. However, it was pleasing to see so many health stakeholders endorse our calls for pharmacist access to the patient record at the European Summit on Hospital Pharmacy last year [Statement 4.3 "Hospital pharmacists should have access to the patients' health record. Their clinical interventions should be documented in the patients' health record and analysed to inform quality improvement interventions." (**http://ejhp.bmj.com/content/21/5/256.full**), as well as to witness the progress being made by the AllTrials campaign for improved transparency in clinical trial reporting (**http://www.alltrials.net/news/2014-the-year-of-influence-for-alltrials/**). These issues will continue to be a focus for EAHP in the year ahead.

HealthManagement **is focused on multidisciplinary healthcare. As pharmacists are key members of the multidisciplinary team, what are some of the initiatives EAHP plans to support pharmacists and to enhance their role in improving patient care and outcomes?**
In the hospital, multidisciplinary experts working as a team with the patient at the centre of the combined efforts is the ideal approach. Yes, inter-professional barriers can become an obstacle to improvement and service delivery, so constant attention must be paid to this factor.

From EAHP's perspective, we are acutely aware that few of our ambitions for the future of our profession can be achieved unless they are aspirations that are also shared by the professions we work with. For this reason, the new foundation of our practice development activity – the 44 European Statements of Hospital Pharmacy - were formed and agreed not by hospital pharmacists alone, but through a thorough and robust consensus process with representatives of European patients as well as doctors' and nurses' organisations. We have stated that everything EAHP wishes to achieve for hospital pharmacy is underpinned by the principle of working in a multidisciplinary team. Having now formed our vision for the future of the profession, it will be my privilege during my term as President of EAHP to turn vision into reality. Just as it was vital to work with other professions in forming the vision, so too I will be seeking to continue that engagement with doctors and nurses and, of course, patient groups in respect of implementation activity.

What do you foresee in the future of pharmacy?
I am fortunate to work in a profession that I love, that has continued to develop and to challenge me to excel in the interest of patient care since I graduated. I see the onward trajectory of development for hospital pharmacy continuing, with a greater integration of the hospital pharmacist into the care of each individual patient in the hospital and across the care settings. I believe that greater use of technology in even the smallest of our hospitals is part of the future. However, the future of hospital pharmacy lies in our graduates, with their ongoing commitment to maintaining and developing their skills and knowledge in the interest of patient care and practised in a spirit of collegiality with all other healthcare professions.

This interview will be in our next issue, which has a cover story on "Ageing." What do you perceive to be the biggest challenges for hospital pharmacists with respect to an ageing population?
It is recognised that Europe has an ageing population and that polypharmacy is an issue that particularly presents in the elderly. I think the biggest challenge for individual hospital pharmacists, as part of the multidisciplinary team, will be empowering the individual elderly patient to be knowledgeable of and have an understanding of their medicines in the context of their illness and well-being. This will require additional consideration of the needs of the individual when facing the combined factors of aging and illness.

The hospital pharmacy profession is challenged with getting resources to enable the daily needs of the elderly patient to be met by the multidisciplinary team. This is certainly a challenge from ensuring the integration of patient safety considerations in new technology to managing the medication reconciliation needs in a busy hospital, to ensuring robust evidence for the use of new medicines in the elderly as well as the ever-growing problem of medicine shortages.

Evidence-based care is a priority for hospital pharmacists, and we need the inclusion of elderly patients in clinical trials in order to inform treatment choices. People are living longer, and have an expectation that treatments will produce cures and improve their quality of life. It is not acceptable to exclude the elderly patient from clinical trials of new medicines. To potentially exclude the elderly from the benefit of these new medicines or to increase the risk when these medicines are used could even be considered unethical.

The commitment of hospital pharmacists to lifelong learning and maintaining expertise is very real. Accessing a constantly expanding number of new medicines to treat the growing incidence rate of chronic disease as well of from the innate desire of hospital pharmacists to contribute effectively to patient care underpins this commitment. This same commitment will drive hospital pharmacists to further develop their expertise in addressing the needs of the elderly person in the hospital and related care settings as the need arises. ■

THE REPUTATION RIDDLE
NURTURING STAKEHOLDER VIEWS IN THE MEDICAL INDUSTRY

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While the fruits of a good corporate reputation translate into increased revenue and growth, a poor one can cause considerable commercial damage, and the importance of keeping reputations strong should not be underestimated.

This is especially pertinent in the medical industry, where patient safety, ethical procurement and shrinking budgets are finding too many firms unprepared and vulnerable to expensive loss of goodwill among key stakeholders, be they customers, regulators, investors, essential suppliers, distributors, procurement managers, commissioning groups, politicians or the press. The rising cost of medicines, regulatory requirements, demands for longer, larger clinical trials, patents expiring too soon and the demand for cheaper medicines are all critical business issues that can too easily lead to pitfalls in communications.

Key Stakeholders

Reputation, however, is not something that can be owned, but develops as a result of how a business is perceived by its key stakeholders, such as customers, employees, suppliers and the press, with each group holding a different perspective according to their particular expectations. While it cannot be controlled, it is possible to influence how your business is perceived through developing an understanding of each stakeholder group and using the resulting insight for action.

The creation of a stakeholder map identifying these different groups and what matters to them versus what matters to your firm can be useful here in pinpointing which groups are worth influencing the most and what a conversation with them should be about.

For conversations with external stakeholders to be a success, however, reputation must also be nurtured at every level within the business itself, from sales staff to the board of directors. Lloyds Bank, for example, starts every board meeting not with sales or the balance sheet, but with reputation, understanding that its employees are not only stakeholders themselves, but also a channel of communication with other stakeholder groups (Dunne 2014).

The most successful companies are those that adopt this more proactive approach. The medical and healthcare companies with the best reputations amongst consumers, 3M, Bayer and Abbott Laboratories, which feature in the top 100 of the Reputation Institute's 2014 Global RepTrak® 100 study (Reputation Institute 2014), take their reputations very seriously, using them as input in strategy development. To achieve this, they monitor feedback from key stakeholders, and use the insight gained to build a clearer understanding of where to invest and what to communicate, making better business decisions as a result.

Hospitals, Clinics and Practitioners

Hospitals and clinics also need to be aware of their reputation among stakeholders. One successful example is King Edward VII Hospital Sister Agnes, a leading private London hospital offering high-level exclusive medical services. They have been proactive in putting reputation right at the centre of their operations by implementing an organic, consistent strategy to communicate with patients, thus boosting reputation with key stakeholders ahead of any potential issues it may face in the future.

The hospital identified customer satisfaction and perception of service as its key stakeholder positioning tool. Not only does the hospital continue to invest in modern medical equipment and top consultants, but they also make sure that they circulate their successes and investment news via a channel that patients are responsive to: print and online. Consistent brand messaging

is further maintained across PR, marketing and advertising in order to provide a consistent, structured and approachable identity.

Given the proliferation of review sites for hospitals, clinics and even practitioners, the importance of reputation in the healthcare and medical sector is moving ever more to the forefront of preoccupations. A USA report by National Research Corporation measured the relationship between hospital reputation and consumer preference, and found that a good media and patient perception translates into a higher likelihood of selecting a particular hospital or clinic for treatment, which in turn is key to securing investors. Three out of five consumers stated that hospital reputation is "very important" when they are evaluating a hospital (National Research Corporation 2014).

Pharmaceutical Sector

A combined European and USA survey asked patients for their opinions on the corporate reputation of pharma in general, and 29 leading pharma companies in particular, and highlighted that, out of eight healthcare sectors evaluated, pharma only came in seventh, as two-fifths (42%) of respondents gave pharma a "good" or "excellent" rating for reputation (PatientView 2014a).

By contrast 60% of respondents rated medical device companies good to excellent, and 46% gave the same score to biotech companies. Private healthcare services were rated highly by 50%. The lowest scorers were unpopular health insurers (PatientView 2014b).

Specifically, negative patient views in the pharmaceutical sector related to a perceived lack of fair pricing, of transparency and of integrity. Given this highly negative backdrop, far too many pharmaceutical businesses simply choose to passively sit back, and wait for something to happen that tars them with the same brush as the rest of the industry.

Once reputational damage has been done, businesses can only run for cover and take the reactive approach: responding with reputation-enhancing measures to whatever situation the business finds itself in. But this has its disadvantages, as Takeda Pharmaceutical Company and Eli Lilly found to their cost last year, after a U.S.

jury judged that they had hidden evidence that their Actos diabetes drug could expose patients to a greater risk of bladder cancer. The punitive fine of $9bn is just the tip of the iceberg of the knock-on reputational damage they now face (Skapinker 2014).

GlaxoSmithKline (GSK), for example, faces a chain of reputational issues after bribery allegations in Poland (Ward et al. 2014) were added to those being investigated in Iraq and China, where a £300m fine was levied for corruption. Further to the Chinese sanction, the U.S. Department of Justice and UK Serious Fraud Office are now both also investigating GSK for reportedly bribing doctors to prescribe its drugs (Ward et al. 2014).

In reaction to the news, and in order to stem the sales decline caused by the investigation, GSK is attempting to recover goodwill in the eyes of stakeholders, such as investors and the public as well as emerging economy governments, by pledging to support scientific development in China and to improve pricing flexibility. Like many pharmaceutical businesses, GSK sees emerging markets as a key opportunity for growth, so nurturing a positive reputation among stakeholders there is vital (Ward et al. 2014).

Another instance where a pharmaceutical company's existing reputation affects stakeholder expectations is that of Pfizer: the company plans to acquire AstraZeneca; however, the takeover is being portrayed as a move to transition from U.S. corporate tax to lower UK tax. Employee expectations, an important influencer of wider public opinion, are also very low in spite of the assurances about their jobs, especially after Pfizer's reduction of the research centre in Sandwich, Kent, in 2012 (Skapinker 2014).

But there are also positive signs that the industry is trying to get beyond a merely reactive approach to a more holistic way of fostering reputation: Pfizer has been publicly publishing all physician payments since 2010. Further to the recent Chinese trial, GSK has also promised to publish all clinical studies of its medicines, and launch an online system so that independent researchers could get anonymised data from drugs trials (Ward et al. 2014).

PatientView reports that ViiV Healthcare, Gilead and AbbVie are consistently among the top scoring pharma companies for reputation among patients for a range of issues. ViiV and Gilead are the top two scorers for patient-centricity, high-quality information for patients, patient safety records, useful products, transparency and integrity. Sanofi and Teva have also climbed the ranks, thanks to a consistent and holistic approach placing patient safety at the core of their operations (PatientView 2014a).

The Medical Technology Sector

2014 research by PatientView reveals that the MedTech industry has the highest rate of goodwill among patients in the medical industry. Specifically, businesses that produce implantable medical devices post a better performance for corporate reputation than manufacturers of hospital equipment, and firms focusing on specialist therapeutic areas do better than manufacturers in multiple therapeutic areas. 3M Healthcare, also identified by the Reputation Institute as a best practice medical example, Abbott Laboratories and Alcon are the businesses that enjoy the best reputation in the eyes of patients (PatientView 2014b).

However, incidents do still happen and damage a whole segment of the market. In the last year, for example, concerns over metal mesh used to treat pelvic organic prolapse, and which reportedly has caused agony to a number of patients then forced to undergo surgery to remove mesh that was eroding and cutting into their organs, has come to the forefront in Scotland. Not only have 400 women reportedly launched legal action, but the National Health Service (NHS) in Scotland has suspended procedures (Cooper 2014).

However, patients and the media are not the only stakeholders, and although their views influence those of investors and buyers for example, businesses need to remember that identifying and mapping key stakeholders and their expectations is important to ensuring that target audiences are addressed consistently and appropriately.

Conclusion

For the proactive approach to be successful therefore, perceptions of brand amongst all stakeholder groups must be constantly tracked and acted upon. While standardised 'black box' models exist, their rigidity makes them unsuitable for measuring reputation. Instead, a customisable framework is required that allows the benchmarking of corporate reputation across any stakeholder group and that can be used across all markets and methodologies.

One way of achieving this, pioneered by the Reputation Institute, is to monitor feedback through all touch-points to track the emotional connection between a company and its stakeholders alongside perceptions of rational connections, such as perceptions on products/services, innovation, workplace, and citizenship. These results can then be analysed to create actionable insights, which in turn are used to nurture reputation through marketing and communications strategies across all platforms, including social media.

Influencing reputation is inevitably a slow-burn of a job that requires commitment from the whole organisation and the ability to monitor, analyse, and act on stakeholder perceptions of the brand or business. As the success of brands like King Edward VII Hospital Sister Agnes, ViiV and 3M reveal, not only is it possible to enhance corporate reputation in the medical industry, but it is well worth it too. ■

Key Points

- The importance of a good corporate reputation should not be underestimated, especially in the medical industry.
- The rising cost of medicines, regulatory requirements, demands for longer, larger clinical trials, patents expiring too soon and the demand for cheaper medicines are critical issues that can lead to pitfalls in communications.
- Reputation develops as a result of how a business is perceived by its key stakeholders including customers, employees, suppliers and the press. The most successful companies are those that adopt this more proactive approach.

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IMPROVING THE PROVISION OF A COMPLIANCE AID DISPENSING SERVICE FOR PATIENTS AT NORTH BRISTOL NHS TRUST

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North Bristol National Health Service (NHS) Trust (NBT) is the first Acute Trust to improve the provision of Compliance Aid Dispensing through a third-party dispensing partnership for discharge patients, particularly patients with long term conditions.

In accordance with the objectives of the Quality, Innovation, Productivity and Prevention (QIPP) programme, our innovative solution of outsourcing work to a commercial community partner without significant upfront funding has enabled NBT Pharmacy to provide a high quality service and manage a doubling workload within existing budgetary constraints.

Background
Compliance aids

Compliance aids are "Multi compartment compliance aids" (MCAs) often called "blister packs". They are medicine storage devices that usually contain 7 days of medication and act as a reminder for patients to take their medicines, enabling them to manage their own often complex and confusing drug regimens.

We continue to have an ageing population and more people that need supporting in their own homes, so the issue of supplying compliance aids is an increasing one.

MCAs can support some patients to remain in their own homes longer, reducing some need for residential care. Providing medication in an unsuitable format leads to patient confusion/medication errors. The National Patient Safety Agency highlights that medication errors can cause harm to patients, and can lead to increased morbidity/mortality, inflated healthcare costs and hospital re-admissions (National Patient Safety 2007; 2009).

MCAs also act as a visual prompt for carers, indicating that patients have taken their medicines, or at least removed them from the device. Nationally, the need for compliance aids is increasing, reflecting the ageing population and an increase in complexity and average numbers of drugs taken.

The supply of MCAs is a national issue throughout pharmacies, both in hospitals and in the community. MCAs are NOT the answer to all medication issues, but are suitable if patients are assessed appropriately (see Figure 1).

NBT
Our work started when NBT was a large Acute Teaching Trust on two sites with approximately 1000 beds, 53 wards and 9000 staff.

Despite implementing an assessment tool to minimise inappropriate use of compliance aids, the demand for their dispensing has doubled during the last five years to over 200 per month, exceeding capacity and causing:
- Delayed discharges;
- Inappropriate discharges (when medication was not supplied in a compliance aid) causing problems in primary care and possible re-admissions;
- Non-compliance;
- Complaints (from GPs, patients and relatives).

Various service improvements and actions at NBT did not enable capacity to meet demand. We realised that we could not solve the issue in house and needed to explore outsourcing options.

In 2007 NBT became involved in the Safer Patients Initiative (SPI2): 2007 – 2009 and then the Southwest Quality and Patient Safety Improvement programme: 2009 – now Safer Care South-West. The Safer Patients Initiative was a programme developed by the Institute of Healthcare improvement (IHI) and the Health Foundation (HF).

At the end of May 2014 we moved into a new hospital on one site with approximately 850 beds and 27 ward areas.

Rationale Behind Usage
Drivers influencing usage include:
- Disability Discrimination legislation (Disability Discrimination Act 1995; 2005 and Equality Act 2010) requires that pharmacists and dispensing practices should make "reasonable adjustments" to enable disabled persons to use their medicines.
- The National Institute for Health and Clinical Excellence (NICE) clinical guidelines (National Institute for Health and Clinical Excellence 2009) and Cochrane Review (Mahtani et al. 2011) both suggest MCAs may be of value in patients who have been assessed as having practical problems in managing their medicines.
- The Royal Pharmaceutical Society (RPS)

report (Picton and Wright 2013) on Medicines Optimisation has four key principles including:

- ● Principle 1
  Aim to understand the patient's experience.
- ● Principle 3
  Ensure medicines use is as safe as possible.
- The second RPS report *Improving patient outcomes: the better use of multi-compart-ment compliance aids* (Royal Pharmaceutical Society 2013) is aligned to the principles of medicines optimisation and says that MCAs may be useful as a support system.
- The NHS England Patient Safety Alert *Risks arising from breakdown and failure to act on communication during handover at the time of discharge from secondary care* also high-lights the importance of medicine use and safety (NHS England 2014).

The decision to outsource from NBT's perspec-tive was primarily patient-focused. We started our work to support patients who needed MCAs back in 1998. At that time, we were not sup-plying MCAs, but recognised that if medication was not dispensed in suitable containers, then some patients may not be able to manage their medicines, and may have to be re-admitted very quickly.

Before this project the demand for the dis-pensing of compliance aids doubled over five years, This exceeded in-house capacity and caused;

- Delayed discharges;
- Inappropriate discharges;
- Complaints.

Figure 3 shows how our average monthly work-load has continued to grow from 2004 to 2014.

Aims and Objectives

The aim of this initiative was to improve the pro-vision of compliance aids in accordance with the objectives of the Quality, Innovation, Productivity and Prevention (QIPP) programme by:

- Managing the increasing workload;
- Reducing discharge waiting times;
- Reducing length of stay;
- Supporting patients to manage medicines at home and reduce some need for residen-tial care.

Method

NBT Pharmacy devised a phased and innovative solution that did not require significant upfront funding by outsourcing the work to a commer-cial community partner – LloydsPharmacy and the wholesaler AAH Pharmaceuticals (parent company Celesio). This evolved from a mixed service of both in-house dispensing and supply through

Figure 1. Example of an MCA

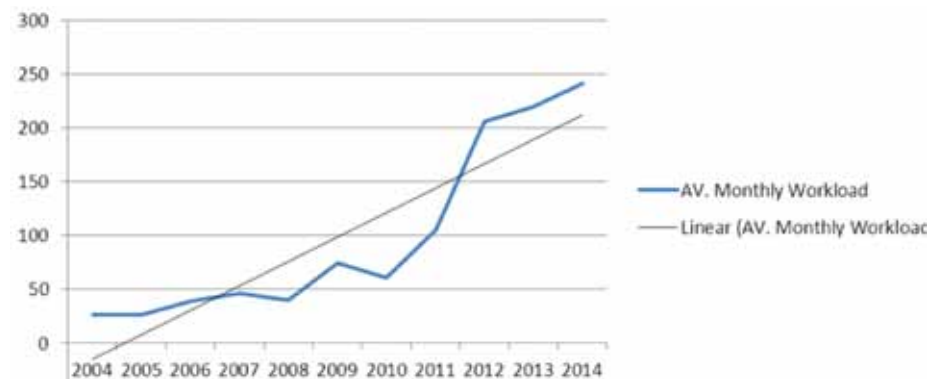**Figure 2.** New Southmead Hospital: May 2014

Figure 3. Average Monthly Workload

Phase	Description	Turnaround SLA (Hours)	Monthly Rate (Average)	Monthly Rate (Peak)	Duration
Pre-Pilot	Performed in house	N/A > 48	34	40	12 Months
Phase 1	Pilot with LloydsPharmacy Community Branch	22-46	50	74	18 Months
Phase 2	Pilot with managed central service pro-vided by The Hub	21-45	56	61	2 Months
Phase 3	Service extended to both NBT sites	21-45	80	105	5 Months
Phase 4	Service levels increased to reduce maximum turn-around time	21-26	141	206	20 months
Phase 5	Golden patient service introduced for limited patients	Golden patient 4.5 Normal patient 21-26	210 (includes 25 Golden pts)	280 (includes 42 Golden pts)	27 months

Table 1. Overall Results from the Phases

Figure 4. PDSA cycle (Plan, Do, Study, Act)
Source: NHS Institute for Innovation and Improvement 2008 (Quality and Service Improvement Tools)

Figure 5. Average Monthly Workload for NBT

Figure 6. Average Monthly Workload for NBT: Phase 1 And 5

negotiation with community pharmacies, to outsourcing work.

We achieved our results with the use of the Model for Improvement and Plan, Do, Study, Act (PDSA) cycles and tests of change on one ward. We established ongoing tests of change with ongoing measurement.

Phase 1: Feb 2009 – June 2010
We piloted "small tests of change" with a LloydsPharmacy community branch to provide a dispensing service for Southmead Pharmacy against a service level agreement. All prescriptions were clinically screened by an NBT pharmacist before faxing to LloydsPharmacy.

> **"WE CONTINUE TO HAVE AN AGEING POPULATION AND MORE PEOPLE THAT NEED SUPPORTING IN THEIR OWN HOMES, SO THE ISSUE OF SUPPLYING COMPLIANCE AIDS IS AN INCREASING ONE"**

Turnaround time ranged from 22–46 hours. Southmead received daily weekday deliveries by a LloydsPharmacy driver. Time was taken to embed practices. The pilot was successful, but demand for this service rapidly exceeded capacity within the branch.

Phase 2: July 2010 – Aug 2010
Dispensing transferred to the central AAH premises in Bristol ("The Hub"), who sub-contracted dispensing to LloydsPharmacy. Prescriptions from NBT were scanned and emailed to "The Hub". AAH carried out deliveries via their usual van fleet.

Phase 3: Sept 2010 – Jan 2011
The service extended to Frenchay Pharmacy.

Phase 4: Feb 2011 – Sept 2012
There was an increase in deliveries, including Saturdays. Southmead Pharmacy continued to pack in house for discharges required at short notice. Skill mix was introduced in the form of
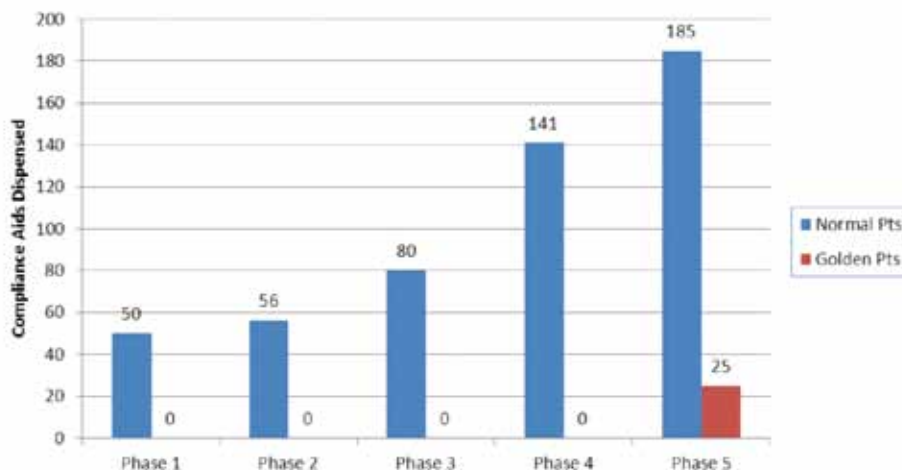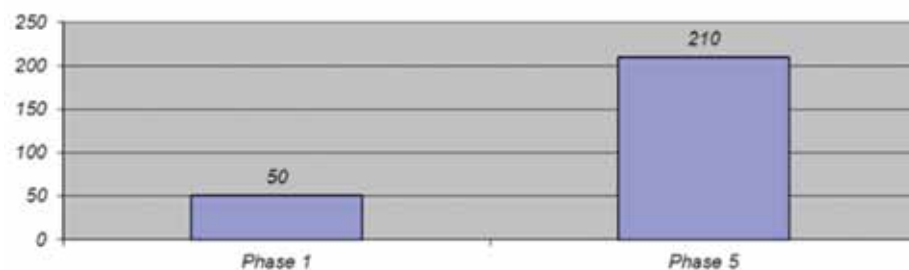
Band 4 technicians to release pharmacists' involvement with the Hub. Regular review meetings were held to discuss progress and developments.

Phase 5: Oct 2012 – present time
The outsourcing was further enhanced by the introduction of a "Golden Patient" service, which enabled a same day turnaround of 4.5 hours (Reserved for short stay wards only).

Compliance aid data is collated on a monthly basis, eg workload, dispensing/delivery errors, wastage of medication. Wastage is a fine balance between dispensing in a timely fashion to avoid delaying discharge versus the possibility of medication changes.

Results
Table 1 shows the overall results from the phases

The main impacts of our work are shown by how we have managed an increase in demand and the impact on patients' waits (ie turnaround times):

Monthly workload and Turnaround times
Phase 1
• Average: 50 MCAs
• Turnaround time: 22-46 hours
Phase 5
• Average: 210 MCAs
• Turnaround time: 21-26 hours
• (4.5 hours for "Golden Patients")

We managed a 300 percent increase in demand.

Phase 1
• Average: 50 MCAs

Phase 5
• Average: 210 MCAs
• 94% of MCAs are now dispensed by "The Hub"
• (13% "Golden Patients")
• This is more easily seen in the following increases in monthly workload graphs showing different aspects of the work:
• Figure 5 – monthly workload for NBT: normal vs "golden patients"
• Figure 6 – monthly workload for NBT: phase 1 vs phase 5
• Figure 7 - monthly workload for NBT: Hub vs in house

We decreased patient waits by 50 percent

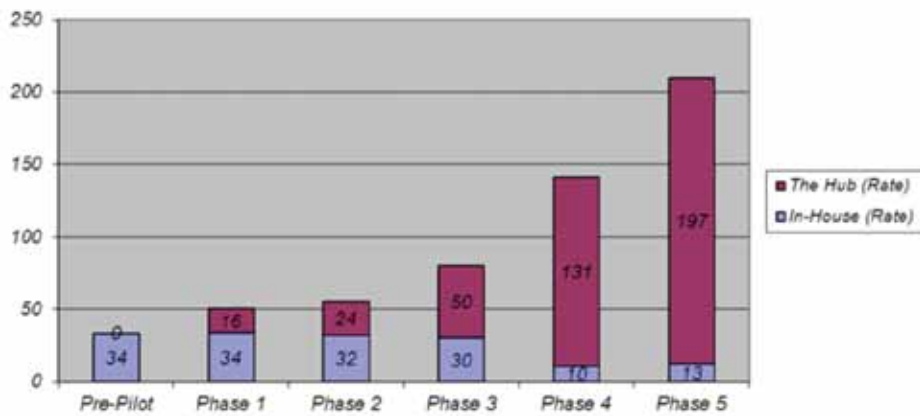**Phase 1**
• Turnaround time: 22-46 hours
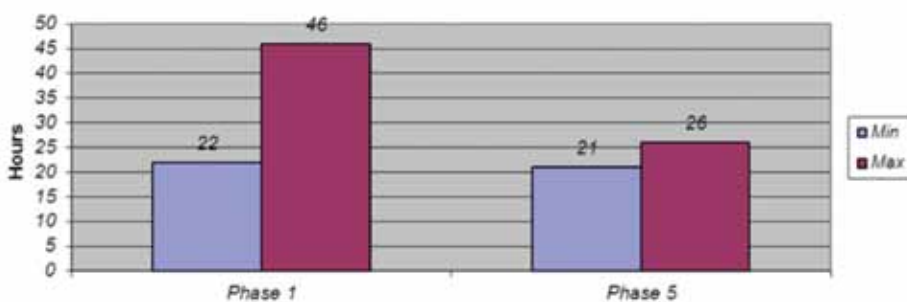
Figure 7. Average Monthly Workload NBT

Figure 8. Average Turnaround: Phase 1 and 5: Hub

Phase 5
- Turnaround time: 21-26 hours
- (4.5 hours for "Golden Patients")

For our efforts to improve the use of compliance aids and promote safety in medicine use, we have been shortlisted as finalists for several awards, including: finalists for the Health Service Journal (HSJ) Awards 2014; Finalists for the HSJ Value in Healthcare Awards 2014; Finalists for the Alliance Healthcare Pharmacy Awards 2011.

Conclusion
NBT has developed an innovative and mutually beneficial partnership between an Acute Trust and a commercial pharmacy provider to deliver a high quality patient-focused service for our patients, particularly for patients with long-term conditions, resulting in the successful management of increasing demand for compliance aids.

This has enabled:
- Faster turnaround of patients;
- Reduction in bed-blocking;
- Improved service for patients;
- Managing increasing workload demands.

In pharmacy, the implications are:
- Leaner processes and reduced workload in the dispensary;
- Improved skill mix in the whole process;
- Improved staff morale, reflecting smoother operational processes and reduction in complaints.

The increasing demand for compliance aids is an issue for Trusts nationally, and we feel strongly that our successful outsourcing initiative can be used in other Acute Trusts to improve practice and effectively manage the increasing demand for compliance aids in accordance with QIPP.

Future Work
We are now looking at:
- 7 days a week service
  In *Everyone Counts: Planning for Patients 2013/14*, Sir Bruce Keogh, National Medical Director of NHS England highlighted seven-day services across the NHS over the next three years (NHS England 2013).
  The new 7-day working approach is being adopted by NBT and the Hub is reviewing provision of a Sunday/ Bank holiday service.
- Further skill mix
  In house, we are now looking at using band 3 technicians with the band 4 technicians.
- Re-launch of Pan Bristol Assessment tool
- We will also be liaising across Bristol and North Somerset to review and re-launch our assessment tool currently referenced on the RPS website.

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MEDICATION COMPLIANCE AIDS
TOWARDS SMARTER AND SAFER USE

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Medication compliance aids (MCAs) are used extensively in Bristol. In July 2014, 20% of all the drugs for patients being discharged (To Take Away [TTAs]) prepared by the North Bristol Trust (NBT) pharmacy were dispensed in MCAs. 94% of these were for patients already using MCAs at the time of their hospital admission, rather than being initiated during their admission. Other local hospital providers report high level of demand for MCAs, so NBT does not appear to be an outlier in the locality. However, there are large variations in MCA use across the NHS, with some hospitals dispensing very few.

Discussions with local health and social care providers suggest that the main drivers for MCA use in the community are convenience, a belief that MCAs improve compliance and a belief that they are safer than using original packaging. In some cases, residential homes refuse to accept patients unless medication is dispensed in a compliance aid, regardless of the patients' ability or wish to manage their own medicines. The belief that MCAs generally enhance compliance and safety is misplaced. MCAs do not help most patients comply, and increase the risks of medication errors for some groups. They can help a small minority of patients but, unless carefully targeted, can increase risk to others. They can increase cost, waste and medico-legal risk. They also present an obstacle to discharging patients from hospital, as dispensing is much more time-consuming than conventional TTAs.

MCAs can support autonomy and independence when targeted at the right patients, following a robust assessment by a pharmacist. However, wholesale use of compliance aids in particular care settings does not allow patients to exercise autonomy, and can deprive them of control and of the opportunity to participate in the management of their healthcare. The draft National Institute for Health and Clinical Excellence guidance on medicines management in care homes recommends that, "People who live in care homes are supported to self-administer their medicines unless a risk assessment has indicated that they are unable to do so" (National Institute for Health and Clinical Excellence 2014).

Who Benefits?

Evidence suggests that the two groups of patients who can benefit from MCAs are:

- Patients with physical impairment (affecting the ability to use conventional packaging) but no formal/ informal carers; and
- Patients with cognitive impairment and formal/informal carers. (Patients with cognitive impairment but no carers were not helped by MCAs) (Athwal et al. 2011).

Not all patients in these two groups will benefit from an MCA: individual assessment is key to good practice. The Royal Pharmaceutical Society's recommendations are that:

- The use of original packs of medicines with appropriate support is the preferred option of supplying medicines to patients in the absence of a specific need requiring an MCA as an adherence intervention.
- In support of independence and re-ablement, patients who can safely self-administer their medicines should be encouraged to do so, and where they are unable to do so, there must be appropriate training for carers so that they are able to administer medicines from original packaging.
- Every patient identified as having medicines adherence issues should have a robust individual assessment to identify the best intervention based on their needs and the evidence currently available (Royal Pharmaceutical Society 2013).

Risks

MCAs are not the safest option for many patients. The evidence is that they actually increase the rate of drug errors in nursing homes and their use generates other problems (Alldred et al. 2009), including:

- Greater medico-legal risk for prescribers and dispensers, as the transfer of

medication out of its original packaging is outside the manufacturers' guidance on approved use;
- Instability of many drugs when exposed to light and moisture or through contact with other drugs in MCAs;
- Reduced engagement by patients and carers in self-management of medication;
- Difficulty conveying safety information: though information leaflets are supplied with the MCAs, it is difficult for patients to know which leaflet applies to which tablet;
- Increased costs and waste as outlined above;
- Increased risks from controlled drugs, eg and anticoagulants;
- Incompatibility of MCAs with many drugs eg some anticonvulsants;
- Incompatibility of MCAs with many drug regimes, eg PRN drugs, suspensions, effervescents;
- Use of concomitant drug regimes for drugs that are not compatible with MCAs (eg. PRN opiates) increases the risk of unintentional under- and over-dosing;
- Increased risk to children and vulnerable adults in households as MCAs are not child-proof.

Most non-compliance with medication is intentional and MCAs have no impact upon it.

Adopting Best Practice
Although many providers in Bristol already followed best practice, some providers were using MCAs for everyone in a particular care setting (residential homes or domiciliary care), without an individual assessment of that patient's needs. The providers were often acting from the best of intentions, in the mistaken belief that they were making patients safer and supporting compliance. There was also widespread ad-hoc use of MCAs in the community, often apparently without an assessment by a community pharmacist as to the individual's suitability for an MCA. As well as the potentially detrimental effects on patients outlined above, the over-use of MCAs was creating excessive workload for pharmacists in hospital and the community and creating delays in discharge from hospital. The health and social care community in South Gloucestershire (from where the majority of patients at NBT are drawn), supported by the Local Pharmaceutical Committee (LPC), worked together to improve use of compliance aids. A protocol for use across the locality has been agreed.

The principles of the new protocol are:
- People should be supported to understand their medication and use it safely.
- Wherever possible, people should be supported to manage their own medication. This includes people living in care homes.
- Each patient's needs must be assessed on an individual basis, and any intervention must be tailored to the patient's specific requirements.
- Medication compliance aids should only be used when likely to make the user safer.

The intention is that the protocol will be supported by a common assessment tool so that, whether a compliance aid is started in the community or in hospital, the same criteria will be used to assess whether an individual will benefit from using an MCA.

"THE BELIEF THAT MCAS GENERALLY ENHANCE COMPLIANCE AND SAFETY IS MISPLACED"

The process of agreeing to work towards this goal has been a positive example of cross-organisational working across an entire locality to improve patient safety and autonomy and to use resources more efficiently. The support of the LPC and of care homes' representatives has been particularly valuable in building a foundation for integrated work on medicines management in the future. ■

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RISKS IN DIETARY SUPPLEMENTS
THE NECESSITY OF INPATIENT POLICIES

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The use of natural substances for treatment and healthcare dates back 5000 years, and has become popular in the last two decades. The rise in the use of these treatments has been driven by the increasing use of traditional medicine by the poor in developing economies as well as from the expansion of the use of alternative medicine to complement conventional medicine in developed economies.

Natural substances can be used in different forms for treatment. They can be used in their natural state, eg. the ingestion of garlic cloves to manage hypertension or high cholesterol. However, the widest use of natural substances is in the form of dietary supplements, which include vitamins, minerals, herbs and other botanicals, amino acids, enzymes, organ tissues, glandulars, and metabolites. Even many of the drugs available on the market are derived from plants, e.g. atropine, belladonna, colchicine, digoxin, Taxol, tubocurarine, vinblastine etc.

With the increasing popularity of dietary supplements, the safety of these treatments has become one of the major concerns of local and international health authorities and regulators. Although most countries have regulations for these products, since they are not classified as drugs, they are easy to reach and can be used without supervision.

The World Health Organization (WHO) reports that most people assume that dietary supplements are completely safe, just because they are herbal or natural. Gardnier et al. (2008) showed that even some children's hospitals in the USA are not concerned with the risks involved in unconsulted use of dietary supplements.

Although the warnings and studies by the United States Food and Drug Administration (FDA) (FDA 2008) and WHO (2005) to increase awareness on this issue seem to have resulted in progress, (eg. Philadelphia Children's Hospital is reported to have removed unproven dietary supplements from its list of approved medications) there is still a long road to success. The focus of this study is to summarise the regulations on dietary supplements in Turkey and the inpatient policies and practices in VKF American Hospital.

Regulation of Herbal and Dietary Supplements in Turkey

Regulation in Turkey separates pharmaceutical products from dietary and herbal supplements. Pharmaceutical products are supervised and governed by the Directorate-General of Pharmaceuticals and Pharmacy (IEGM), which is a subsidiary establishment of the Ministry of Health. The dietary and herbal supplements are regulated and supervised by the Ministry of Food, Agriculture and Livestock.

The pharmaceutical products are classified into groups by the regulation dated 17 February 2005 (**http://www.resmigazete. gov.tr/eskiler/2005/02/20050217-4. htm (in Turkish)**):

• Medication that can only be obtained on prescription: the types of prescription for specific medicines are also defined by the regulation, namely: renewable or nonrenewable prescriptions, special prescriptions and restricted prescriptions.
• Medication that doesn't require any prescription.

The basic components of Turkish medicine legislation, such as licensing, renewal, marketing and pharmacovigilance procedures have been changed to make them consistent with European Union Directives. The procedures for on-prescription medication and off-prescription medication are the same. The documents and the application folders for licensing, labelling, price controls, marketing restrictions and procedures are the same for both groups. The off-prescription medicines are very restricted, and most of them are vitamins and minerals with medical purposes. All pharmaceutical products are required to be sold only in pharmacies.

On the other hand, the dietary supplements market, supervised by the Ministry of Food, Agriculture and Livestock, has fewer restrictions and regulations (Dietary Supplements Regulation published in the Official Gazette dated 16 August 2013 and numbered 28737). Dietary supplements can be sold anywhere and are easy to reach. The legislation on dietary supplements defines the production techniques consistent with hygienic conditions, preparation, transportation and the storage conditions of the product. A major part of the legislation is about the labelling of the product. According to the legislation:

• There can't be any declarations on the label, presentation or the advertisement of the supplementary product, stating or implying that it has disease prevention capabilities or curative effects.
• There can't be any declarations on the label, presentation or the advertisement of the supplementary product, stating or implying that micronutrients provided by the supplementary product cannot be

met with an adequate and balanced diet.

- The amount of the nutrients, botanical and other substances in the supplementary products and their reference daily portion values are numerically stated on the label of the product. The units of the vitamins and minerals are also defined by the legislation. The amount of vitamins and minerals should be stated as the percentage of the daily recommended value listed by the legislation.

- Supplementary products cannot be produced and marketed for infants under four years old. Dietary supplements produced for children between 4 and 10 years old should state that "it is suitable for children between 4 and 10 years old" along with the name of the product. The products that are not suitable for this age range cannot have any picture or shape that might imply that the product is suitable for children on its label.

- For the products recommended for different gender and age groups, the label of the product might include statements that the product is produced for the recommended group.

- The label of the supplementary products should include the following statements:
  - The name of the product that expresses the classification or the nature of the main ingredients that characterise the product.
  - Recommended daily intake along with a statement "do not exceed the daily recommended intake".
  - A declaration stating "Supplementary products can't substitute a normal diet".
  - A declaration stating "Keep medicine out of reach and sight of children."
  - A declaration stating "Seek the advice of a health professional if you are pregnant or nursing a baby".
  - A declaration "It is not a medicine." The minimum size of this statement is also determined by the legislation.

Dietary Supplement Policies in VKF Amerikan Hospital

The inpatients in VKF American Hospital are not allowed to use patient-owned medication (POM), including dietary supplements, without supervision during their treatment in the hospital. Inpatients are questioned about the medication, including dietary supplements, that they have used, and this is recorded in the evaluation forms filled in by the nursing staff during the admission process.

In case of home supply dietary supplements that are brought by the inpatient, these are stored and administered by the hospital pharmacy. If the physician decides to use home supply medicine, he/she writes this on a prescription. Based on the prescription of the physician, the hospital pharmacy first identifies the POM by controlling the package for the name of the product, expiration date etc. Then, the suitability of the POM is checked by questioning the first-use date and storage conditions before arrival to the hospital, if necessary. In case of a foreign inpatient, the label of POM is translated by an interpreter for necessary controls. If POM isn't suitable then it is not stored by the hospital pharmacy, and the companions of the inpatient are asked to take the POM out of the hospital to prevent any unsupervised use of it.

POM, which is compatible with the storage and stability criteria, is accepted and stored by the hospital pharmacy. The medication management procedures of the hospital require the review of the medication order by a pharmacist or an authorised technician for completeness and appropriateness before dispensing. The ordered home supply dietary supplement's probable allergic reactions, indication suitability, treatment side effects and warnings and interaction with other treatments are checked, and the pharmacist's assessments and recommendations are put on the order to inform the nurse and the physician of the patient.

In addition, oncology patients request information about herbal supplements, such as turmeric and maitake mushrooms. The pharmacist pays special attention to oncology patients, informing the patients about the possible side effects, complications and interactions with their continuing medication, and warning them not to use these herbal supplements during their cytotoxic treatment.

"WITH THE INCREASING POPULARITY OF DIETARY SUPPLEMENTS, THE SAFETY OF THESE TREATMENTS HAS BECOME ONE OF THE MAJOR CONCERNS OF LOCAL AND INTERNATIONAL HEALTH AUTHORITIES AND REGULATORS"

Conclusion

As discussed above, patients are not well-informed about the effects of dietary supplements, and they are assumed to be safe to use. The regulations on these supplements do not involve strict review processes and are lighter compared to medicine application procedures. The legislation and regulations generally focus on the information required to be stated on the labels of the products. Since there are no pre-marketing safety tests, the side effects and interactions of some of these dietary supplements are still unknown. The use of these supplements without supervision might be very risky, especially taken along with other medication. Therefore, hospitals should have written policies about patient use of dietary supplements. ∎

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