

Hospital



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COMMUNITY HEALTH: THE ROLE OF THE HOSPITAL

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LEARN FROM YOUR MISTAKES...



Willy Heuschen

It was a spectacular apology that David Cameron offered in parliament for the deplorable state of affairs that was allowed to persist for years at Stafford Hospital. As far as we know, the poor quality of care of a hospital had never before been quite so intensively, media-frenziedly discussed in any European parliament as it was in this case. The official apology of the British Prime Minister was offered to victims, patients and families who had been forced to fight long and hard in order to have their complaints heard. An investigation under Robert Francis QC names the versatile reasons on 1,800 pages.

In first place it is the hospital management, but even more so the National Health Service (NHS) and the government officials involved that must now face up to the serious accusations. According to the BBC, the investigation assumes that the disgraceful standard of care of Stafford patients is by no means an isolated case. Its 290 recommendations therefore not only address the Stafford Hospital – they are also a summons to all hospitals, and in particular to the NHS as well as to official governmental authorities. Amongst others, Francis demands a sustainable change in the NHS' organisational culture. We have an additional report on this subject in the inner sections and will try to let our British hospital colleagues have their say in the next edition of *(E)Hospital*.

As hospital managers we can all learn from these occurrences. First of all: Addressing the topic of abuse and neglect should not be limited to a single country, nor should we now be tempted to make sweeping generalisations about all hospitals. It cannot be ruled out that health systems in other European countries might also be forced to face accusations in a similar vein. On the other hand, it is also true that many hospitals still offer a superb quality of healthcare – even in light of ever decreasing budgets and impeding systemic conditions. It is part of the job of the EAHM to analyse this area of tension between predetermined frame works and capacity and, where necessary, to give out written warnings. This area is therefore also a focus of the lecture topics at the 24th EAHM congress in Luxembourg.

Furthermore, the EU Commissioner for Health should take particular care regarding the disclo-

sure of quality characteristics within the EU guideline on cross-border healthcare. Luckily there were no patients of other EU member states among the 'Stafford victims'. But what if there had been? Surely the European Court of Justice would have become involved in double quick time, questioning the national jurisdiction before European action. The guideline mentioned above can prevent this, if its legal requirements are processed in a timely fashion by the EU states and also by the partners in the health area. The subject of 'quality' has been at the top of the EAHM's agenda for many years now. After our seminar in 2012 in Dusseldorf our advisory board on European Affairs compared the quality indicators in place in different countries, thereby providing important impetus for prevention. We will report on this topic as well, both in our journal and at our congresses.

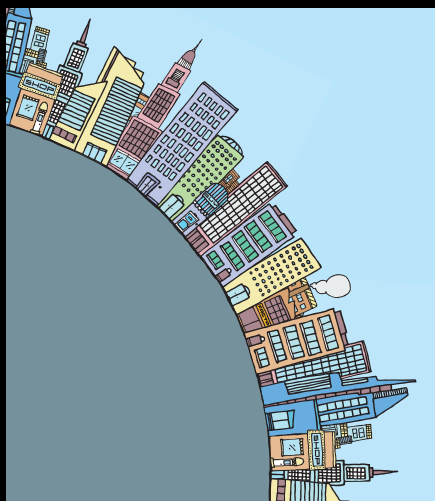
Another lesson can be learned from the occurrences at Stafford Hospital. When searching for causes for the scandalous conditions and the allocation of responsibility it will most probably be inevitable to investigate not only the quality management but also the hospital's public supply mandate, the job description as well as the powers of the hospital managers, and last but not least the management structure of the institution. As without these written responsibilities and structures investigated in practice the basic preconditions for patient-orientated and efficient dealings will be lacking. The EAHM and in particular our scientific subcommittee have been heeding these facts for years. The previous results produced by the advisory board, especially in light of the occurrences in Stafford, show once again how much we can learn from each other on EU level, in particular regarding the management of our health institutions. Part of this process is no doubt the critical self-appraisal of our working mode in hospitals and a comparison on European level, without pointing the finger of blame and incrimination against each other.

Willy Heuschen

EAHM Secretary General
Editor-in-Chief



The editorials in *(E)Hospital* are written by leading members of the EAHM. However, the contributions published here only reflect the opinion of the author and do not, in any way, represent the official position of the European Association of Hospital Managers.



Community Health: The Role of the Hospital

This issue we look at the role of the hospital and its commitment to patient care and the wider community. Our French colleagues introduce us to the topic and outline the many challenges that face the hospital managers of the future. Jos Olbrechts focuses on his hospital's philosophy which aims to put both patient and staff satisfaction at the core of its activities. To end our cover story, Managing Editor Lee Campbell takes a look at the newly published Francis Report in the UK and its implications for quality and safety in hospitals.

Pharma Special

This issue we have a special pharmaceutical supplement to keep you up to date with the latest developments in the field. Fulvio Braido and colleagues introduce us to the increasingly important topic of biosimilars and their role in personalised medicine. Other topics dealt with in this supplement include pharmacovigilance, the future role of pharmacists and personalised chemotherapy drug selection.

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Focus: IRELAND



Doing more with less is one of the great mantras of management. However, during this time of constrained resources, can service quality really be improved while cost savings are made? In the last two years, the Irish Health Service has demonstrated that it is possible and much of the progress can be attributed to better managers and to better management. Some of the figures speak for themselves. 2012 saw a 98% decrease in the number of adults waiting more than nine months for inpatient and day case surgery. There was a 95% reduction in the number of children waiting more than 20 weeks for inpatient or day case surgery.



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EAHM COLLABORATE TO DEVELOP INTERNATIONAL LEADERSHIP AND MANAGEMENT COMPETENCIES



PROFESIONAL ASSOCIATION OF HOSPITAL MANAGERS
 EUROPEAN ASSOCIATION OF HOSPITAL MANAGERS
 EUROPEAN ASSOCIATION OF HOSPITAL MANAGERS

Building on the WHO strategic objective to develop managerial competencies, the International Hospital Federation (IHF) proposed an international approach to developing core leadership and managerial competencies for healthcare managers, in partnership with the following organisations:

- Pan American Health Organisation (PAHO)
- American College of Healthcare Executives (ACHE)
- European Association of Hospital Managers (EAHM)
- Jamaica Association of Health Service Executives (JAHSE)
- Taiwan College of Healthcare Executives
- Canadian College of Health Leaders
- Australasian College of Health Service Management
- Management Sciences for Health (MSH)
- National Health System Leadership programme (NHS/IHM)

A two-day workshop took place on 29-30 January 2013 in PAHO headquarters in Washington D.C with 14 delegates from the above organisations participating. Ms. Lucy Nugent, member of the EAHM Scientific Subcommittee and Honorary Secretary of the Health Management Institute Ireland attended on behalf of the European association.

The objectives agreed were:

1. To develop a charter outlining purpose and intent of collaborative group.
2. To reach minimal agreement on the core competencies necessary for health service executives/managers.
3. To develop a framework – including stages of development (from novice to expert) to assess “practice in the real world”.
4. Assessment process – how and by whom

should competencies be assessed.

5. What should the respective role of each association be?

A review of a selection of competency tools currently in use was undertaken and discussion took place regarding the ACHE, MSH, Canadian LEADS and the Australian LEADS (adapted from the Canadian framework) and NHS frameworks. Agreement was reached on the core competencies in the following priority:



Photo: Attendees of the two-day workshop in Washington

1. Leadership;
2. Professional and Social Responsibility;
3. Knowledge of Health and the Healthcare Environment;
4. Communications and Relationship Management; and
5. Business Skills and Knowledge.

While it recognised that base training/education on core competencies is essential to develop “knowledge ability” and skill, there needs to be a period of experiential learning before assessment takes place e.g. ACHE requires a manager to be working for at least two years before being assessed. The issue of validation of any tool requires further consideration, as any existing evaluation of tools appears to be largely empirical. There may be a need to define and potentially expand the competency framework for each country but a core subset would be agreed with possible mutual recognition.

Discussions took place on whether these competencies could be WHO approved but this takes a considerable length of time (2-5 years) so it was agreed to establish an IHF chapter (i.e. a thematic group working on its own issue or agenda) under which this collaborative work can progress (IHF has a memorandum of understanding with WHO and is well placed to subsequently progress with WHO).

Next steps

The next steps in this collaborative process include:

- Web based project site (using Basecamp software) to be established for online discussion and uploading of draft documents and reference material (essential to manage the logistics of geographical spread of participants).
- Terms of Reference for Chapter to be drafted and circulated.
- MSH/PAHO to identify organisations/associations to represent Africa.
- Subgroups established to work on principles/charter, competency document, Oslo conference session (90 minute programme slot available to give examples of competency frameworks and get feedback on consultation document).
- Next meeting agreed to take place at the IHF conference in Oslo June 2013.



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UK: NEW MOBILE PHONE APP TRANSFORMS PATIENT AND FAMILY FEEDBACK

A revolutionary new smartphone app designed by Birmingham Children's Hospital – the first of its type in the NHS – is making patient and family feedback quicker, easier and more effective than ever before.

The Birmingham Children's Hospital Feedback app has been designed to enable children, young people and families to interact with the hospital in an innovative new way to send their thoughts and comments directly to the ward or area they have visited with the simple click of a button.

Patients and families may be waiting in Outpatients when they leave a comment, they may be an inpatient sending the third comment of their admission or they might even be at home – the app gives the flexibility to feed back at any time.

The message, which is anonymous, goes straight to the manager in charge so it can be addressed in real-time,

and as part of the hospital's commitment to openness and transparency the feedback is also made publicly available on the hospital's website.

Michelle McLoughlin, Chief Nurse, has been leading the project. She said: *"We're always looking for ways to improve how we receive feedback because what happens to our children, young people and families really matters to us and we want to get it right first time, every time...The app enables us to gather feedback in a way that our patients and families want to give it so we know immediately what we are getting right and what we need to improve to make their time with us the best it can be."*

Developed in partnership with Digital Life Sciences, the delivery partner behind NHS Local, and supported by NHS Midlands and East, the app was trialled in two areas before being rolled out

across the Trust.

The app also features a ratings function, in line with the national Friends and Family test, which enables the hospital to take an instant snapshot of how likely patients and families say they would be to recommend the hospital as a place to be treated. This information, alongside the messages and comments, is collated, reviewed and analysed to pick up any emerging themes or issues from which action can be taken.

As the first organisation to develop a feedback app of this kind, Birmingham Children's Hospital is keen to work with other Trusts who may be interested in implementing the app in their organisations.

For more information, please visit: www.bch.nhs.uk/feedback

BELGIUM: NEW RECOGNITION SYSTEM IN 2013 FOR HOSPITAL PHARMACISTS

In December 2012, two decrees appeared in the Belgian Official Gazette concerning the recognition of the particular professional title of hospital pharmacist. The decrees both form part of the reform of hospital pharmacist training courses and usher in a new recognition that will become operational in 2013.

Following consultations with academics and professional associations, a clear consensus emerged that a hospital pharmacist training

course should require three years (instead of the current one year). The recently published decrees feature a redesigned recognition system that will become fully operational at the end of June 2013.

In order to ensure a smooth transfer to the new recognition system, the necessary transfer measures have been put in place so that hospital pharmacists recognised under the old system and candidates who have embarked upon a training

course in the old system will still fall under that system for some time to come. Transfer measures have also been provided for traineeship supervisors and traineeship services.

For more information on the recognition system please visit: www.health.belgium.be

More interesting pharmacy related news can be found in our pharma supplement starting on page 19.

For photos and videos of recent events please visit myhospital.eu

EUROPEAN EHEALTH ACTION PLAN

The European Commission's latest eHealth initiative, the "eHealth Action Plan 2012-2020 - Innovative health-care for the 21st century", builds on the foundations of the 2004-2012 plan, and sets out ambitious measures for implementing eHealth across the EU with the slogan of "lifting barriers to smarter, safer, patient-centred health services."

Launched in December 2012, the plan provides a long-term vision for eHealth in Europe, and focuses on the steps for wider delivery of eHealth throughout the Member States and across borders.

velopment and innovation in eHealth and wellbeing to address the lack of availability of user-friendly tools and services, facilitate uptake and ensure wider deployment of eHealth;

Against a background of budget cuts, ageing populations, increasing chronic health conditions, increased mobility and rising patient expectations healthcare ICT offers great promise for a smart, sustainable healthcare system. Uptake of healthcare ICT, particularly for patient access, has been patchy. A 2010 survey of hospitals in Europe showed that 81% have one or

make 10% overall cost savings through nurse telephone support.

Tonio Berg, European Commissioner for Health and Consumer Policy says: "eHealth solutions form a key element in developing "smarter healthcare" – greater access, more efficient services, and higher quality, with greater patient involvement."

Neelie Kroes, EC Vice-President, says: "Digital technology is there to help us change. Whether it's remote monitoring that lets you be cared for at home, robots to help around the house, or simply mobile apps that empower you to take control of your own healthcare."

The eHealth network set up in 2011 will be responsible for drawing up an interoperability framework for cross-border health services and guidelines on eHealth, including a dataset for patient summary records to be exchanged across borders and measures for interoperable electronic identification and authentication, enhanced security of health information and interoperability of databases for medicinal products.

In addition it is proposed that by 2014, the Commission will adopt a Green Paper on mHealth and health and wellbeing applications.

Research and innovation will be supported in several areas, including personalised and predictive medicine, innovations for analytics, diagnostics and decision making, web and mobile technologies and applications, and eHealth systems and services with strong user involvement, focusing on interoperability and the integration of emerging patient-centric technologies for cost-effective healthcare.

For more information, see <http://ec.europa.eu/digital-agenda/en/news/putting-patients-driving-seat-digital-future-healthcare>

Against a background of budget cuts, ageing populations, increasing chronic health conditions, increased mobility and rising patient expectations healthcare ICT offers great promise for a smart, sustainable healthcare system.

eHealth is seen as the key to sustainable health systems for the future. It has wide-reaching applicability in healthcare systems: interaction between patients and health-service providers, institution-to-institution data transmission, and peer-to-peer communication between patients and/or health professionals.

Progress has been made since the first eHealth action plan of 2004, notably the European Patients Smart Open System (epSOS). Barriers to further development include lack of awareness and confidence in eHealth solutions, lack of interoperability, limited evidence of effectiveness, legal and privacy concerns, high start-up costs, and variation in access.

The Action Plan's objectives are to achieve wider interoperability of eHealth services; support research, de-

more electronic patient records systems in place, but only 4% grant patients online access to their health information. 71% use online eBooking systems for patients' appointments with medical staff but only 8% offer patients the opportunity to book their appointment online. 43% of hospitals exchange radiology reports electronically, but only 30% use ePrescription for medicines, 8% telemonitor patients at home, and 5% have some form of electronic exchange of clinical care information with healthcare providers in other EU countries.

eHealth has already shown promise. A recent study across The Netherlands, UK and Germany found that home telemonitoring systems could improve survival rates by 15%, bring a 26% reduction in hospital days per patient and

THE CHANGING ROLE OF THE HOSPITAL

Challenges of Hospital Management

By Roland Ollivier, Emilie Hericher and Cédric Arcos

The situation of hospitals at the end of the last century could be defined as transitional; between a stable model of partly predictable changes and the new schema of the healthcare environment and hospital management we know today. Hospitals are evolving within this new framework and the challenge for the management will be to define a relevant strategy, readable by all teams and at the same time manage uncertainty and constantly adapt to internal and external changes.

Paradoxically, in a world with uncertain futures, the years 2010 to 2020 will herald an integrated view of the management of health organisations.

The many challenges and constraints faced by hospitals will inevitably question their management

The first uncertainties that hospital managers will face regard the use of the hospital during the next decade. Indeed, the progression of chronic diseases correlated with the increasing age of the population may suggest that the rate of hospital use will increase. At the same time, the reorganisation of care could lead to the management of a large proportion of patients outside the hospital. Everything will then depend on the number of years without disabilities of the elderly population, as well as access to healthcare services for a part of the population. Concerning the need for care, in the upcoming years we will fluctuate between the development of personalised medicine, such as expensive targeted therapies for cancer and the use of mass medicine, which could be boosted by the resurgence of infectious diseases.

Thus, the hospital, by the universality of its missions is often disrupted in its organisation, torn between emergency care and planned management of patients. These two aspects of hospital activity can be illustrated by the uninterrupted admissions into emergency departments and outpatient surgery.

In France, the degree of competitive pressure is among the highest in Europe. Its intensity varies with the territory, making it a risk factor or, conversely, an opportunity for public health facilities. For example, if some hospitals suffer locally from increased competition in certain surgical disciplines and oncology. In recent years the share of public hospital surgical activity increased. This trend is expected to continue in the coming years, especially in terms of plans for the retention of doctors and nurses.

The importance of human resources management in the hospital will only continue to grow, not only because it is a critical component in the operation of hospitals, but because they represent a survival issue for most hospitals. This particularly important with the medical staff, whose figures are contradictory. The past decade has been one of continued growth of the workforce with a halt in 2009 for non-medical personal. At the same time, there are about 15,000 vacancies (full-time and part-time combined) for hospital doctors and the weight of the competition is very strong in some medical disciplines.

To date, one of the biggest unknown factors remains the level of resources and financing methods. The major breakthrough of the last decade has been driven by pricing activity coupled with regulation of volume/tariffs. This is has generally enabled hospitals to gain control over their development because of the automatic level of resources generated by the increase in hospital stays. The downside was not really being able to anticipate this level of resources due to constant changes in pricing stays, definitions of the scope of pricing activity and the frequent drop in rates offsetting volumes of activity. But this pricing method is especially questioned in terms of relevance of some stays, hence the emergence of new approaches of pay-for-performance, performance expressed in terms of quality and appropriate care episodes in a management chain.

At the same time, the social protection systems in Europe are affected by the economic crisis: since 2010, some countries have resorted to a severe drop or a cap on hospital allocations.

In comparison, France has not experienced a decrease in resources, neither in relative or absolute value. However, given the objectives of economic competitiveness displayed, the level of social protection is highly regulated in value. The "natural trend" of hospital spending growth in relative value is (3.5%). Consequently, the financial balances are not, in fact, possible without gains in productivity or without additional

contribution from the patient, often by support from their complementary social protection.

The development, or at least the continued investment and equipment, will also be a major challenge for the coming period. Previous years have seen a meteoric rise in the construction of hospital buildings and investments in general. More often than not, investments were made in response to a need but, on the other hand, they led to an increase in debt and sometimes deficits as generally the tariffs do not cover the additional costs associated with these investments. In addition, the economic crisis has dried up access to loans, and it is only recently that the provisions of investment support have emerged through the creation of tools for financing public investment, like in France, with the establishment of a public investment bank in the first half of 2013.

Hospital decision makers will also face the issue of equipment costs notably with the development of operating robots or information systems. The high price of new technologies can slow down their development. For example, a PET scan costs more than €2, 5 millions, plus an extra €2 million every year. Similarly, the Da Vinci robot price is €1, 2 million, plus an extra of €150 000 for maintenance each year.

This will lead to a pressure on organisations to make best use of these new technologies. The opposite may also occur, with some institutions searching for substitutes for costly items. The high cost of construction such as building infrastructure and materials raises the question of the creation or transformation of hospital organisation with regulated and even lower costs. Will there soon be *Smart Hospitals*?

Finally, there is the major subject of the coordinated organisation of care in a geographic area. This organisation is planned by the health authorities but at the same time pricing mechanisms and remuneration models are differentiated between professionals depending on whether they work at the hospital or at a doctor's surgery. This leads to strong competition between the two. Institutions will there-

fore fluctuate between cooperation and competition, which some authors have called "coopetition". This will result in more a comprehensive healthcare organisation, with a view to allow users to move easily between community care and specialised care.

The Integrated Approach to Managing Complex Organisations

Today it is essential for managers, current and future, to have a global vision and "360 degree" competences of the healthcare system and its organisations, hence the importance of a more integrated approach. It is obviously not about dreaming of integrated systems and organisations, but to take into account different parameters, sometimes contradictory effects, in order to guide an organisation today and manage the health services of tomorrow.

Regarding health strategy, the hospital director of tomorrow will need to develop a broader vision and develop its activities in coordination with other institutions within a defined geographic area. It is therefore important to define the scope of activities, shared-or-related, in order to ensure both continuity of care and the allocation of the necessary resources. To be able to develop successful organisations, it will be necessary to convince, on an internal level, all professionals who may be concerned. The management will also need to deploy a strong ability to negotiate with external partners. Therefore, we move from a structural management to the management of activities, and then the management of care pathways.

The management of healthcare organisations will have to rely on the processing of more and more precise data, this could be described as managerial epidemiology. While handling the "big data" is often regarded as a major competitive advantage, this approach requires a clear strategic line and a strong leadership from the directors of institutions, in order to involve all hospital staff in the transformation of organisations.

The establishment of multi-disciplinary teams also promotes a qualitative approach to the management of human resources, both to define the competencies required but also to lead multi-disciplinary groups. Behind this, there are issues of attraction and retention for hospitals as well as financial issues, if we consider the cost of absenteeism and inefficiency. It is in this sense that human resource management should take into account various parameters related to each other.

Finally, managing an institution is also man-

aging processes, following a project or activity from the beginning to the end. This applies particularly to supply management and the provision of services, what is called the "supply chain." But the ambition in this area is mainly to develop the same approach to integrated processes of care, in a kind of device operations management applied to healthcare organisations. In fact, the management of care pathways, which has become a priority in France, is process management. This method of management aims to ensure continuity of care and ensure support in the right place at the right time. In the years to come hospital management will be devoted to this construction.

Conclusions

The hospital managers of tomorrow will have to manage uncertainty, even though teams will demand transparency in reference to their values and their desire to ensure a stable environment

for their patients. The role of hospital manager will be difficult. But the contradictory forces that cross the health system also provide an opportunity to review the nature of the services to be provided and hence the organisation of activities such as working with the support of patients, who are now experts and hospital professionals..

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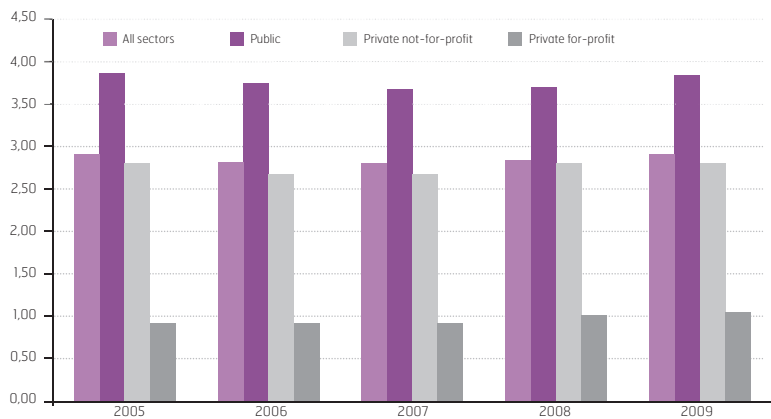
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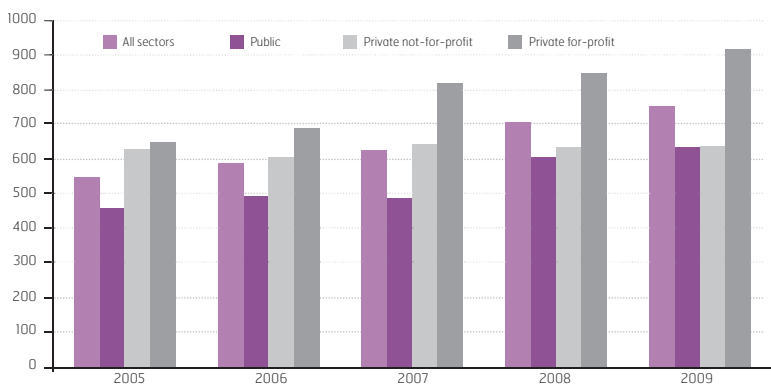
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Graph 1: Number of interventions per room under anaesthesia between 2005 and 2009



Lower health expenditure in the EU in 2010
Growth rate cancels health expenditure per capita
Percentage (for the vertical axis)

Graph 2: Activity on non-hospitalised patients (consultations, sessions and examinations on outpatients) in reported stays registered between 2005 and 2009

Source : Evolution de l'offre et des prises en charge hospitalière entre 2001 et 2009 : technicité croissante pour des séjours plus courts, Dossiers santé et solidarité n°25, DREES, 2012

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THE “SAINT JEAN PHILOSOPHY”

Attractive to Patients and Staff Alike

By Jos Olbrechts

For more than 800 years, the Saint-Jean Clinic has provided care at the heart of Brussels, where it was the first private hospital. In our long history, we have prided ourselves in the ‘Saint-Jean Philosophy’ which characterises us; an all-encompassing philosophy which is probably impossible to define precisely, but most importantly puts the human experience at its centre.

This approach requires constant effort and attention at all levels of our organisation, but is also a fascinating and rewarding process. In addition to the satisfaction of providing the highest standard of care to our patients, we recently had the pleasure of being awarded the ‘Magnet Hospital’ Award by the FPS – Public Health (SPF Santé Publique). This prize recognises the efforts made to improve the welfare of patients and staff members within the hospital, and rewards the organisations demonstrating an ability to attract and retain their staff. In this article, I propose to reflect on this ‘Saint-Jean philosophy’ which, translated into a number of HR initiatives and firm principles, has helped us to achieve the Magnet Hospital status and, by doing so, to serve our patients to the best of our abilities.

The Saint-Jean Clinic: Overview

Our clinic is a general private hospital spread over two locations at the centre of Brussels: the Méridien and the Botanique sites. With 503 beds, we have the capacity for 12,000 standard hospital stays, 9,000 hospital day-care stays, 10,000 surgical operations, 110,000 consultations, 1,100 births, and 21,000 emergency cases each year.

A full spectrum of care is covered by Saint-Jean, including critical care such as cardiac surgery, neurosurgery, oncology, specialised emergency care, intensive care, paediatrics and dialysis. In this perspective, we have a fully comprehensive infrastructure, and we also partner with other healthcare organisations in Brussels and the surrounding area when they need to transfer patients to some of our services that they do not have a structure for.

On a demographic level, we could be considered as a truly Belgian hospital: we treat French-speaking and Dutch-speaking patients from Brussels and beyond, as well as

foreign residents and tourists, due to our central location in the capital. This position brings us a real mix of cultures and languages, which we consider to be our strength, whether in our relationship with our patients or with our staff members.

How to Foster Diversity in Human Resources

In a total of 1,300 employees working at the clinic, 760 are nursing staff, of which 570 are in full-time employment. Their minimum level of qualification is a BA, as we have set high criteria for our nurses. Our turnover is at 10.5%, which is well within the national average. In the ambient shortage of nursing staff, especially in Brussels, Saint-Jean is happy to be able to maintain the excellent level of its staff, and frequently receives unsolicited applications from both graduates and more experienced nurses. We have never had to resort to temporary staff, and our balance sheets are positive, which is quite rare for healthcare organisations.

Our staff members reflect the cultural diversity of our patients, and show the result of a clear and structured objective: in each team, we ensure that there is a balance of French-speaking, Dutch-speaking, and foreign employees. They have all obtained their degree in Belgium, and thus have a similar level of training and skills. Through the independent survey of our patients, we have also been happy to see that they consider the social climate in our clinic to be very good.

We want to provide the opportunity for our employees from both communities to work in their own language while being able to learn either Dutch or French. Each member of staff is entitled to 60 hours of individual language classes, half of which are considered work time. These 60 hours can then be followed by group conversation

classes where staff members can learn medical jargon or practical vocabulary they will need to use in their work.

This focus on cultural diversity, the convivial atmosphere of the clinic and its many practical advantages such as easy access and flexible work times among others, make Saint-Jean an attractive workplace. Furthermore, our hospital prides itself on its constantly evolving approach to HR and on taking a number of measures to improve its staff welfare, which can all be found in the attributes of Magnet Hospitals.

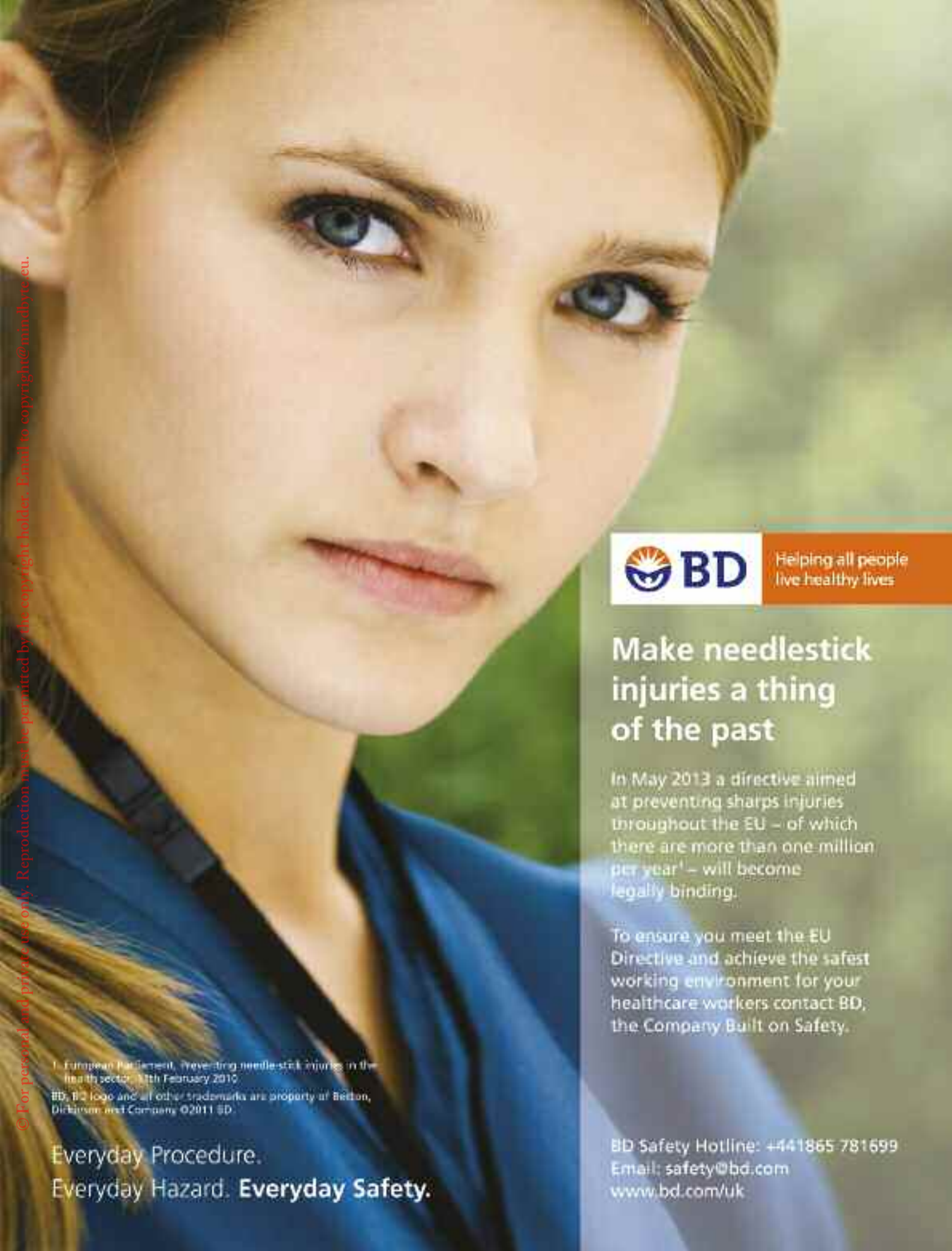
Magnet Hospital

The Federal Public Service – Public Health’s recent award to Saint-Jean in the form of its designation as a ‘Magnet Hospital’ was a wonderful recognition of our commitment to quality, safety and welfare in our hospital. The designation is part of a project of the Ministry of Health, and lists fifteen recommendations.

These recommendations include, for example, that the hospital must respect their staff’s choice of department and work schedule. It must provide security to its employees by offering them permanent employment contracts, as well as give a face to management. We work tirelessly to ensure that each employee works in his or her choice of unit or department. This also stems from a purely managerial point of view: a satisfied worker will deliver excellent results. Furthermore, our ‘Open Door’ policy, implying that there is no barrier in the hierarchy, makes it possible for any member of staff to talk to management on the day they request a meeting.

Other requirements for a Magnet Hospital consist in sharing our vision with staff at all levels, both as a mission statement (our ‘Saint-Jean philosophy’) and as an operational document, such as our ‘Patient Charter’. In this document, we outline our care phi-

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1. European Parliament, Preventing needle-stick injuries in the health sector, 13th February 2010

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losophy, which is made visible to all our patients: we strive to give them an individual, holistic, interactive and informed level of care. The patients know that we aim to respect their language, their religion, their dignity and their privacy, and know what they are entitled to expect from their stay in our clinic.

In addition, we focus a great deal of attention on our young interns and recruits, by designating a 'mentor', a more senior member of staff who will help them to settle in their new roles. This could be represented by the Magnet Hospital recommendation to encourage solidarity and autonomy in staff members. We try to put our employees at the helm of as many decisions and initiatives as possible, and support their continuing education financially and morally. I found that this approach was key to discover and foster some 'hidden talents' in our hospital's teams. One of our employees, Mrs Vass, for

The patients know that we aim to respect their language, their religion, their dignity and their privacy, and know what they are entitled to expect from their stay in our clinic.

instance, was a nurse at Saint-Jean before going on to obtain a degree in Hospital Financial Management and so was perfectly suited to become the Head of our Purchasing Department, where she can draw on her experience as a nurse to make the most informed and thoughtful purchasing decisions. Another one of our employees had studied architecture at the La Cambre school before graduating as a nurse, and we were extremely advantaged by her insights on the design of the new wing of patient rooms she helped us to create. She could ensure that all the practical elements of patient care were taken into account in the plans, which even the best architect could not have known, lacking the point of view of a nurse. This versatility in our staff is a privilege I am most proud of, and I

encourage all the nurses to take on roles in other departments of the clinic, such as administration and logistics, as I feel that their experience is always a crucial addition to the running of Saint-Jean.

To summarise, we operate a 'Hospital-centred management', instead of the financial or medical management approaches usually seen in other hospitals. A hospital-centred management gives every member of staff the possibility of becoming involved, and thus engaged, in the management's decisions. For us this is only logical, as nurses make up the majority of Saint-Jean's personnel, far more than doctors or managers.

Safety Brings Quality

This focus on our nursing staff also applies to ensuring they can work in the safest environment possible. Once again, this is part of the fifteen requirements of the Magnet Hospital Award. These recommendations are in line with the new EU Directive on Healthcare Worker Safety and sharps injuries prevention, published in June 2010 and to be implemented as national law by all EU member countries by May 2013, and state that the hospital management must provide a safe environment to both patients and workers, by using the best, most advanced and safest equipment, but also by preventing risks. I am proud of the fact that we were among the first healthcare organisations in Belgium to introduce 'mobile teams' who could stand in for an absent nurse without it affecting another nurse's schedule and work patterns, and to use safety-engineered medical devices, for example, long before they became the norm. Measures such as monitoring hand hygiene, reporting needlestick injuries or using safety-engineered blood collection devices, infusion devices, injection needles, for example, are all practical adaptations of the risk prevention recommended by the European and Belgian legislations.

However, we are adamant that safety must not be considered as a nurse's concern only. Everyone at the hospital is exposed to risks, accidents and infections, and in order to address this issue, we have recently enrolled in the FPS's 'Patient Safety' project and received funding to appoint a Safety Manager. Mrs Peeters, one of our nurses, received training from the FPS in order to take on the role. Her primary task is to assess the safety culture within the clinic - among doctors, nurses and nurse's assistants, and to report any risk or

near-accident she witnesses. As we encourage an atmosphere of communication and exchange in our departments, this assessment is by no means a way of pointing fingers at possible shortcomings, but a determining tool in preventing risks. The results of Mrs Peeters's survey will be the basis for the new safety plan she will propose to implement at the level of the organisation, as opposed to the nurses' level only, which I am very much looking forward to.

By insisting on safety and welfare at all levels of our organisation, we make our philosophy, the 'Saint-Jean philosophy' visible to our patients who can reap the benefits of our general positive approach to our employees. Indeed, through our internal benchmarking tools as well as the patients survey processed externally, we have observed that the staff reflect the quality of their working conditions and the consideration they enjoy in their team, in their care of our patients.

High standards are Saint-Jean's objective in all respects, be they the regular refurbishment of our premises and rooms, the safety visible on every floor of the clinic, the interaction between patients and their carers, or the level of comfort patients can enjoy in their rooms. The effort and money we invest in this quality are, in our view, a long-term commitment to distinguishing ourselves in our patients' opinion. Reputation and image are no longer a secondary concern for healthcare organisations, as I am convinced that only the hospitals with 'added value' will be able to survive the current saturation of beds.

In a way, quality in care has become our selling point. It would be just as naive as it would be vain to imagine that our hospital is providing better medical care than any other healthcare organisation in Belgium. All our doctors and nurses have had the same standard of training for giving injections or inserting catheters. In this context, there remains only the approach to care, the human experience at the heart of our commitment to patients. This philosophy is a work in constant progress, but would certainly be a fitting definition of the 'Saint-Jean philosophy'.

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THE FRANCIS REPORT: A WAKE-UP CALL FOR THE UK NHS

The final report of the public inquiry into care provided by the Mid Staffordshire NHS Foundation Trust has sent shockwaves across the NHS in the United Kingdom. The implications of this report, which received significant media attention, are likely to have a profound effect on the healthcare sector in the UK and serve as a warning for hospitals and healthcare systems around the world.

The Inquiry has been examining the commissioning, supervisory and regulatory bodies in the monitoring of Mid Staffordshire hospital between January 2005 and March 2009. It has been considering why the serious problems at the Trust were not identified and acted on sooner, and identifying important lessons to be learnt for the future of patient care. It builds on Mr Francis's earlier report, published in 2010 after the earlier independent inquiry on the failings in the Mid Staffordshire NHS Foundation Trust between 2005 and 2009.

The Inquiry identifies a story of terrible and unnecessary suffering of hundreds of people who were failed by a system which ignored the warning signs of poor care and put corporate self interest and cost control ahead of patients and their safety. The findings and recommendations are relevant to hospitals across Europe and indeed the world. During these times of economic uncertainty and decreasing budgets hospitals must strive to put the patient at the centre of all activities.

Robert Francis QC, Chairman of the Inquiry made 290 recommendations designed to change this culture and make sure patients come first by creating a common patient centred culture across the NHS.

The Chairman's recommendations include:

A structure of fundamental standards and measures of compliance:

- A list of clear fundamental standards, which any patient is entitled to expect which identify the basic standards of care which should be in place to permit any hospital service to continue.
- These standards should be defined in genuine partnership with patients, the public and healthcare professionals and enshrined as duties, which healthcare

providers must comply with.

- Non-compliance should not be tolerated and any organisation not able to consistently comply should be prevented from continuing a service which exposes a patient to risk.
- To cause death or serious harm to a patient by non-compliance without reasonable excuse of the fundamental standards, should be a criminal offence.

Openness, transparency and candour throughout the system underpinned by statute. Without this a common culture of being open and honest with patients and regulators will not spread. Including:

- A statutory duty to be truthful to patients where harm has or may have been caused.
- Staff to be obliged by statute to make their employers aware of incidents in which harm has been or may have been caused to a patient.
- Trusts have to be open and honest in their quality accounts describing their faults as well as their successes.
- The deliberate obstruction of the performance of these duties and the deliberate deception of patients and the public should be a criminal offence.
- It should be a criminal offence for the directors of Trusts to give deliberately misleading information to the public and the regulators.

Improved support for compassionate, caring and committed nursing

- Entrants to the nursing profession should be assessed for their aptitude to deliver and lead proper care, and their ability to commit themselves to the welfare of patients.
- Training standards need to be created to ensure that qualified nurses are competent to deliver compassionate care to a consistent standard.
- Nurses need a stronger voice, including representation in organisational leadership and the encouragement of nursing leadership at ward level.
- Healthcare workers should be regulated by a registration scheme, preventing those who should not be entrusted with the care of patients from being employed to do so.

Stronger healthcare leadership

- The establishment of an NHS leadership college, offering all potential and current leaders the chance to share in a common form of training to exemplify and implement a common culture, code of ethics and conduct.
- It should be possible to disqualify those guilty of serious breaches of the code of conduct or otherwise found unfit from eligibility for leadership posts.
- A registration scheme and a requirement need to be established that only fit and proper persons are eligible to be directors of NHS organisations.

Government Apology

Prime Minister, David Cameron spoke out on the issue stating, "What happened at The Mid-Staffordshire NHS Foundation Trust between 2005 and 2009 was not just wrong, it was truly dreadful." Addressing the House of Commons, Cameron also saw fit to apologise to the patients and families concerned. "On behalf of the government – and indeed our country – I am truly sorry." He apologised for the system that "allowed this horrific abuse to go unchecked and unchallenged for so long."

Talking about the report, Francis emphasised the importance of enforcing standards by law. "Senior managers should be made accountable, patients need to be protected from poor nursing standards and all staff should be empowered to be open and transparent when it comes to the well-being of the people in the care."

Conscious of shock and scandal surrounding the findings of both the independent and public inquiries, Francis was keen to highlight a positive path for the future, "The recommendations I am making today represent not the end but the beginning of a journey towards a healthier culture in the NHS where patients are the first and foremost consideration of the system and all those who work in it. It is the individual duty of every organisation and individual within the service to read this report and begin working on its recommendations today."

The report can be read in full at www.midstaffpublicinquiry.com

A MULTIDISCIPLINARY APPROACH TO FINANCIAL PLANNING

Clinical Aspects and IT Requirements

By Wilhelm Frewer and Hans-Peter Busch

Public health authorities face massive strain on their financial capacity and resources due to the explosion in the development of new medical technology, and the ageing population. New reforms in legal initiatives prompted a radical change of the market structures which are being replicated in today's health systems. The EU, for example, intends and has planned for some time, to reform previously monopolistic, traditional ways, because public services of general interest are more and more evolving into competitive structures. The establishment of health services as competitive structures will inevitably lead to a process of natural selection and only economically successful participants will survive to lead the healthcare market.

Competition in the healthcare market will impact both the health insurance and service levels (Figure 1). Consequently, there is a continuous need to increase effectiveness and efficiency, and thus to improve processes, in the healthcare sector generally and in the organisation of hospitals and medical practices in particular. The concept of competition in healthcare refers to both performance and cost competition, with a given emphasis on improved quality. "It is not the major players that will push the smaller ones out of the market, but the fast will push out the slow" (W. von Eiff, Medical Data Institute, Münster). Thus, the successful management of hospital departments and medical practices requires suitable structures and optimisation processes in the fields of medical quality, service quality and efficiency.

Organisational Structures in Brüderkrankenhaus Trier

The Department for Radiology, Ultrasound and Nuclear Medicine in the Brüderkrankenhaus Trier has 69 employees, allocated as shown in Table 1. Medical imaging greatly influences the optimisation of the entire treatment pathway for patients in the hospital, as it plays a central part within the hospital, providing services to a large number of internal hospital departments as well as referring third parties (e.g. local practices). The imaging diagnostics and interventional treatment divisions are therefore particularly meaningful as service providers to all clinical departments of the hospital (Figure 3).

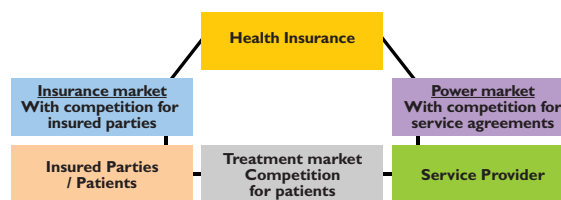
How Processes Impact Payment

It is essential that the organisation of the treatment process be viewed holistically, as a com-

Table 1: Allocation of Employees

Medical Centre Manager	Medical Technology Manager
▶ 6 Section Heads	6 Area Managers
▶ 18 Doctors	35 Technology Assistants
• Radiologists	Organisational Forces
• Surgeons	
• Internists	
• Nuclear Medicine	
• EDV Specialist	EDV Specialist
• Angiologists	Graduate Economist

Figure 1: Impact of Competition on Health Insurance and Service Levels



plete and entire process in order to execute a well-managed payment system. Along with the provision of individual services, interdisciplinary counselling must be provided prior to the diagnostic and treatment of disease patterns (e.g. vascular diseases), in particular in the context of medically and economically efficient diagnostic and treatment paths. Avoiding a CT examination through set treatment paths or interdisciplinary team meetings creates value both for the patient, potentially leading to less or no radiation exposure, and for the overall value creation chain of the hospital. In a system of diagnosis-based fixed reimbursement, the unperformed exam will be compensated in any case, while still respecting patient safety and a high medical quality.

How We Do It

Our department's revenue streams include:

- Outpatient services;
- Private patients;

- Internal activity allocation;
- External referrers; and
- Additional revenue from new offerings (Cardio-CT; screening, leasing of equipment and personnel from other health providers, increasing the number of private patients, etc.)

Increasing your service offering also generates new revenue when carried out in an efficient way. For us, our efficiency increased with the establishment of two ambulatory care centres. These systems allow for better utilisation, additional margins and the integration of ambulatory and stationary spheres, representing extension of the value chain. Cost savings are derived from the ratio of total costs to total revenues and internal transfer pricing. The positive difference between revenues and costs allows an increase in budget in the areas of personnel, equipment and investment.

Organisation of Our Budget

An interdisciplinary framework is not just useful for high quality medical treatment and process

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optimisation. In terms of budgetary planning, we carry out annual budget meetings that involve the administration personnel as well as the central management team, who create the frame for an overall targeted planning for the economic management of the medical imag-

the upcoming year and are generally based on the data of the preceding year. The size of the service volume is determined to a high degree by the internal service allocation of the referring parties, who are responsible for the effectiveness of the service request but also for the

and the hospital management. Well-prepared target-oriented meetings, with a proper analysis of the service development and costs, can be crucial for the department's future development.

In a monthly reporting of internal controlling, carried out in close coordination with the department of business administration, the data is provided to the responsible managers of the relevant cost centres in the MID. Budgets consist of both a value based cost component (input) and volume based services (output).

Cost adjustments in personnel and material costs are made using a flexible planned cost calculation that takes any resulting potential higher or lower revenue into account. For example, productivity increases in the form of more services at lower costs are rewarded by a bonus for the medical imaging department's employees. In case of a productivity increase, this will be negotiated as planned/target parameter for the next year, so that the efficiency criterion is continually driven upwards (Figure 5).

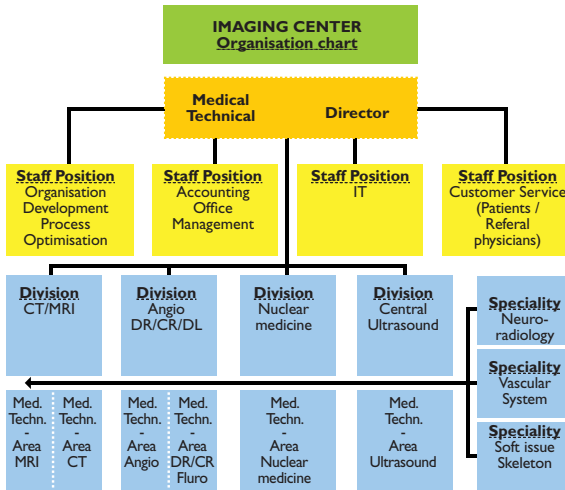


Figure 2: Imaging Department's Organisational Chart

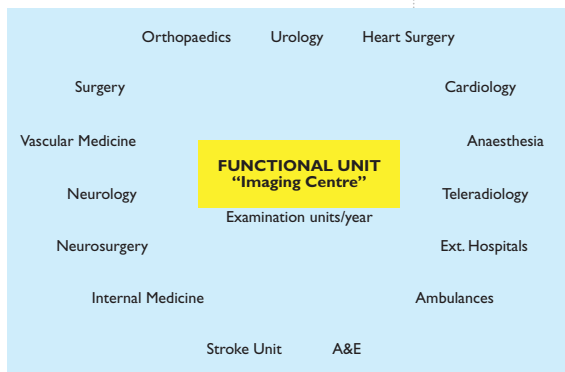


Figure 3: The Imaging Department at the Intersection of Interdisciplinary Treatments

ing department (MID). This is subdivided into service area planning, cost planning and revenue planning. The parameters we use to measure the success of this plan include the service volume, which is rated by service points, and the cost of personnel and materials. Overall cost-effectiveness is the result of the relationship between revenues and costs.

involved prices. The MID's management is responsible for the productivity and the cost-effectiveness of the service provision (Figure 4).

In this way, any deviations that arise between planning and execution becomes apparent and can be addressed by management. In the hospital, parameters offering service and cost information are particularly important in preparing the annual budget meetings between a department

When Does Fee-For-Service Work?

By setting up a budgetary management system that operates under the umbrella of optimised efficiency, a hospital or medical practice is better equipped to survive and will add some protection in the face of challenging or changing financial conditions. In a hospital, efficiency, which in this case refers to the relationship between revenue and costs, refers to the sum of individual services (e.g. out-patient services, emergencies), but beyond this also to the realisation of treatment complexes – diagnosis related groups (DRG). Approximately 70 – 80 percent of the revenue of hospitals consists of diagnosis-based fixed compensation. The DRG system is a service-based compensation scheme that follows the motto "fee for service". A comparison of the annual volume of personnel and material costs

Figure 4: The medical imaging department from an economic perspective

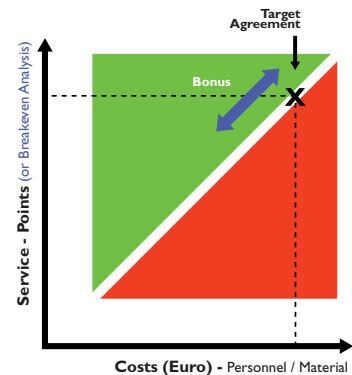
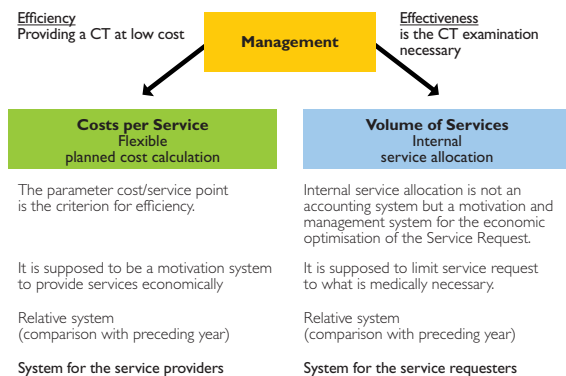


Figure 5: Flexible Planned Cost Calculation

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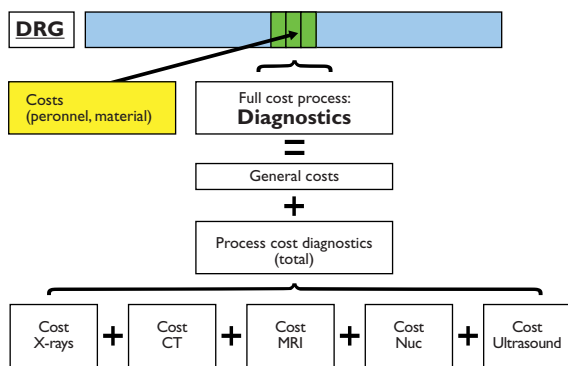


Figure 6: The Costs of DRG for Imaging

with the sum of the corresponding DRG portions can be used as a criterion of efficiency. This applies especially to the personnel costs, which represent the largest cost pool.

which allows for the deriving of effectiveness assessments. How the examination mix in a complex diagnosis-based, fixed compensation case (e.g. B70B, stroke) looks in retrospective com-

DRG	Cost Medical service actual	Cost MTD* actual	Cost AD*/MTD actual	Medical service acc. to INEK with baserate BKT (target)	MTD acc. to INEK with baserate BKT (target)	AD/MTD acc. to INEK with baserate BKT (target)	Diff. actual/target personal
Gesamt	811.728,74	1.033.031,86	1.844.760,60	790.791,60	1.137.746,04	1.928.537,64	-83.777,04
E71B	24.098,73	23.500,74	47.599,47	19.303,47	27.762,80	47.066,26	533,21
B70B	18.141,97	24.099,52	42.241,49	22.632,01	25.667,07	48.299,08	-6.057,59
F54Z	16.946,57	22.768,72	39.715,29	18.219,06	19.710,80	37.929,86	1.785,43
B70D	16.827,91	22.510,68	39.338,59	18.297,89	23.513,81	41.811,70	-2.473,11
F59B	16.429,40	22.030,25	38.459,65	17.698,29	19.846,84	37.545,13	914,52
B76G	13.624,15	18.281,40	31.905,55	10.757,95	15.264,54	26.022,49	5.883,06
I53Z	12.580,82	16.303,26	28.884,08	16.837,86	23.283,40	40.121,26	-11.237,19
B20B	11.721,26	15.704,04	27.425,30	20.899,34	24.628,04	45.527,39	-18.102,09
B81B	10.777,46	14.378,51	25.155,97	8.231,30	11.348,85	19.580,15	5.575,82
A09C	10.660,20	14.322,61	24.982,81	12.025,52	15.709,22	27.734,74	-2.751,93

Table 2: Comparison of Personnel Costs with the Calculated Data sets of InEK for the DRGs with the Highest Number of Radiological Service Points in the Krankenhaus der Barmherzigen Brüder Trier

* AD – medical service * MTD – medical technical service Source: Busch H.P. 2010

DRG	OPS	OPS - Text	BKT rel. Share OPS/Case	DRG Browser rel. Share OPS/Browser	Difference BKT/DRG Browser
F59B	3-607	Arteriography of the lower limb vessels	73,23%	57,63%	15,60%
F59B	8-836.0b	Percutaneous transluminal vascular intervention	54,33%	54,21%	0,12%
F59B	3-605	Arteriography of the vessels of the basin	32,28%	45,38%	-13,10%
F59B	8-83b.c3	Additional information to materials: use of a vascular Closure System, Clipsystem	24,41%	0,00%	-
F59B	8-836.09	Percutaneous transluminal vascular intervention: Angioplasty (ballon); other abdominal vessels	22,05%	22,33%	-0,28%
F59B	8-840.06	Percutaneous transluminal implantation of not drug-eluting stents: one stent other abdominal vessels	22,05%	0,00%	-
F59B	8-840.0b	Percutaneous transluminal implantation of not drug-eluting stents: one stent vessels thigh	14,96%	0,00%	-
F59B	8-836.0c	Percutaneous transluminal vascular intervention: Angioplasty (ballon); vessels lower leg	11,81%	11,92%	-0,11%
F59B	3-828	MRI of peripheral vessels with contrast medium	11,81%	3,84%	7,97%

Clinical pathway!

Table 3: From the DRG-Portion to the Analysis of the Clinical Treatment Paths

Source: Busch H.P. 2010

Benchmarking Costs And Services

In order to evaluate the results of productivity external hospitals are used as comparators (external benchmarking). This way, costs for personnel and material may be compared e.g. with the cost data of the DRG calculation, and analysed (Figure 6).

Revenue, the process sequence and the type and number of the procedures used must be compared and reviewed for optimisation needs. The same applies to service data, the comparison of

comparison with other hospitals is shown in Table 2.

Benchmarking against the procedures used on average in the German Institute for the Compensation System in Hospitals (InEK) calculation shows the possible optimisation need of the clinical treatment path.

Further, utilisation management within the scope of external benchmarking against 500 hospitals in Europe (Philips Utilization Services) enables the assessment of the quality of the process workflow based on the criteria of patient flow management, examination flow man-

agement, schedule logistics management, optimisation of the procedures.

Process Optimisation

The optimisation of the organisational structure has a direct impact on the value chain of medical imaging departments. In the DRG context, the entire treatment path in the hospital is compensated, so that a continuous optimisation of processes in the areas of medical quality, service quality and efficiency is necessary to secure revenue. (See Zapp, W./Dorenkamp, A. (2002), page 65). On these three pillars, the centre must be managed according to the rules of a business enterprise.

Diagnosis based fixed compensation (the price is a "Date") requires an optimisation in the areas of effectiveness (i.e. looking at whether the indication and/or the MR examination was necessary) and efficiency (i.e. analysing the way in which the examination was conducted). In this context, productivity (costs per examination) must be used as criterion of success. Further, it is necessary to use resources where they are needed the most according to the rationality principle.

The difference between the revenue determined by the DRG compensation and the costs can be enlarged by the increase of productivity and the avoidance of unnecessary examination numbers. New equipment (e.g. 3-Tesla MRT, flat plate detectors) afford the possibility to increase patient throughput.

The economic success of the MID requires continuous efforts in order to be able to succeed in the areas of medical quality, service quality and efficiency.

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(E)Hospital knows that hospital managers need to keep up to date with the latest innovations and news across all medical specialities to better understand the needs and challenges of each hospital department. For this reason we have been publishing specialist supplements with each issue. Two copies are included: An insert for your own use and a pull out to pass on to a relevant colleague.

This issue the focus is on pharmaceuticals. The supplement introduces us to an increasingly important trend in the pharma sector: biosimilars. Fulvio Braido and colleagues explain exactly what biosimilars are and their role in personalised medicine. Other articles cover pharmacy as a profession and the future role of pharmacists; personalised chemotherapy drug selection; and the EU PROTECT project on pharmacovigilance.



BLOCKBUSTERS, BIOTECHNOLOGICAL DRUGS AND BIOSIMILARS

Present Situation and Perspectives

By F. Braido, F. Balbi, D. Bagnasco, G.W. Canonica

Background

Nowadays, available drugs cannot adequately treat all patients: side effects without clinical improvements or clinical improvement associated with relevant side effects can occur, as well as benefits and adverse events. The expectations for new drugs are, therefore, very high, both from the healthcare system and the public. However, the development process of new drugs requires a huge amount of research. As a matter of fact, out of 5,000-10,000 molecules designed, only 250 reach the pre-clinical phase; among them about 10 are tested in phase I, II and III trials and only one is approved and launched on the market.

This process, due to its costs, is becoming more and more difficult to be maintained by pharmaceutical industry. That is why, in the recent past, a decreasing number of chemical drugs addressed to large consumption and relevant sales (blockbusters), have been placed on the market. In the future, a closer partnership between the pharmaceutical companies and academic research will be necessary to develop a new

business model for "health industry".

Moreover, we are experiencing a shift from "traditional medicine" to "targeted/personalised medicine". This new model will imply the development of molecules tailored on a genetic and phenotypic pattern, increasing the number of potentially treatable patients and maximising the therapeutic efficacy and reducing side effects. Simultaneously, the development of drugs targeted to a broad segment of patients is bound to decrease.

Biotech drugs (cytokines, hormones, clotting factors, monoclonal antibodies, vaccines) represent an essential part of modern pharmacotherapy: a total of 174 biological medicinal products obtained approval between 1995 and 2007 by EMA and FDA, and, at present more than 450 organic products are under development. The percentage of sales from biotechnology products (bio-engineered vaccines and biologics), within the world's top 100 drugs, is set to increase from 11% in 2000 and 31% in 2009 to 48% by 2016. Moreover, taking into account the broader market, sales from biotechnology products are set to gain 23% of the world

pharmaceutical market by 2016, versus its share of 17% in 2009. The estimated market of biosimilars for 2015 is 1 to 3.5 billion dollars depending on the molecule.

For some biologics, patent has already expired (three expired in 2012, while 32 will expire from 2013 to 2015); on the basis of these observations, in next years all treatment areas will be involved in this process, although, some of them, such as respiratory medicine, not immediately. New biologic drugs, in addition to the increasing number of generic chemical drugs, represent the new therapeutic perspective in the future.

Biosimilars

The term "biosimilars" refers to biopharmaceuticals which are manufactured by non originator pharmaceutical companies following expiration of patent period. They are similar in terms of quality, safety and efficacy to an already licensed reference product, whose similarity is defined as 'the absence of a relevant difference in the parameter of interest'. They will be mar-

keted by an independent application, following expiry of patent and regulatory data/market exclusivity periods of the reference product. Creating an identical copy of a biologic drug is nearly impossible; even when the DNA coding sequence is known, the complexity of posttranslational modification (eg. glycosylation and methylation) and of manufacturing processes, makes the replication of the original structure very difficult. As a matter of fact, they are defined “similar” and not “equivalents”, as it happens instead for chemical drugs. “The process is the product”: this characteristic defines biotechnology products.

The development of a biosimilar from a

US the BPCI Act (Biologics Price Competition and Innovation Act), defines an abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” to or “interchangeable” with an FDA-licensed biological product; a biological product may be defined “biosimilar” if data show that the product is “highly similar” to an already-approved biological product. These guidelines focus on common issues raised by sponsors interested in developing proposed biosimilar products, biologics license application (BLA) holders, and other interested parties regarding FDA’s interpretation of the Biologics Price Competition and Innovation Act of 2009. Moreover, these guidances

failed to fulfill their own specification. If for this kind of therapy, with adequate haemoglobin monitoring, a variance in potency may not represent a critical issue, such variability would not be acceptable for monoclonal antibody therapy, treating transplant rejection, etc). Since current analytical techniques and preclinical experimental studies cannot detect or predict all the biological and clinical differences between the biosimilar and the original brand, EMA requires more rigorous clinical trials before approving biosimilars than would typically apply to a small molecule drug. Although lab tests (radio immune precipitation and double antigen bridging ELISA assay) are sensitive for detecting high affinity antibodies, the immunological safety can only be demonstrated in clinical trials and post marketing surveillance.

Great attention should also be paid in drugs storage and handling. Moreover, a strict control on adverse event occurrence, data about drug such as dosage given and brand name, international nonproprietary name (INN) is fundamental. As regards biosimilars, a unique INN should be necessary, in order to facilitate prescribing and dispensing of biopharmaceuticals and the pharmacovigilance process. For each biosimilar deviation from reference product, safety and efficacy data should be known. Implicit in the characteristics of biosimilars should be their interchangeability.

As for the equivalent drugs (generic), biosimilars availability could represent a cost-saving for healthcare providers (over 2 billion USD). For example, the introduction of a biosimilar of erythropoietin in Germany with a significant lower price than reference drug has determined an overall 33% price reduction of the initial price of the drug. As expected by German SHI system analysis, the decrease of drug prices will lead to savings of over one billion USD per year by 2017. We are at the beginning of a revolution in patient care and physician practice.

Asthma

Asthma is a chronic inflammatory disease which presents multiple phenotypes and underlying endotypes. For this reason, the objective of target therapy are the different molecules involved in Th2 pathway (IgE, IL-4R-alfa receptor, IL-13 IL5). Omalizumab (anti IgE), as demonstrated in several randomised trials and meta-analyses, has

The development of a biosimilar from a biopharmaceutical previously registered drug avoids the costly step of drug discovery.

biopharmaceutical previously registered drug avoids the costly step of drug discovery. As a matter of fact the production of a new biotech drug implies a 8-12-year project project with an investment ranging from 500 million to 1 billion dollars, with a probability of success of the overall project around 5%; on the contrary, biosimilar development requires shorter times (7-8 years) with a cost of about 100-150 million dollars and probability of success of around 50%. It is realistic to believe that this process will involve especially large pharma companies or large producers of generics who have sufficient resources, clinical development expertise, distribution network and marketing skills. Small biotech companies and players in emerging markets will be involved in the process, although not alone.

In the last years, several documents concerning both the production and the marketing of biomolecules have been published: EMA guidelines and documents regarding key concepts and principles (CHMP/437/04), clinical (EMA/CHMP/89249/04), non-clinical (EMA/CHMP/BWP/42832/2005) and quality (EMA/CHMP/49348/05) details and expectations of biosimilars. In the

describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the EU, fourteen biosimilars of somatotropin, epoietin-alpha, epoietin-zeta and filgrastin have been approved until 2011. No differences have been detected among these biosimilars and reference products in terms of composition and primary structure, higher order structure conformation, post translational modifications, polarity, charge, isoforms, size, detection of aggregates, binding and biological activity. On the contrary, due to significant biophysical and clinical variation in terms of efficacy, tolerability and side effects, other biosimilars have not been approved (for instance interferon-alpha-2a pegylated thrombopoietin - treatment-associated-thrombocytopenia).

Clear guidelines and tight control are necessary to guarantee efficacy and safety. For instance, Isoform distribution among eleven different epoietin-alpha products from four extra European different countries (Korea, Argentina, China and India) showed important variations of bioactivity in vivo (from 71 to 226%); for this reason, five products



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shown its clinical efficacy and its ability to reduce airways remodelling, while anti IL-5 (Mepolizumab and Reslizumab) showed its efficacy in eosinophilic asthma. The introduction of Lebrikizumab, an anti IL-13 antibody, and the discovery of a biomarker (periostin) related to the action of IL-13 has made it possible to divide patients into responders and nonresponders, according to this biomarker.

Several biotech approaches are currently under investigation in asthma treatment. While new molecules appear on the horizon, old biotech products for asthma treatment (such as Omalizumab) will soon be available as biosimilars. The use of these molecules will result in a reduction of the costs for treatment, while the identification of specific subsets of patients will help the provision of effective therapy, maximizing the effectiveness and minimizing side effects.

Clinical immunology and allergy treatment will therefore change in the next future, since biological allergen immunotherapy products are likely to become biosimilars, and some of these products have already been registered by EMA.

Clear guidelines and tight control are necessary to guarantee efficacy and safety.

Conclusions

A targeted approach is increasingly replacing mass therapy in clinical and pharmaceutical research. In this scenario, new biotech products are appearing while others are gradually approaching patent expiration. This approach will enable the availability of new tailored treatments for well selected patient populations and the reduction of treatment costs. Specific research and updated knowledge for an appropriate and safe use of these products is necessary.

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References available upon request,
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BIOSIMILARS AT A GLANCE

The European Medicines Agency defines similar biological or 'biosimilar' medicine as a biological medicine that is similar to another biological medicine that has already been authorised for use.

Biological medicines are medicines that are made by or derived from a biological source, such as a bacterium or yeast. They can consist of relatively small molecules such as human insulin or erythropoietin, or complex molecules such as monoclonal antibodies.

Biosimilars can only be authorised for use once the period of data exclusivity on the original 'reference' biological medicine has expired. In general, this means that the biological reference medicine must have been authorised for at least

10 years before a similar biological medicine can be made available by another company.

Role of the European Medicines Agency

The Agency is responsible for assessing applications from companies to market biological medicines for use in the European Union (EU), including biosimilar medicines.

Requirements for authorisation of biosimilar medicines

For biosimilar medicines, the company must show that their medicine:

- Is similar to the reference medicine;

- does not have any meaningful differences from the reference medicine in terms of quality, safety or efficacy. This information should come from studies carried out by the company itself.

The authorisation for biosimilar drugs can often be quicker than the authorization of original biological medicine. This is due to the fact that information on the safety and efficacy of the reference medicine is already available. Once authorized and on the market the EMA monitors the safety of biosimilars like all other medicines.

For a list of the current approved biosimilars on the market or more information on the topic please visit the EMA website: **www.ema.europa.eu**

EUROPEAN HOSPITAL AND COMMUNITY PHARMACISTS ISSUE **JOINT STATEMENT** ON **FUTURE PHARMACIST ROLES**

The two organisations representing community and hospital pharmacists in Europe have come together to make a declaration on the development of the pharmacy profession.

The joint statement by the Pharmaceutical Group of the European Union (PGEU) and the European Association of Hospital Pharmacists (EAHP) is entitled “The Role of the Pharmacist in Optimising Patient use of Medication” and represents a call to action to national governments to, firstly, enable pharmacists to increase their role in optimising patient use of medicines, and, secondly, to improve the systems supporting multi-professional care across Europe.

EAHP and PGEU believe that pharmacists, as experts in medicines, should be at the heart of national strategies to ensure best outcomes for patients. This includes pharmacists educating patients about the optimal use of their medicines, and helping to ensure that potential polypharmacy problems, which can arise when a patient takes multiple medications, are satisfactorily resolved and reconciled.

The development of these roles for pharmacists is especially relevant in view of Europe’s ageing population, combined with the pressures on public spending that are likely for the foreseeable future. In this sense, it has never been more important to ensure national spending on medicines achieves intended outcomes in a cost-effective manner.

Pharmacists, in both community and hospital settings, are uniquely placed to facilitate this, so long as health policy makers recognise the opportunity and make the necessary commitments to its achievement.

Finally, the joint statement also highlights the need for multi-professional approaches to healthcare delivery to ensure integrated and seamless patient care. This includes improving systems for communication between health sectors when a patient transfers between hospital

and community (and vice-versa), especially in relation to situations where changes are made to a patient’s medication.

The two organisations believe that the main barriers preventing closer cooperation between settings and disciplines in the health sector are:

- Insufficient commitment to the goal of multi-professional care from health service management and national/regional policy makers which often leaves patient needs unmet;
- Lack of existing interventions that support and promote professional trust and collaboration between different professionals involved in patient care;
- Difficulties in the transfer and collection of relevant information (e.g. access to patient medical records); and
- Lack of practice precedent or individual professional experience of multi-professional team working, which creates unnecessary tension between professionals.

Speaking on the publication of the statement, Dr. Roberto Frontini, EAHP President said:

“The joint statement by EAHP and PGEU represents our shared goals in maximising the benefits the health service derives from pharmacists’ expertise in medicines. More than ever before decision makers in the health sector must ask and answer important questions about improving value and the outcomes achieved for patients. The pharmacist’s positive role in ensuring optimal use of medicines by patients is therefore a central consideration to successfully meeting the challenges of today and tomorrow.”

Ms Isabelle Adenot, PGEU President said:

“While patients receive primary care as well as hospital-based care, European pharmacists practise in both settings and share the challenge of improving the rational use of medicines. Having a common roadmap can help them to progress. This is the purpose of our joint statement.”

EAHP and PGEU believe that pharmacists, as experts in medicines, should be at the heart of national strategies to ensure best outcomes for patients.

PGEU and EAHP call for commitment from Governments to achieving multi-professional care, and for the integration of the multi-professional team concept within health professional education curriculums.

For more information on the statement and the organisations, please visit: www.eahp.eu, www.pgeu.eu



24th EAHM Congress
24^e Congrès de l'AEDH
24. Kongress EVKD
LUXEMBOURG 2013 

HOSPITAL MANAGEMENT IN TIMES OF CRISIS CONSTRAINTS, CHALLENGES AND OPPORTUNITIES

28 - 30 NOVEMBER 2013
LUXEMBOURG



OVERVIEW

Luxembourg2013 is the forum in which more than 600 CEOs, Hospital managers from all over Europe will share their experiences and best practices in healthcare management. Take advantage of this opportunity to position yourself among the key decision makers from European hospitals.

This year, the congress will focus on how to deal with economic constraints and transform them into opportunities. Many people strongly believe that funding is the crucial factor to the effectiveness. When the economy is weakened and the hospital budget reduced, what can a hospital manager undertake to continue to deliver better care? This is what the congress will try to address.

CONFERENCE

Sessions will focus on practical means to preserve or enhance quality of care even in the face of static budgets.

Roundtables will give the opportunity to share best practice and discuss their added-value.

Posters sessions will be dedicated to **Improvement of patient outcomes with static budget**. The best posters will be rewarded and published on the congress website.

HOSPITAL VISITS

Healthcare developments in Luxembourg will also be addressed. You will have the opportunity to visit hospital and discuss with professional the innovations set.

EXHIBITORS

At the exhibition, healthcare professionals will provide in-depth insight into the latest developments in healthcare.

UNIQUE NETWORKING OPPORTUNITY IN THE HEALTH SECTOR

The congress will offer networking opportunities with key decision makers from the major hospitals in Europe, the healthcare industry representatives in an informal, effective business setting.

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SITE UNDER CONSTRUCTION

PRELIMINARY PROGRAMME

WEDNESDAY, 27 NOVEMBER 2013

PRE-CONGRESS PROGRAMME

- Hospitals visits
- Presidential dinner for sponsors

THURSDAY, 28 NOVEMBER 2013

OPENING CEREMONY

The official speakers and the keynote speaker
"Patient Value in Hospital Management"
(10.00 - 12.30)

GOLDEN HELIX AWARD

(13.30 - 14.00)

STRATEGIC GUIDELINES IN CRISIS

(MERGERS, JOINT VENTURES, OUTSOURCING,
HUMAN RESOURCE MANAGEMENT, FINANCIAL
RESOURCES)

- Two 30-minute lectures (14.00 - 15.00)
- Poster Session - presentation (15.00 - 15.30)
- Break (15.30 - 16.00)
- Two 30-minute lectures (16.00 - 17.00)
- 45-minute roundtable (17.00 - 17.45)

RECEPTION HOSTED BY THE CITY OF LUXEMBOURG

(Evening)

FRIDAY, 29 NOVEMBER 2013

BUSINESS PROCESS RE-ENGINEERING

(LEAN MANAGEMENT, PURCHASING, USE OF IT)

- Two 30-minute lectures (09.00 - 10.00)
- Break (10.00 - 10.30)
- Two 30-minute lectures (10.30 - 11.30)
- 45-minute roundtable (11.30 - 12.15)

NEW BUILDINGS, NEW LOGISTICS, NEW TECHNOLOGIES

- Two 30-minute lectures (14.00 - 15.00)
- Poster Session: awards ceremony (15.00 - 15.15)
- Break (15.15 - 15.45)
- Two 30-minute lectures (15.45 - 16.45)
- 45-minute roundtable (16.45 - 17.30)

GALA DINNER AT CASINO 2000, Mondorf-les-Bains (L)

(Evening)



INFORMATION

VENUE

The Congress will be held in Luxembourg business centre, at the prestigious Conference Centre (Luxembourg/Kirchberg). The building is located 5 min from downtown Luxembourg and is well connected by public transport.

OFFICIAL LANGUAGES

The official congress languages will be English/German/French. All presentations will be in one of these three languages.

SIMULTANEOUS INTERPRETING

All presentations will be simultaneously interpreted into English/German/French.

REGISTRATION

Online registration for attendees and accompanying persons will begin on 1 March 2013 via the congress website:

www.eahm-luxembourg2013.lu

ACCOMMODATION

Participants can book their hotel rooms online from 1 March 2013, plan your trip with a few clics:

www.eahm-luxembourg2013.lu



HOPKINS SCIENTISTS CREATE METHOD TO PERSONALISE CHEMOTHERAPY DRUG SELECTION

In laboratory studies, scientists at the Johns Hopkins Kimmel Cancer Center have developed a way to personalise chemotherapy drug selection for cancer patients by using cell lines created from their own tumours. If the technique is successful in further studies, it could replace current laboratory tests to optimise drug selection that have proven technically challenging, of limited use, and slow, the researchers say.

The Problem

Oncologists typically choose anticancer drugs based on the affected organs' location and/or the appearance and activity of cancer cells when viewed under a microscope. Some companies offer commercial tests on surgically removed tumours using a small number of anticancer drugs. But Anirban Maitra, MBBS, professor of pathology and oncology at the Johns Hopkins University School of Medicine, says the tissue samples used in such tests may have been injured by anaesthetic drugs or shipping to a lab, compromising test results.

By contrast, he says "our cell lines better and more accurately represent the tumours, and can be tested against any drug library in the world to see if the cancer is responsive."

The Solution

The Johns Hopkins scientists developed their test-worthy cell lines by injecting human pancreatic and ovarian tumour cells into mice genetically engineered to favour tumour growth. Once tumours grew to one centimetre in diameter in the mice, the scientists transferred the tumours to culture flasks for additional studies and tests with anticancer drugs.

In one experiment, they successfully pinpointed the two anticancer drugs from

among more than 3,000 that were the most effective in killing cells in one of the pancreatic cancer cell lines. A report on the success was published online January 22nd 2013 in the journal *Clinical Cancer Research*.

The new method was designed to overcome one of the central problems of growing human tumour cell lines in a laboratory dish; namely the tendency of noncancerous cells in a tumour to overgrow cancerous ones, says James Eshleman, M.D., Ph.D., professor of pathology and oncology and associate director of the Molecular Diagnostics Laboratory at Johns Hopkins. As a consequence, it has not been possible to conventionally grow cell lines for some cancers. Still other cell lines, Eshleman says, don't reflect the full spectrum of disease.

To solve the problem of overcrowding by noncancerous cells, Maitra and Eshleman bred genetically engineered mice that replace the noncancerous cells with mouse cells that can be destroyed by chemicals, leaving pure human tumour cells for study.

"Our technique allows us to produce cell lines where they don't now exist, where more lines are needed, or where there is a particularly rare or biologically distinctive patient we want to study," says Eshleman.

Research

In its proof of concept research, the Johns Hopkins team created three pancreatic ductal adenocarcinoma cell lines and one ovarian cancer cell line. They then tested one of the pancreatic cancer cell lines (called Panc502) against the Johns Hopkins Drug Library of 3,131 drugs, identifying tumour cells most responsive to the anticancer drugs digitoxin and nogalamycin.

For 30 days, they watched the effects in living mice of the two drugs and a control medicine on tumours grown from implanted cells derived from Panc502 and an additional pancreatic cell line, Panc410. They measured the size of tumours twice a week. Both drugs demonstrated more activity in reducing the tumour appearance and size in Panc502 than in Panc410, supporting the notion that the cell line technology may better predict sensitivity to the two drugs.

The investigators have given one type of their genetically engineered mice to The Jackson Laboratory in Bar Harbor, ME, a mouse genetics research facility, for breeding and distribution to other laboratories and are looking to partner with a company to distribute two other types.

Study co-authors were Hirohiko Kamiyama, Sherri Rauenzahn, Joong Sup Shim, Collins A. Karikari, Georg Feldmann, Li Hua, Mihoko Kamiyama, F. William Schuler, Ming-Tseh Lin, Robert M. Beaty, Balasubramanyam Karanam, Hong Liang, Michael E. Mullendore, Guanglan Mo, Manuel Hidalgo, Elizabeth Jaffee, Ralph H. Hruban, Richard B. S. Roden, Antonio Jimeno, and Jun O. Liu, of Hopkins; and H. A. Jinnah of Emory University School of Medicine in Atlanta.

The work was supported by the National Institutes of Health, National Cancer Institute (CA130938, CA62924 and CA122581), the Sol Goldman Pancreatic Cancer Research Center, the Stewart Trust Fund, the Lustgarten Foundation, the Mary Lou Wootton Pancreatic Cancer Research Fund, the Michael Rolfe Pancreatic Cancer Foundation and the HERA Foundation.

For more information, please visit: www.hopkinsmedicine.org

PHARMACOVIGILANCE

EU PROTECT Project Achieves Key Objectives

The PROTECT project, a public-private partnership for innovative methodologies in pharmacovigilance and pharmacoepidemiology coordinated by the European Medicines Agency, has reached a crucial stage with the delivery of two databases which will offer access to important data resources for pharmacovigilance activities and pharmacoepidemiological studies.

The PROTECT Project

The goal of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe. The project is developing a set of innovative tools and methods that will enhance the early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefits and risks. These methods will be tested in real-life situations in order to provide all stakeholders (patients, prescribers, public health authorities, regulators and pharmaceutical companies) with accurate and useful information supporting risk management and continuous benefit-risk assessment.

The overall objective of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe. In order to achieve this overall goal, PROTECT has been designed as a comprehensive and integrated project aiming to develop and validate a set of innovative tools and methods that will:

- Enhance data collection directly from consumers of medicines in their natural language in several European Union countries, using modern tools of communication;
- Improve early and proactive signal detection from spontaneous reports, electronic health records and clinical trials;
- Develop, test and disseminate methodological standards for the design, conduct and analysis of pharmacoepidemiological studies applicable to different safety issues and using different data sources;
- Develop methods for continuous benefit-risk monitoring of medicines, by integrating data on benefits and risks from clinical trials, observational studies and spontaneous reports, including both the underpinning modelling and the

presentation of the results, with a particular emphasis on graphical methods; and

- Test and validate various methods developed in PROTECT using a large variety of different sources in the European Union (e.g. clinical registries) in order to identify and help resolve operational difficulties linked to multi-site investigations.

A methodological framework for pharmacoepidemiological studies will be developed and tested to enable data mining, signal detection and evaluation in various types of datasets, including data of spontaneous reports, registries and other electronic databases. Means of combining results from clinical trials, spontaneous reporting and observational data will be developed, comparing Bayesian modelling, multi-criteria decision analysis and other analytical methods. Methods for graphical expression of benefit-risk will be tested with different stakeholders.

Collection of data directly from patients is essential in many situations. PROTECT will trial direct patient data collection in natural languages using web-based, telephone and text messaging systems. It will test the transferability of the data into a common language and explore linkages to data from electronic health records and registries.

Using methods developed in the project, validation studies performed with additional data resources available in the European Union will help create the foundation for multi-site investigations. Development will continue beyond the initial Innovative Medicines Initiative (IMI) funding, with training given and results disseminated using the EMEA-led European Network of Centres for Pharmacovigilance and Pharmacoepidemiology and relevant publications.

PROTECT consists of 33 public and private partners coordinated by the European Med-

icines Agency. It is managed by a Coordinator and Deputy Coordinator with extensive experience in pharmacovigilance, aided by a strong governance structure, including a Steering Committee, an experienced project management team and a distinguished international External Advisory Board.

Two Databases Delivered

The project has reached a crucial stage with the delivery of two databases, which will offer access to important data resources for pharmacovigilance activities and pharmacoepidemiological studies.

The first of these two databases, the Drug Consumption Database, is a comprehensive and structured source of information on drug consumption in Europe. It is the result of reviewing, compiling and updating knowledge about European sources of data on drug utilisation in the out- and in-patient healthcare settings. Information is currently available for 17 EU countries (Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, Norway, Poland, Portugal, Spain, Sweden, The Netherlands, and The United Kingdom) up to October 2012. Work is in progress to expand data available.

The second database, the PROTECT ADR database, is a listing of all adverse drug reactions (ADR) contained in section 4.8 of the summary of product characteristics (SmPC) of medicinal products centrally authorised in the EU. It is based on the Medical Dictionary for Regulatory Activities (MedDRA) terminology. The goal of this database is to improve the efficiency of the detection process of ADRs by allowing quick identification and filtering or flagging of listed and unlisted ADR. This database is updated every 6 months and currently contains information up to 30 June 2012.

For further information, please visit: www.imi-protect.eu

BOOKS IN REVIEW

The safe handling of hazardous drugs is a key aspect of hospital pharmacy and something we have covered before in previous *(E)Hospital* pharma supplements. There are many publications out there to help educate staff and managers to the hazardous and the proper safety procedures.

Safe Handling of Hazardous Drugs

Martha Polovich, Oncology Nursing Society; 2nd edition, 2011



The newly updated and revised second edition helps translate safe handling recommendations that nurses can use in their daily practice. Contents include topics such as identifying the adverse effects of hazardous drug exposure, defining evidence for occupational hazardous drugs exposure, and safety measures that readers can take into the workplace. Nurses can use this new edition as a means to examine their own workplace and how their institution's policies and procedures might be better improved to limit the amount of hazardous drug exposure, thereby lessening the risks to nurses while at work.

Safety and Health Handbook for Cytotoxic Drugs

Samuel J. Murff, Government Institutes, 2012



Many healthcare workers must deal on a daily basis with the transportation, preparation, storage, clean up, and disposal of cytotoxic drugs, which are used in chemotherapy because of their harmful effect on cancer cells. These drugs also have harmful effects on good cells, and they therefore pose a significant health risk to those who work with them. Yet there is little safety and health information available about them, and what information is available is scattered across a vast array of literature. The Safety and Health Handbook for Cytotoxic Drugs collects this information so that healthcare workers can better understand the drugs they work with and the safety and health procedures that should be followed. In it, author Samuel J. Murff presents comprehensive technical and procedural information on 106 of the most common cytotoxic drugs. The book provides guidance on quickly dealing with spills, reducing unnecessary exposure, and complying with pertinent regulations and standards in order to better equip healthcare workers to maintain a safe work environment.



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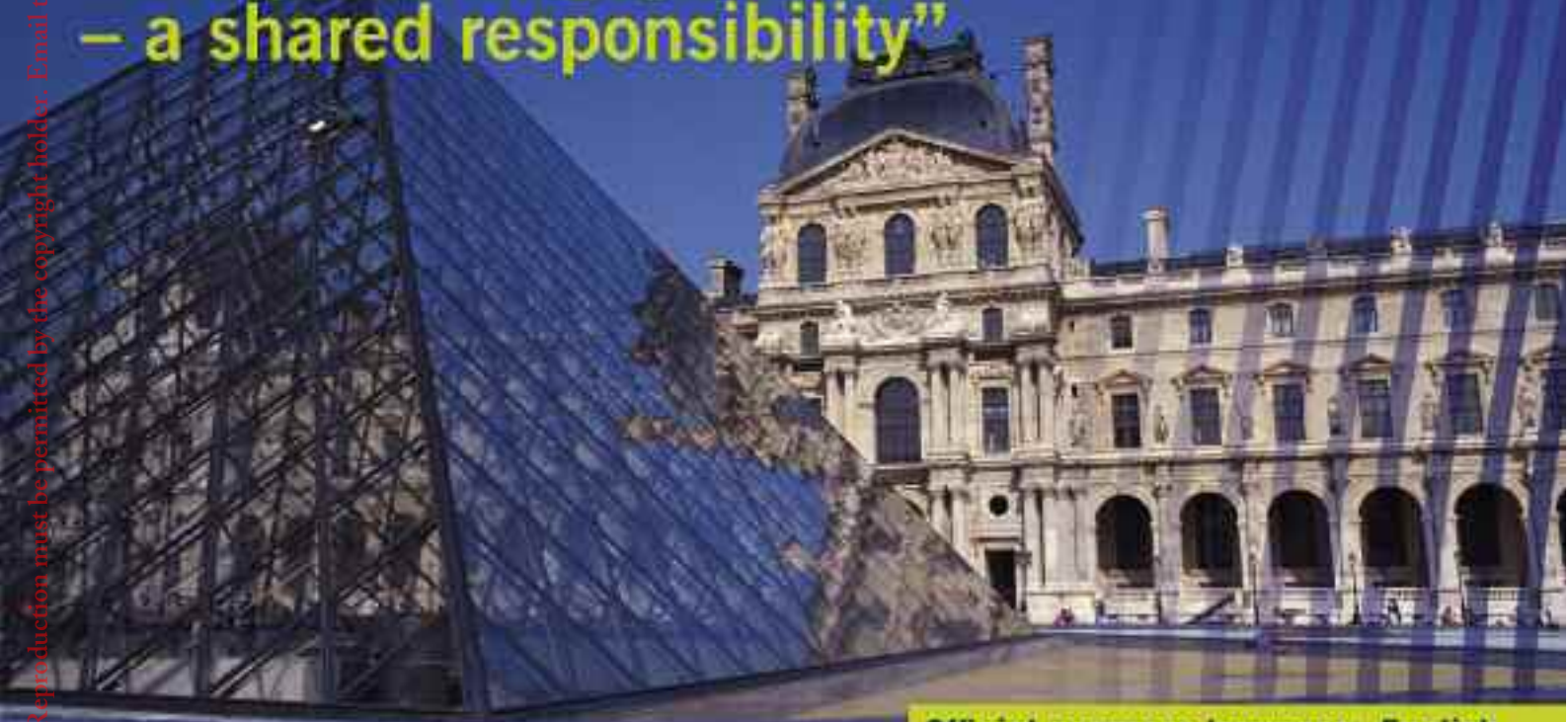
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DATA PRIVACY IN A WIDER PERSPECTIVE OF RISK MANAGEMENT

Data privacy awareness has increased significantly within the health sector over the last few years; this is mainly due to EU and national legislation. Another reason is the adoption of new technologies, such as the electronic patient file and electronic prescriptions. However, data privacy is not limited to Information Technology (IT); the physical protection of paper files, CD ROMs, USB sticks, etc. should be taken into account when tackling data privacy.

Data privacy should be seen in a wider perspective of risk management and governance. Due to recent events (e.g. the financial crisis), governance and risk management are hot topics for media coverage, especially within the financial sector. However these topics are also high on the agenda in the boardrooms of private companies in the corporate world, due to earlier scandals like Enron and Worldcom. Risk management is still in its infancy in healthcare, even though risks are probably highest, involving human life.

Responsibilities Regarding Risk Management

Regardless of the type of organisation, it is the responsibility of management to manage all risks of the organisation. This is also the case in healthcare and non-profit organisations. Besides, it is not only the responsibility of management to manage risk; it is also the responsibility of the board of directors to supervise whether risks are adequately managed within the organisation.

Worse: If risks are not adequately managed and events (accidents) occur, the directors can be held (legally) liable for this. This is not just theory, but happens in practice. Members of the board of directors often do not realise they are the final responsible and might be held liable in case of serious events. This is also apparent in healthcare, where directors are often appointed in an informal way and risks relate to human life.

Many risks, especially in healthcare, cannot be reduced to zero. Even when precautions are taken events could still occur. Precautions reduce the probability or the impact of a risk, however risks are often not completely eliminated. Therefore it is important, in case of such an event, to be able to prove that measures were taken to manage the risk and that the management has reflected and taken conscious decisions to man-

age the risk. Then, if it happens at least the management took all possible measures and cannot be accused of negligent omission.

Which Risks Should be Managed?

All risks of the organisation should be managed. There is a wide variety of risks, the most common categories are:

- Medical and patient safety risk;
- Operational risk;
- Legal & compliance risk;
- Financial risk; and
- IT risk.

Risks relate to all activities of the organisation, both at the care and at the administrative side. Within the above risk categories, there are many distinct risks that should be managed. For all important risks, control measures should be taken to prevent them from occurring and very often, IT plays an important role in this.

What Does it Mean to Manage Risks?

Proper risk management implies that:

- All important risks within the organisation are known and assessed, this is typically done in a risk assessment exercise;
- Based on the risk assessment, conscious decisions are taken to address the risks (or not!);
- Based on these decisions, appropriate actions are taken and measures are implemented to address the risks.

A risk assessment is typically performed with the aid of external consultants, preferably with experience in healthcare. The main reason for this is that many of the risks are generic and also present in similar organisations. A good consultant has a sector-specific risk model to conduct the risk assessment. The risk assessment is typically

performed in two phases:

1. Identification of all risks: This is typically done in workshops with management starting from the generic risk model;
2. Evaluation of all identified risks: There are several methodologies to evaluate risk; in practice both the probability and impact of the risk occurrence (the event) are evaluated.

The risk assessment exercise will provide you with an inventory of all risks and their evaluation. Of course, the highest risks will be addressed first.

In a next stage, decisions are taken on how to address the risks, based on their importance and possible measures. Basically, risks can be addressed in the following ways:

- Reduce the risk by implementing control measures;
- Delegate the risk, in practice this is most often done via insurance;
- Avoid the risk, for example by ending the related activities; and
- Accept the risk and take no action.

Indeed, the decision might be not to take any action. This might be because the risk is low and the cost is high. Most important is that these are conscious decisions, by management or even the board.

The decisions should also be documented, known and supported by all relevant people. Because, if 'an accident' happens, we want to avoid 'finger-pointing' and 'I thought you were taking care of this'. Based on the decisions made, an action plan is defined, which takes into account the priorities defined in the risk assessment.

What About IT Risks?

IT often plays an important role in management of many risks, especially operational and financial risks. On the other hand, there are also the specific IT risks.

These are typically categorised with the acronym CIA:

- Confidentiality of information;
- Integrity of information; and
- Availability of information and systems.

Confidentiality of information is much related to data privacy. A commonly used definition of the confidentiality principle is: 'Only authorised people should have access to (view) confidential information'. Confidentiality risks are related to the abuse of the information. Typical control measures are related to the secure protection of confidential information.

“it is important to find the equilibrium between operational efficiency and security”

Integrity of information is related to the correctness of the information. A common definition of the integrity principle is: "Only authorised people should have access to change information." Integrity risks are related to unauthorised changes to information. In healthcare these changes might ultimately lead to inappropriate medical decisions and actions, such as wrong medication. Therefore, integrity of information is probably even more important than confidentiality of information (data privacy) from a risk point of view. Fortunately, typical control measures are similar and also related to the secure protection of information.

A lot of information has been digitalised over the last years, and a lot of activities have been automated. New technologies have been adopted, such as the electronic patient file and electronic prescriptions. As a consequence, dependency on IT systems has increased tremendously in the last few years, hence the importance of systems availability. Needless to say, what the impact of unavailability of critical systems might be, fortunately also non-IT management easi-

ly relates to this, which facilitates decisions on investments to increase systems availability. Examples are systems redundancy, virtualisation of CPU and storage, Disaster Recovery Plans (DRP), etc.

Information Security: Burden or Need?

In many organisations during the last year the focus has been on systems availability and infrastructure. Less effort has been made on confidentiality and integrity of information. An important reason for this is that information security is not a popular subject and often associated with passwords. End-users do not always see the benefits of this, especially not in highly operational environments, such as hospitals.

Therefore, it is important to find the equilibrium between operational efficiency and security. Identification via badges or biometrics (eg. finger prints) are examples of efficient and secure solutions.

Awareness creation on information security is not easy, the message should be: Not only, an unauthorised person would gain access to confidential information (infracting data privacy laws); not only, an unauthorised person would be able to modify critical information; but most important: people would believe it was YOU! Indeed, all actions performed on IT systems are logged nowadays. In case of malicious events, these logs are investigated and the events will be linked to you personally.

And, as earlier discussed, questions will probably also be raised towards management and the directors whether all precautions have been taken to prevent this from happening; and whether sufficient efforts were made towards information security.

An Action Plan Towards Information Security

We have seen that information security is an important element of risk management. Therefore it should be no surprise that the approach to address information security is similar to the approach on risk management.

In a first phase, a risk assessment is performed consisting of:

- Identification of critical information from confidentiality and integrity point of view, starting from an inventory of all systems and information;

- Evaluation of the identified critical information: The degree of criticality is determined based on the potential impact of confidentiality or integrity breach of the information.

Please note that the aspect of availability can easily be included in this exercise. It should also be noted that in similar organisations, critical information is also similar.

In a next phase, an inventory is made of the information security measures already in place to protect the critical information. These measures include security procedures, access controls, passwords, security settings, access rights, etc.

Based on the criticality and security measures in place, it is determined whether additional measures should be taken. What is sufficient? This is a difficult and subjective discussion. Most organisations refer to information security standards; the most common is the ISO27001 standard. However, this standard consists of 130 security controls to be put in place to comply with the standard. This is not feasible for most organisations.

So even when using standards, subjective decisions need to be taken on what is acceptable and not. These decisions should not be taken by the IT manager alone, other members of the management team and often even the Board should be involved.

Conclusion

Data privacy should be seen in a wider context of information security and risk management. Perfect security protection does not exist; risks can never be completely eliminated. Even in 'Mission Impossible', security was insufficient to keep the hero out of the computer...

The most important thing is that conscious decisions are taken, based on analysis and that these are formally documented and appropriate actions are taken. So that finally, liabilities are limited in case of events and no one should say "Ich habe es nicht gewusst." ("I didn't know about it").

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NEW WAYS OF OPTIMISING IMAGING SERVICES

The Golden Rules of Cost Management

By Bernd May

Both managers in the medical imaging department (MID), as well as hospital managers, are seeking new ways to provide an optimised service within a climate of shrinking healthcare budgets, competition from private imaging centres, and increased demand for evidence-based medical provision. In this article, I will outline four key ways in which the MID can attain these goals, and demonstrate through a comparison of the performance, cost-effectiveness and management of several types of medical imaging facilities, that there is much work to be done to remain competitive. The following are key factors for optimised cost management:

- Select appropriate exams to reduce length of hospital stays;
- Recognise that labour is one of the key cost drivers in the department;
- Hospital managers must realise the impact of the high costs of running and maintaining equipment; and
- All types of medical imaging facilities would benefit by considering a public-private co-operation for provision of imaging services.

Selecting Appropriate Exams

Financial management in the MID in a diagnosis related group (DRG)-driven hospital can be assessed by looking at both revenue and cost. Revenues are generated, for example, from diagnostic services provided to outpatients as well as from treatments provided in interventional radiology, based on specific DRGs. Costs are strongly tied to the diagnostic function and effectiveness of an MID. However, as there are no specific DRGs allocated for diagnostic service provision in our present system, costs are being charged to the referring departments according to the amount and structure of utilisation (fee-per-service, e.g. an ultrasound ~ 60-70 euros, conventional x-ray ~ 50-60 euros, CT ~ 100-160 euros, MRI ~ 200-400 euros, depending on the specifications of modality, average daily load and staffing).

In an ideal world, the diagnostician would stream the patient's pathway, as follows:

1. Respond to the requirement of any referring department on demand;
2. Verify the indication for referral by trained diagnosticians;
3. Control the diagnostic pathway in the MID using trained radiologists;
4. Employ an imaging procedure that delivers adequate sensitivity and specificity;
5. Avoid any diagnostic sequences with various modalities (same or different); and
6. Make findings available in the referring department the same day (≤ 3 hours after exam).

These criteria are all about optimising the financial and budget management issues of any MID. However, these are merely ideals. In the real world, there are two major financial issues to be defined: the total running costs of diagnostic service and the outcome of inpatient care per DRG. Nevertheless, we can clearly see that the provision of inpatient care has a significant overall financial impact on medical imaging.

Reducing Length Of Stay By

$$\text{DRG-turnover} = \frac{365}{\text{mean stay}} \times \text{number of beds} \times \text{average reimbursement per patient} \times U$$

U: degree of bed utilisation

Equation 1: Calculating DRG Turnover

$$\frac{1}{\text{mean stay} - \frac{1}{2} \times 1.5} > \frac{1}{7 - \frac{1}{2} \times 1.4} = \frac{1}{2} \times \frac{1}{1 - \frac{1}{10}} = \frac{1}{2} \times (1 + \frac{1}{10} + \dots) \approx \frac{1}{2} \times$$

Equation 2: Optimised Resources

Streamlining Exam Selection

Our analysis shows that the total costs of the medical imaging department range from about 4–7 percent (on average 5 percent) of overall DRG turnover in the hospital. The cost saving potential amounts to about 20 percent of total cost of the MID, i.e. about one percent of DRG turnover of the hospital. We examined data from our radiology information system (RIS) to estimate the financial impact of inpatient imaging services, and found that on average, between 50 and 90

percent (with a mean of 75 percent) of all inpatients receive medical imaging services during their hospital stay, of which about two thirds are referred for multiple diagnostic services either with the same or a different modality, i.e. 50 percent of all inpatients are being diagnosed by means of at least two modalities resulting in at least 1.5 days of an extension of their stay in hospital. To estimate the cost impact of these multiple imaging exams, we must take a look into the relationship between DRG turnover, mean stay, number of beds per hospital and average reimbursement per inpatient (Equation 1): The most significant factor we should look at to drive down costs is the mean stay, which is about seven days per inpatient. We can reduce costs by ensuring that the first diagnostic exam prescribed is the optimal one, avoiding a spiral into further tests which prolongs hospital stays and wastes resources. This could potentially reduce the mean stay by 1.5 days for 50 percent of all inpatients, which can be shown by

altering the equation (Equation 2).

This formula proves that the abovementioned outcome of better referrals and wiser exam choices, avoids a diagnostic domino effect and can optimise the total turnover of the hospital by 10 percent. This strategy of avoiding unnecessary exams for all inpatients in the hospital, most of whom will require some sort of diagnostic imaging exam at some point in their stay, clearly supports a quality foundation for the management of medical imaging services.

Do Oncologic And Trauma Patients

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Really Need Multiple Exams?

One argument presented by the directors of medical imaging to the above cost management method is their belief that the majority of inpatients suffer from either oncological or trauma-related diseases, which require multiple diagnostic exams before and after treatment. From the analysis of RIS data from many large- and medium-sized hospitals as well as university clinics, we have been seeing a different result, as oncological and trauma patients in particular are experiencing highly redundant diagnostic exam pathways of the same organ with different modalities, which easily can be reduced by at least a factor of two if proper case management is applied.

We concede that the analysis of clinical and diagnostic pathways and the discussion of the results with clinicians and diagnosticians will always be a challenging task to fulfill, but it is worth doing, since it is beneficial for the quality of service for patients as well as the performance and revenue of the hospital.

Hospital Managers and Imaging Costs

The majority of hospital managers concentrate their efforts on controlling the direct costs of the MID, which only has a maximum financial impact of up to one percent of DRG turnover. About 80 percent of the total running costs of any MID consist of both labour costs, accounting for up to 60 percent, with costs of equipment (depreciation and interest of financing modalities, running costs for customer service, etc.) accounting for the remaining 20 percent. Hospital managers would be better placed if they would

turn their attention to labour and equipment financing and maintenance as significant cost drivers for medical imaging.

To get to an estimate of the cost saving potential of focusing on labour costs, we recommend using a benchmarking tool. The primary benchmark is the productivity of medical staff (radiologists and technicians, see Figure 1). The overall costs of labour are divided into about 75 percent going towards medical staff cost and the remaining 25 percent being allocated to administrative staff (in a DRG environment, the cost of medical staff accounts for 90 percent of costs for CT and MRI, about 33 percent of costs for conventional x-ray and approximately 25 percent for ultrasound).

The productivity graph allows you to discriminate the productivity of the MID between four groups of hospital:

- University clinics (UC);
- Large acute hospitals (LAH);
- Medium acute hospitals (MAH); and
- MAHs that work with a private imaging practice (P). These tend to be the best financial performers of each of the four in this group, followed by MAH, LAH and finally the university clinics.

University clinics, being burdened by the heavy costs of teaching, educating and training young academics, have traditionally meant reduced productivity and increased labour costs. However, one way in which university clinics are addressing this sluggish performance is by separating research as an entity from the management of inpatient care, which means that the productivity of physicians can be increased (see

U2 on the productivity graph). From the productivity graph you can easily see one important result at first glance, which is that the ratio of maximum and minimum productivity of radiologists is about 2.5 whereas the same ratio of technicians is about 1.4. The radiologists in the private imaging practices (marked, P in the graph) are the best performers in terms of productivity.

For the group labelled L2, large acute hospitals, the productivity is accounted for as CT technicians were receiving an incentive for increasing their productivity (in this case, a very high case load of 12,000 patients between 8.00 a.m. and 5.00 p.m. on one CT). The performance of the technicians in the medium acute hospital (here, labelled, M) was the result of a low number of MRIs being performed in favour of a high percentage of conventional x-rays (a case cycle for MRI of about 30 to 40 minutes and for conventional x-ray of about 10 minutes).

Modalities That Require High Staff Numbers Drive Costs

Managing an imaging department in the face of financial restrictions requires looking into those exams which require a higher number of medical staff (see Figure 2). Interestingly, in our graphs you can see that a large acute hospital (L1) is on the same level as two high-end university clinics (U3, U5), whereas the productivity of the L1 staff is better than all of the university clinics. This indicates a dedicated workflow management process is the key factor for success. Interventional radiology and particularly MRI are fast-growing areas within MID, requiring more medical staff than conventional x-ray.

Another important indicator for medical staff is the correlation with complexity of diagnostic effort, measured by the average number of investigations per patient and the number of readings per investigation, the first one correlating with the number of times a patient is visiting a modality (technician), the second one with the number of organs per investigation to be analysed and read by a diagnostician (see Figure 3). If the management of the MID adheres to the quality criteria 2, 3 and 4 in the early part of this paper, the complexity of diagnostic efforts will be significantly reduced, consequently impacting labour cost. Budgeting for labour costs need not necessarily mean neglecting the quality of services provided, it simply means that a logical approach to stream-

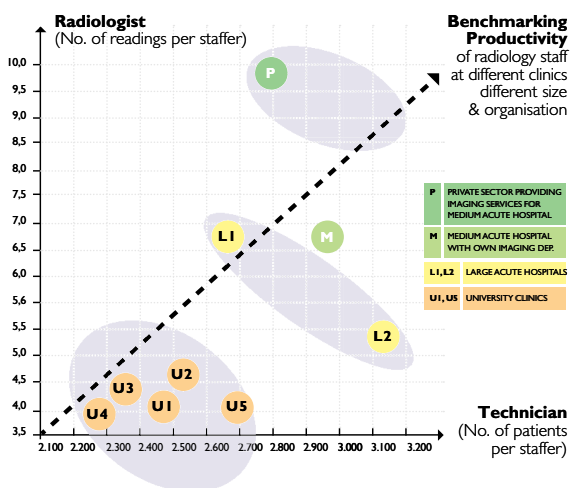


Figure 1: Productivity Graph Comparing Different Types of Medical Imaging Department

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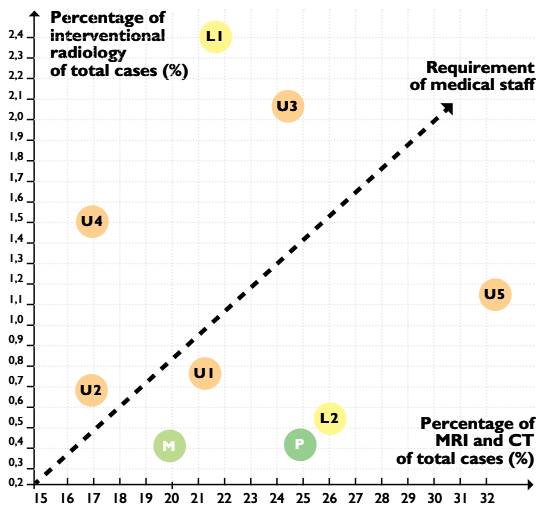


Figure 2: Medical Staff Requirement Correlation with Exam Type

lining treatment pathways and making sensible, evidence-based choices of imaging exams will tie in with an overall approach to cost management.

Another way of benchmarking cost issues is to take account of innovations of modalities which are improving specific productivity, and finally proper IT to support an efficient workflow (RIS/PACS, networked with HIS) and overall approach to cost management.

Consider a Public-Private Cooperation

We briefly discuss the issue of gaining additional revenues with MID from serving outpatients. The most rewarding and self-sustaining approach is being represented by the group labelled P (Figure 1), in which a private practice cooperates with a hospital to provide imaging and interventional radiol-

ogy services to its inpatients. To consolidate such a cooperation financially, organisationally and economically, it is recommended to set up a legal body shared by both parties. This approach is applicable to all types of imaging facilities, even large acute hospitals and university clinics. The organisation of such a cooperation aims at leaving inpatient and outpatient care with the private practice and financial controlling with the hospital. Radiologists in the private practice are thus incentivised and rewarded for their high productivity. This type of contracting of inpatient care is based on a payer-per-exam model. Generally, a hospital will save at least 20 percent of the total running cost of its MID before the cooperation and get additional revenue from the earnings per share.

In addition, this kind of cooperation leaves

the door open for an expanded collaboration in which the private practice can use their clinical strengths to serve outpatients (e.g. non-invasive cardio-imaging, interventional radiology, onco-imaging, paediatric imaging, etc) and generate additional DRG turnover for the hospital. In some of these cases, patients will need inpatient care in a further step which generates increased DRG turnover.

The imaging department in the context of a public-private cooperation would be well placed to run on a much lower cost basis, as it benefits from a much better utilisation of the most expensive resources (labour, equipment, etc.).

A shareholder structure in this framework gives the hospital management the strategic power to plough entrepreneurial and medical resources into the imaging department, further strengthening it. Through this strategy, even the financing of innovations would be better placed, as young academics are receiving training in workflow management which builds their job prospects and the reputation of the medical centre. This creates a triple win-win situation, for the hospital, private practitioners and, last but not least, the patients.

In Conclusion

Our studies, represented by the graphs provided, clearly show that clinical imaging within the MID is not always operated or managed in the best way. Without wishing to commoditise our profession, medical imaging cannot ignore modern business strategies and hope to remain competitive with private enterprises, particularly in this challenging financial climate of shrinking healthcare budgets. We must do our utmost to maximise revenue and manage our operating costs, while continuing to provide a high level of service to patients and referrers. I hope that within this paper, you have found some suggestions for new ways to manage the business of diagnosing and treating patients.

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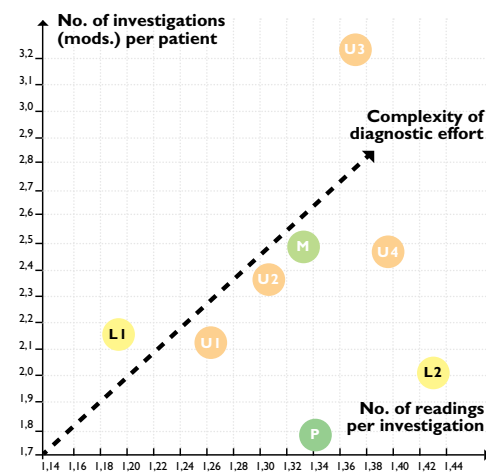


Figure 3: Medical Staff Requirement Correlation with Complexity of Diagnostic Effort

THE ROLE OF MANAGEMENT DEVELOPMENT IN THE IRISH HEALTH SERVICES

Doing more with less is one of the great mantras of management. However, during this time of constrained resources, can service quality really be improved while cost savings are made? In the last two years, the Irish Health Service has demonstrated that it is possible and much of the progress can be attributed to better managers and to better management.

Some of the figures speak for themselves. 2012 saw a 98% decrease in the number of adults waiting more than nine months for inpatient and day case surgery. There was a 95% reduction in the number of children waiting more than 20 weeks for inpatient or day case surgery.

The management processes involved are not rocket science. They rely on sound, fundamental principles of management. They include multi-disciplinary teams who develop strategies and are prepared to break the mould. Resources are focused on critical problem areas and well-constructed plans with strong monitoring and feedback system are relentlessly implemented.

Visible leadership and communication with key stakeholders is vital. The launch of the Department of Health Strategy – Future Health – was accompanied by a communications drive by the Minister and his officials throughout the

country, during which he met thousands of managers. Both the Minister and his officials have placed management development high on the agenda for action under the change programme.

In fact the policy document states the importance of a strategic leadership, governance and development framework which ensures that services are delivered cost-effectively, are safe and of high quality and are managed in compliance with the highest standards of governance.

The Health Management Institute of Ireland continues to play its role in the development of managers through its regional events, management forums, publications and training activities and resources. Its work has received the endorsement of key stakeholders within the health system and it is developing its resources to expand this role over the coming years.

Author:

Richard Dooley

President

Health Management Institute of Ireland



THE IRISH HEALTHCARE SYSTEM

Like most European countries, Ireland, and consequently, its health service, is having to cope with an ageing population. Each year the total number of people over the age of 65 grows by around 20,000 persons. The Department of Health predict that the population of over-65s will more than double over the next 30 years. This will have significant implications for health service planning and delivery.

Ireland is also facing severe economic constraints, with increasing unemployment and reductions in expenditure. Recent figures show increasing numbers and percentages of the population eligible for a medical card and decreasing numbers opting for private health insurance. Hospitals and other health-care providers are now set with the task of doing more with less. The goals are efficiency and effectiveness.

An example of changing practice which is both more beneficial for the patient and more cost-effective can be seen in the acute hospital sector where a gradual decline in inpatient admissions is being more than offset by a rapid rise in daycase treatments.

In overall population health terms, the past decade presents a clear picture of rapid decreases in mortality rates accompanied by a rapid rise in life expectancy. Mortality from circulatory system diseases fell by almost 36% between 2002 and 2011 and cancer death rates reduced by 8%. Mortality from circulatory system diseases is now virtually the same as that for cancer whereas it was 50% higher ten years ago and almost 100% higher 20 years ago. Between them, these two causes accounted for 63% of all deaths registered in 2011.

Hospital Activity

Volume of activity is itself a measure of the growing capacity of the acute hospital system, and the rapid increase in daycase care in recent years provides an indication of safer and more efficient delivery of care. Excluding dialysis, as recently as 2005, there were 100,000 more inpatients treated than daycases. 55% of all hospital admissions are now for daycase treatment. Despite the rise in daycases, the average length of stay for the remaining inpatients has shown a gradual decline to 5.7 days in 2011, which represents a decline of almost 10% since 2005.

The requirement for acute inpatient care both in terms of admissions and average length of stay increases steeply with age. Persons over the age of 65 account for almost 50% of all bed usage although they represent just 12% of

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the population. There has been an increase in the rate of total discharges in almost every age category since 2002, with the largest increases seen in the older age categories.

Despite increasing demand, progress continues to be made in lowering waiting times for treatment and in reducing the numbers of patients waiting on trolleys in emergency departments. Figure 1 shows the very significant reductions towards the target of having nobody waiting longer than nine months for elective treatment.

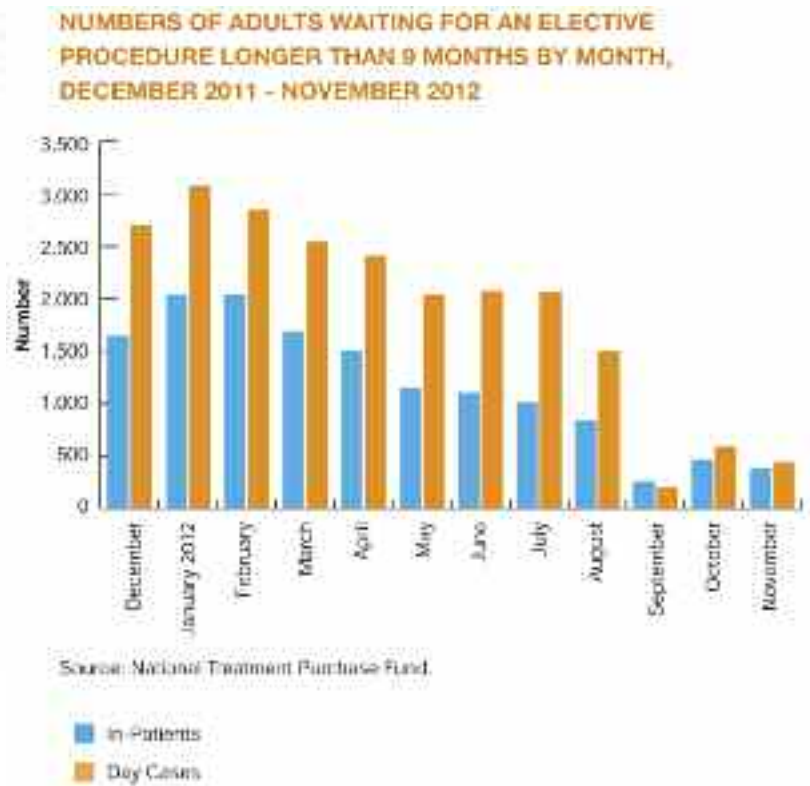
Health Service Expenditure

Total public expenditure on health increased by close to 50% between 2003 and the estimates for 2012. The non-capital side represents about 97% of total expenditure. Without taking inflation into account, capital expenditure is now nearly 25% lower than in 2003. Provisional figures for 2012 show an estimated decrease of 10.5% in total public expenditure on health since the peak in 2009.

International data puts Ireland as 13th highest out of 34 OECD countries in terms of total public and private health expenditure per capita. The recent OECD Report, "Health at a Glance, Europe 2012" records a fall of 8% in per capita health expenditure between 2009 and 2010 which was the largest reduction of any European country. When looked at from the perspective of proportion of national production spent on health, the picture which appears depends on whether Gross Domestic Product (GDP) or Gross National Income (GNI) is used as the denominator. Unlike most other countries, a significant proportion of Ireland's GDP refers to profit exports which are not available for national consumption. For this reason, GNI is a more meaningful measure. When total health expenditure (public and private) is expressed as a percentage of GNI, Ireland records a figure of 10.9% which ranks 9th highest among 27 OECD countries for which data were available for 2010. This is a drop of three places since the previous year (2009). By contrast, data for 2008 and 2009 showed significant increases in health expenditure as a percentage of GNI due to the rapid slowdown in economic development outpacing reductions in health expenditure.

This information was adapted from the Department of Health document, "Health in Ireland, Key Trends 2012" available at www.doh.ie

Figure 1



The Irish Healthcare System

Basic Health Statistics

INDICATOR	YEAR	VALUE
% of population aged 0-14 years	2010	21
% of population aged 65+ years	2010	11
Crude death rate per 1000 population	2010	6
Estimated infant mortality per 1000 live births (World Health Report)	2010	3
Estimated life expectancy, (World Health Report)	2009	80
Hospital beds per 100000	2010	315
Infant deaths per 1000 live births	2010	4
Life expectancy at birth, in years	2010	81
Life expectancy at birth, in years, female	2010	83
Life expectancy at birth, in years, male	2010	79
Live births per 1000 population	2011	16
Physicians per 100000	2011	324
Total health expenditure as % of gross domestic product (GDP), WHO estimates	2010	9

Source: European Health for All database (HFA-DB)

CROSS-BORDER COLLABORATION IN IRELAND

The Institute of Healthcare Management (IHM) is the leading membership organisation for health and social care managers and leaders in Northern Ireland. In recent years, IHM Northern Ireland and the Health Management Institute of Ireland (HMI) have collaborated in a number of cross-border initiatives, including shared learning for members.

Louise McMahon, current Chair of IHM previously worked in the Republic of Ireland and remains a member of HMI. She continues to have strong links with her former colleagues in HMI and attended the HMI's successful conference in Dublin in October 2012 with colleagues. As a result, important connections have been established. For example, one of Ireland's foremost clinical leaders, Professor John Higgins, has been invited to present in the series of Leadership Masterclasses in Northern Ireland.

In November 2012, the HMI President, Richard Dooley, travelled to Belfast for the IHM Northern Ireland's Annual Conference. The conference was attended by more than 120 people. IHM Northern Ireland was pleased to offer the Minister for Health in Northern Ireland, Mr. Edwin Poots M.L.A. and Dr. Rafael Bengoa, the then Minister of Health for the Basque Country, the opportunity to sign a Memorandum of Understanding (MoU) between the two regional governments at the conference. This provides the opportunity for healthcare managers and clinicians from the two jurisdictions to co-operate and learn from each other's experiences.

The conference was also attended by the Permanent Secretary of the Department of Health and the Chief Medical Officer and saw the presentation of a number of awards. These included awards for developing and experienced managers, quality and, for the first time, the inaugural Medical Manager Award, with generous sponsorship from a spectrum of companies interested in engaging with senior health service leaders.

The focus of the conference was the relentless pace of change for managers and leaders in health and social care in Northern Ireland. Delegates were particularly interested in hearing from Dr. Ambrose McLoughlin,

Secretary General of the Department of Health of Ireland who described the challenging change agenda for health services managers in Ireland. Across the border between the north and south of Ireland, managers and leaders are sharing experience, knowledge and expertise – particularly in performance management, commissioning and the development of hospital networks.

A central element of current policy in Northern Ireland, 'Transforming Your Care', sees the development of Integrated Care Partnerships between the primary and secondary care sectors and includes the voluntary and community sectors to ensure appropriate management of long-term conditions outside hospital. An initially small research project in this area is in development with Professor Bernadette Hannigan, Chief Scientific Advisor to the Department and Professor Mike Clarke of Queens University, Director of the Medical Research Council All Ireland Hub for Trials Methodology Research.

There is a long history of collaboration between health and social care professionals on the island of Ireland. Communities living close to the border in both jurisdictions have benefited from the sharing of services, including out of hours GP services and cross-border renal dialysis. This allows services to be provided to relatively smaller population groups, avoiding the need to travel long distances to larger centres of population.

Furthermore, co-operation with the Dublin maternity hospitals is part of the contingency planning for neonatology services in Northern Ireland, including in-utero transfers where necessary. Another recent significant development in cross-border collaboration is the commitment of the Irish government to buy radiotherapy capacity at Altnagelvin Hospital in Derry for people living in Donegal in the north western part of the island.

Northern Ireland is having a particularly exciting year in 2013 and the whole island will be working together to host and promote these events.

- The G8 summit of world leaders will take place in County Fermanagh in June at the Lough Erne resort on a 600 acre (240

hectare) peninsula with a Nick Faldo designed golf course, where the world's best golfer Rory McIlroy has played.

- The World Police and Fire Games – the third largest international multi-sport event in the world – will see 25,000 visitors including 10,000 competitors from 70 countries come to Northern Ireland in August.
- Derry City will host the cream of U.K. and international acts in the year long City of Culture Festival – including the Turner Prize, London Symphony Orchestra, Royal National Ballet and the Hofesh Schechter Company.
- Derry will also be the venue for the all-Ireland Fleadh Cheoil na hÉireann, which is the biggest competition and celebration of Irish music anywhere in the world and is coming to Northern Ireland for the first time ever.

Behind the scenes for all these events, health and social care services have been engaged in careful contingency planning, with strong leadership from the emergency services.

This all goes to show how the Northern Ireland Institute of Healthcare Management and the Health Management Institute of Ireland, as well as managers and leaders north and south of the border, engage on a daily basis to seek solutions to problems and to implement innovations to improve services. We hope that this will continue and grow in the future.

Author:

Louise McMahon

Chair of Institute of Healthcare Management





Willy Heuschen

TIRER LES LEÇONS DE SES ÉCHECS

Les excuses que David Cameron a prononcées au Parlement britannique pour les abus qui avaient pu se produire pendant des années dans l'hôpital de Stafford étaient extraordinaires. À notre connaissance, la mauvaise performance d'un hôpital dans l'accomplissement de sa mission de service public n'avait jamais été dénoncée aussi efficacement par les médias dans un Parlement européen. Les excuses officielles du Premier ministre britannique étaient adressées aux victimes, aux patients et aux familles qui avaient longtemps lutté avant que leurs plaintes ne soient entendues. Les diverses causes ont fait l'objet d'une expertise de 1 800 pages établie par un comité présidé par Robert Francis.

C'est la direction de l'hôpital en tout premier lieu, mais également le National Health Service (NHS) et les représentants du gouvernement qui doivent faire face aux graves allégations et prendre leurs responsabilités. Le rapport d'enquête suppose, selon la BBC, que le traitement honnête qu'ont subi les patients à Stafford a pu également se produire dans d'autres établissements. Les 290 recommandations ne concernent pas seulement l'hôpital Stafford, ils sont un appel à tous les établissements de santé et en particulier au NHS et au gouvernement. Robert Francis appelle, entre autres, à un changement durable dans la culture du NHS. Nous vous présentons un article sur ce thème dans les pages intérieures et nous nous efforçons également, dans notre prochain magazine, de donner la parole à nos collègues britanniques.

En tant que gestionnaires hospitaliers, nous pouvons tous tirer les leçons de ces événements. Tout d'abord, la très légitime discussion que ces abus ont provoqué ne doit ni se limiter à un pays, ni être généralisée à tous les établissements hospitaliers. On ne peut exclure la possibilité que les systèmes de soins d'autres pays européens se voient contraints de subir de telles allégations. En retour, il est tout aussi vrai que de nombreux hôpitaux sont encore capables de dispenser d'excellents soins de santé, en dépit de la dégradation des conditions financières et des difficultés qui en découlent. Une de nos tâches, à l'AEDH, est en particulier d'analyser la distance qui existe entre des conditions environnementales prédéterminées et la performance, et si nécessaire de solliciter une nouvelle initiative de l'établissement concerné. Cette question fera partie des sujets développés lors du prochain congrès de l'AEDH qui se tiendra à Luxembourg.

En outre, le commissaire européen en charge de la santé

devrait examiner avec une attention toute particulière les caractéristiques propres à la qualité en vertu de la directive de l'Union européenne sur les soins de santé transfrontaliers. Heureusement, aucun patient provenant d'un autre État membre de l'UE ne figurait parmi les victimes de Stafford. Mais que ce serait-il passé si cela avait été le cas ? On aurait certainement fait rapidement appel à la Cour de justice et on se serait efforcé, par l'action européenne, de remettre en question la juridiction nationale. Ce que la directive ci-dessus pourrait éviter si ses exigences sont traitées à bon escient par les différents pays de l'UE et par ses partenaires actifs dans le secteur de la santé. Le thème « qualité » fait partie depuis des années des sujets de prédilection de l'AEDH. Suite à notre séminaire en 2012 à Düsseldorf, notre conseil aux affaires européennes s'est donné pour tâche de comparer les indicateurs de la qualité pratiqués dans différents pays afin de donner un nouvel élan à la prévention. Nous aurons l'occasion d'en parler dans ce magazine, mais également au cours de notre prochain congrès.

Une autre leçon peut être tirée des événements qui se sont déroulés à l'hôpital de Stafford. Dans l'étiologie des circonstances scandaleuses et la répartition des responsabilités, nous devons contrôler, en plus de la gestion de la qualité, probablement aussi la mission de service public de l'hôpital, la description des fonctions ainsi que les pouvoirs du gestionnaire et, enfin, la structure directionnelle de l'établissement concerné. Car en l'absence de normes écrites et d'une définition des responsabilités et des structures vérifiables dans la pratique, les exigences de base pour une action efficace et respectueuse du patient viennent à manquer.

L'AEDH et plus particulièrement son conseil scientifique portent une grande attention à ces conclusions depuis de nombreuses années. Les résultats précédents montrent encore une fois, même si on les expose à la lumière des événements de Stafford, qu'en ce qui concerne le management, notre association européenne peut autant apprendre des directions des établissements de santé que ces dernières peuvent apprendre de notre association. C'est un formidable appel à une auto-évaluation critique de notre façon de travailler dans les hôpitaux et à une comparaison au niveau européen, sans toutefois s'autoriser à blâmer son voisin.

Willy Heuschen,

Secrétaire général et rédacteur en chef de l'AEDH



Les éditoriaux d' *(E)Hospital* sont rédigés par des membres des instances dirigeantes de l'AEDH. Les contributions publiées ici ne reflètent cependant que l'opinion de leur auteur et ne représentent en aucune façon la position officielle de l'AEDH.

L'AEDH DEVIENT PARTENAIRE AFIN D'ASSURER LE DÉVELOPPEMENT DU LEADERSHIP ET DES COMPÉTENCES MANAGÉRIALES À UN NIVEAU INTERNATIONAL

S'appuyant sur les objectifs stratégiques de l'OMS prévoyant de développer les compétences managériales, la Fédération Internationale des Hôpitaux (International Hospital Federation, IHF) a proposé de soutenir les bases du leadership et les compétences managériales des gestionnaires de la santé à un niveau international. À cette fin, elle a établi un partenariat avec les organismes suivants :

- Organisation panaméricaine de la santé (OPS)
- American College of Healthcare Executives (ACHE)
- Association européenne des directeurs d'hôpitaux (AEDH)
- Jamaica Association of Health Service Executives (JAHSE)
- Taiwan College of Healthcare Executives
- Collège canadien des leaders en santé
- Australasian College of Health Management Service
- Management Sciences for Health (MSH)
- National Health System Leadership programme (NHS/IHM)

Un atelier de deux jours a eu lieu les 29 et 30 Janvier 2013 au siège de l'OPS à Washington DC. Il réunissait 14 délégués des organisations participantes. C'est Mme Lucy Nugent, membre du sous-comité scientifique de l'AEDH et secrétaire honorifique de « Health Management Institute Ireland » qui a représenté l'association européenne.

Les objectifs fixés étaient les suivants :

1. développer une charte définissant les grandes lignes et les intentions du groupe de collaboration ;
2. parvenir à un accord minimal sur les compétences de base nécessaires pour les cadres et les gestionnaires d'un établissement de santé ;
3. élaborer un plan – comprenant les différentes étapes du développement,

de débutant à expert – pour évaluer « la pratique dans la réalité » ;

4. créer un processus d'évaluation : comment et par qui les compétences doivent-elles être évaluées ;
5. quel devrait être le rôle respectif de chaque association ?

Une sélection des outils de compétences couramment utilisés est actuellement soumise à un examen approfondi et des discussions sont organisées concernant les compétences requises à l'ACHE, au MSH, Canadian LEADS et Australian LEADS (adapté du modèle canadien) ainsi qu'au NHS. L'accord qui a été conclu sur les compétences de base les place dans l'ordre de priorité suivant :

1. le leadership ;
2. la responsabilité professionnelle et sociale ;
3. les connaissances en matière de santé et d'environnement des soins de santé ;
4. la gestion de la communication et des relations ;
5. les compétences et les connaissances en affaires.

Tout en reconnaissant qu'une formation de base procurant les compétences essentielles est indispensable pour l'acquisition et le développement de « la capacité de la connaissance » et de la compétence, on préconise une période d'apprentissage au sein d'une structure hospitalière avant de soumettre la personne à une évaluation. L'ACHE, par exemple, demande aux gestionnaires de travailler pendant une période au moins égale à deux ans avant de les évaluer. La question de la validation d'un outil nécessite un examen plus approfondi, car tous les outils existants d'évaluation semblent n'être que trop empiriques. Il peut être nécessaire que chaque pays puisse définir et éventuellement élargir le cadre de compétences requis, mais un sous-ensemble de base

serait déterminé avec possibilité d'une reconnaissance mutuelle.

Des discussions ont eu lieu pour savoir si ces compétences pourraient être approuvées par l'OMS mais cela prend un temps considérable (2 à 5 ans). Il a été décidé de créer un « chapitre IHF », c'est à dire un groupe thématique travaillant sur cette difficulté particulière et sur son calendrier – l'IHF a signé un protocole d'accord avec l'OMS et est bien placée pour progresser par la suite avec elle.

Les prochaines étapes

Les prochaines étapes de ce processus de collaboration comprennent :

- un site Web du projet (en utilisant le logiciel Basecamp) : il sera implémenté pour permettre des discussions en ligne et le téléchargement des documents en cours d'élaboration et du matériel de référence – indispensable pour gérer la logistique au vu de la répartition géographique des participants ;
- des termes de référence par chapitre : ils devront être rédigés et distribués ;
- « Management Sciences for Health » et l'« Organisation panaméricaine de la santé » pourront identifier les organisations ou associations pouvant représenter l'Afrique ;
- des sous-groupes : ils seront mis en place pour travailler sur les principes de la Charte, les documents relatifs aux compétences, et la session de la conférence d'Oslo – un programme de 90 minutes est prévu pour donner des exemples de cadres de compétences et obtenir un retour sur le document présenté ;
- la prochaine réunion se tiendra pendant le congrès IHF, à Oslo, en Juin 2013.



L'évolution du rôle de l'hôpital

Par Roland Ollivier, Emilie Hericher, Cedric Arcos

La situation des hôpitaux à la fin du siècle dernier pourrait être définie comme transitoire, entre un modèle stable de changements partiellement prévisibles et le nouveau schéma de l'environnement des soins de santé et de la gestion des hôpitaux que nous connaissons aujourd'hui. Les hôpitaux évoluent dans ce nouveau cadre et le défi managérial sera de définir une stratégie pertinente, adaptée à toutes les équipes, et dans un même temps de gérer l'incertitude et de s'adapter en permanence aux changements internes et externes. Paradoxalement, dans un monde à l'avenir incertain, les années 2010 à 2020 sont porteuses d'une vision plus globale de la gestion des établissements de santé.

En ce qui concerne la stratégie de la santé, les directeurs des hôpitaux de demain devront disposer d'une vision plus large et développer des activités en coordination avec d'autres institutions au sein d'une zone géographique définie. Afin d'assurer la continuité des soins et la compensation au niveau des ressources, il est donc important de définir la portée de ses activités, et si elles se feront sur un mode partagé ou associé.



La philosophie de la clinique Saint-Jean

Par Jos Olbrechts

Cela fait plus de 800 ans que la Clinique Saint-Jean dispense des soins en plein cœur de la ville de Bruxelles. À la diversité culturelle des patients répond celle des membres du personnel. C'est la conséquence d'un objectif clair et structuré : on compte dans chaque équipe le même nombre d'employés francophones, néerlandophones, et d'origine étrangère. L'accent mis sur la diversité culturelle, l'ambiance conviviale de la clinique et ses nombreux avantages pratiques – entre autres sa facilité d'accès et la flexibilité du temps de travail – font de la clinique Saint-Jean un lieu de travail attrayant. La clinique Saint-Jean a établi un management centré sur l'hôpital qui se différencie de l'approche gestionnaire uniquement financière ou médicale que l'on rencontre habituellement dans ce genre de structure hospitalière. Une gestion centrée sur l'hôpital donne à chaque membre du personnel la possibilité de s'impliquer, et par là même de s'engager dans les processus décisionnels entrepris par la direction.

Si nous renforçons aussi énergiquement la sécurité et le bien-être à tous les niveaux de notre organisation, c'est pour que notre philosophie, la philosophie de Saint-Jean, soit perceptible par nos patients. Ils ne peuvent qu'en récolter les bénéfices. Et c'est ce que nous constatons grâce à nos outils de benchmarking internes et aux questionnaires patients traités en externe : les soins que le personnel procure à nos patients reflètent la qualité de leurs conditions de travail et la considération dont ils font l'objet au sein même de leur équipe.



Le rapport Francis : un coup de semonce pour le National Health Service britannique

Par Lee Campbell

Le rapport final de l'enquête publique sur les soins fournis par le « Mid Staffordshire NHS Foundation Trust » a produit des ondes de choc à travers tout le NHS au Royaume-Uni. La Commission d'enquête a examiné la mise en service et les organes de surveillance et de réglementation du « Mid Staffordshire hospital » entre Janvier 2005 et Mars 2009. L'enquête a pu constater la souffrance terrible et inutile de centaines de personnes qui n'ont pas pu bénéficier d'un système de santé. On a pu ignorer les signes des mauvais soins qui leur étaient accordés et considérer que l'intérêt personnel de l'entreprise et le contrôle des coûts étaient bien plus importants que les patients et leur sécurité. Le Premier ministre David Cameron s'est excusé auprès des patients et de leurs familles pour la médiocre qualité des soins.

Robert Francis, président de la commission d'enquête, a émis 290 recommandations afin de s'assurer que cette argumentation n'aura plus cours et que les patients seront dorénavant considérés en priorité. Il a suggéré une culture commune centrée sur le patient au sein du NHS et proposé les adaptations suivantes :

- une structure de standards obligatoires et des mesures de mise en conformité ;
- l'ouverture, la transparence et l'honnêteté dans tout le système, sous-tendus par la loi. Sans cela, une culture commune d'ouverture et d'honnêteté envers les patients et les organismes de contrôle ne pourra pas être diffusée ;
- une prise en charge améliorée s'attachant à l'aspect humain et des soins infirmiers engagés et bienveillants ;
- un leadership fort au niveau des soins de santé.



Une approche multidisciplinaire de la planification financière

Par Wilhelm Frewer, Hans-Peter Busch

La concurrence régnant sur le marché de la santé aura un impact sur l'assurance maladie et les niveaux de service. On se rend compte qu'il existe un besoin constant d'accroître l'efficacité et l'efficience, et donc d'améliorer les processus, tant dans le secteur de la santé en général que dans l'organisation des établissements hospitaliers et des cabinets médicaux. Ainsi, leur bonne gestion nécessite des structures adaptées et des processus d'optimisation dans les différents domaines, en particulier celui de la qualité médicale, de la qualité du service et de l'efficacité.

L'optimisation de la structure organisationnelle a un impact direct sur la chaîne de valeur des services d'imagerie médicale. Dans le cadre des « groupes de diagnostic homogènes » (diagnosis related group, DRG), tous les aspects du traitement sont couverts par l'assurance maladie. Pour que cette rémunéra-

tion soit assurée, une optimisation continue des processus dans les domaines de la qualité médicale, de la qualité du service et de l'efficacité est nécessaire. Sur la base de ces trois piliers, le centre se doit d'être géré selon les règles d'une entreprise commerciale.

▶ De nouvelles dispositions pour l'optimisation des services d'imagerie

Par Bernd May

Les gestionnaires des services d'imagerie médicale et les directeurs d'hôpitaux sont à la recherche de nouvelles façons de fournir un service optimisé dans un climat de diminution des budgets de la santé, de concurrence entre les centres d'imagerie privés, et de la demande accrue d'une approche médicale fondée sur des données factuelles.

Voici les principaux conseils pour une optimisation de la gestion des coûts :

- sélectionner les examens appropriés pour réduire la durée des séjours à l'hôpital ;
- reconnaître que le travail est l'un des principaux facteurs de coût ;
- Les gestionnaires hospitaliers doivent prendre conscience de l'impact des coûts élevés de fonctionnement et d'entretien des équipements ;
- Toutes les modalités d'imagerie médicale auraient intérêt à envisager une coopération public-privé pour la prestation de services d'imagerie.

▶ Blockbusters, médicaments biotechnologiques et biosimilaires

Par F. Braido, F. Balbi, D. Bagnasco, G.W. Canonica

Nous sommes en train de vivre le début d'une décentralisation des soins prodigués aux patients et de la pratique médicale. Actuellement, nous nous dirigeons vers une thérapie ciblée, première étape vers un traitement personnalisé où le bon médicament à la bonne dose est administré à la bonne personne au bon moment. Ce processus est devenu possible grâce aux progrès de la recherche fondamentale et aux plans de recherche et de développement des entreprises pharmaceutiques. Nous vivons le passage de l'utilisation de molécules chimiques principalement développées pour traiter de grandes populations de patients (Blockbusters ou médicaments vedettes), vers une nouvelle génération de médicaments, pour la plupart biotechnologiques, mis au point pour modifier un mécanisme pathogène spécifique.

Comme l'expiration des brevets protégeant les produits chimiques a correspondu au développement des médicaments

génériques, l'expiration de ceux des nouveaux produits biotechnologiques verra apparaître l'avènement des biosimilaires. Ces derniers se réfèrent aux produits biopharmaceutiques qui, après l'expiration de la période de brevet, seront fabriqués par d'autres laboratoires pharmaceutiques que celui qui l'a lancé à l'origine tout en restant similaires en termes de qualité, de sécurité et d'efficacité. Cela se traduira par des recherches spécifiques, une surveillance clinique et une remise à jour des connaissances des médecins afin que l'utilisation de ces produits soit sûre et appropriée.

▶ Focus sur l'Irlande

Faire plus avec moins est l'un des grands mantras du monde de la gestion. Cependant, en cette période de limitation des ressources, peut-on réellement améliorer la qualité en réalisant des économies ? Au cours des deux dernières années, le « Irish Health Service » en a démontré la pertinence et aussi que de nombreux progrès peuvent être réalisés grâce à une meilleure équipe managériale et à une meilleure gestion.



Les chiffres parlent d'eux-mêmes : 2012 a vu une diminution de 98 % du nombre d'adultes devant attendre plus de neuf mois et une réduction de 95 % du nombre d'enfants devant attendre plus de vingt semaines pour une hospitalisation ou une opération chirurgicale en ambulatoire. Les processus managériaux impliqués ne sont pourtant pas extraordinaires. Ils s'appuient sur des principes de gestion solides et fondamentaux. Ils donnent la main à des équipes multidisciplinaires qui élaborent de nouvelles stratégies et sont prêts à changer leurs habitudes. Les ressources sont concentrées sur les points qui posent le plus de problèmes. On a récemment assisté à l'implémentation de plans prévoyant une vigilance importante et un système de feedback. L'essentiel demeure dans une direction bien présente et dans la communication avec les principales parties prenantes.



Willy Heuschen

AUS VERSAGEN LERNEN ...

Spektakulär war die Entschuldigung von David Cameron im britischen Parlament für Missstände, die laut Presseberichten, über Jahre im Hospital von Stafford geschehen konnten. Unserem Wissen nach wurde die schlechte Leistung eines Krankenhauses in der Wahrnehmung seines Versorgungsauftrages noch nie so Medienwirksam in einem europäischen Parlament thematisiert. Die offizielle Entschuldigung des britischen Premiers galt den Opfern, Patienten und Familien, die lange kämpfen mussten, um ihren Klagen Gehör zu verschaffen. Ein Untersuchungsausschuss unter Leitung von Robert Francis nennt auf 1800 Seiten die vielseitigen Ursachen. Dabei müssen die Krankenhausleitung an erster Stelle, aber besonders auch der National Health Service (NHS) und die Regierungsverantwortlichen sich den schwerwiegenden Vorwürfen und ihrer Verantwortung stellen. Der Untersuchungsbericht vermutet laut der BBC, dass die beschämende Versorgung der Patienten in Stafford wahrscheinlich kein Einzelfall ist. Die 290 Empfehlungen betreffen daher nicht nur die Stafford Klinik, sie sind eine Aufforderung an alle Kliniken und besonders an den NHS sowie an die Regierungsstellen. Francis fordert u.a. einen nachhaltigen Wandel in der Organisationskultur der NHS. Zu diesem Thema berichten wir auch im Innenteil und bemühen uns in der nächsten EHospital Ausgabe britische Krankenhauskollegen zu Wort kommen zu lassen. Aus diesen Vorkommnissen haben wir Krankenhausmanager einiges zu lernen. Zunächst ist die berechtigte Thematisierung dieser Missstände weder auf ein Land zu beschränken noch auf alle Kliniken zu verallgemeinern. Nicht auszuschließen ist, dass möglicherweise auch Gesundheitssysteme anderer europäischer Länder sich solche Vorwürfe gefallen lassen müssen. Im Gegenzug stimmt es auch, dass viele Krankenhäuser eine noch immer hervorragende gesundheitliche Versorgung leisten und dies trotz rückläufiger Finanzmittel und hemmender Systembedingungen. Zu den Aufgaben der EVKD gehört daher auch dieses Spannungsfeld zwischen vorgegebenen Rahmenbedingungen und Leistungsvermögen zu analysieren und wenn nötig anzumahnen. Dieses Spannungsfeld gehört daher zu den Vortragsthemen beim 24. EVKD Kongress in Luxemburg.

Des Weiteren müsste der für Gesundheit zuständige EU-Kommissar die Offenlegung der Qualitätsmerkmale im Rahmen der EU-Richtlinie zur grenzüberschreitenden Gesundheitsversorgung mit besonderer Aufmerksam-

keit überprüfen. Zum Glück befanden sich unter den ‚Stafford Opfern‘ keine Patienten anderer EU-Mitgliedstaaten. Aber was wäre wenn? Sicherlich würde der EuGH dann schnell bemüht und die nationale Zuständigkeit durch europäisches Handeln in Frage gestellt. Die oben genannte Richtlinie kann hier vorbeugen, wenn deren Auflagen von den EU Staaten, aber auch von den Partnern im Gesundheitsbereich zielgerecht bearbeitet werden. Das Thema ‚Qualität‘ zählt seit Jahren zu den Hauptthemen der EVKD. Nach unserem Seminar in 2012 in Düsseldorf vergleicht unser Beirat der europäischen Angelegenheiten die praktizierten Qualitätsindikatoren verschiedener Länder und kann Impulse zur Vorbeugung leisten. Selbsterverständlich werden wir darüber regelmäßig in *(E)Hospital*, aber auch bei unseren Kongressen berichten.

Eine weitere Lehre lässt sich aus den Vorkommnissen im Stafford Hospital ziehen. Bei der Ursachenforschung der skandalösen Umstände und deren Verantwortungszuteilung muss neben dem Qualitätsmanagement wohl auch der Versorgungsauftrag des Hospitals, die Funktionsbeschreibung sowie die Befugnisse der Klinikmanager und nicht zuletzt die Führungsstruktur der Einrichtung überprüft werden. Denn ohne diese schriftlich vereinbarten und in der Praxis überprüften Zuständigkeiten und Strukturen fehlen Grundvoraussetzungen für ein patientengerechtes und -effizientes Handeln. Diese Erkenntnisse beherzigen die EVKD und besonders ihr wissenschaftlicher Beirat seit Jahren. Die bisherigen erarbeiteten Ergebnisse des Beirates, auch vor dem Hintergrund der Vorkommnisse in Stafford, zeigen einmal mehr, dass wir im EU-Verbund auch bzgl. des Managements unserer Gesundheitsrichtungen voneinander lernen können. Dazu gehört zweifelsohne eine kritische Selbstbewertung unserer Arbeitsweise in den Krankenhäusern und ein Vergleich auf europäischer Ebene, ohne sich mit dem Zeigefinger zu beschuldigen.

Willy J. Heuschen,

EVKD Generalsekretär u. Chefredakteur



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EAHM ZUSAMMENARBEIT ZUR ENTWICKLUNG INTERNATIONALER FÜHRUNGSSTÄRKE UND MANAGEMENT-KOMPETENZEN

Aufbauend auf der strategischen Schwerpunktsetzung der World Health Organisation (WHO) bezüglich der Entwicklung von Management-Kompetenzen schlug die Internationale Krankenhausvereinigung (International Hospital Federation IHF) in Zusammenarbeit mit den folgenden Organisationen einen internationalen Ansatz vor, um grundlegende Führungs- und Manager-Kompetenzen für Gesundheitsmanager zu entwickeln:

- Pan American Health Organisation (PAHO)
- American College of Healthcare Executives (ACHE)
- European Association of Hospital Managers (EAHM)
- Jamaica Association of Health Service Executives (JAHSE)
- Taiwan College of Healthcare Executives
- Canadian College of Health Leaders
- Australasian College of Health Service Management
- Management Sciences for Health (MSH)
- National Health System Leadership programme (NHS/IHM)

Ein zweitägiger Workshop fand vom 29.-30. Januar 2013 im PAHO Hauptquartier in Washington, DC statt, unter der Teilnahme von 14 Abgeordneten der oben genannten Organisationen. Frau Lucy Nugent, Mitglied des EAHM wissenschaftlichen Unterausschusses und ehrenamtlicher Sekretär des Health Management Institutes in Irland nahm im Namen der Europäischen Vereinigung daran teil.

Die vereinbarten Zielsetzungen waren:

1. Entwicklung einer Charta zur Umschreibung des Zwecks und der Absichten der zusammenarbeitenden Gruppe

2. Eine minimale Vereinbarung über die für Manager im Gesundheitsbereich nötigen grundlegenden Kompetenzen
3. Entwicklung eines Rahmenwerks – einschließlich Entwicklungsstadien (von Neuling zu Experten) – zur Bewertung der „Praxis in der realen Welt“
4. Bewertungsprozess – wie und von wem sollen die Kompetenzen bewertet werden
5. Wie soll die jeweilige Rolle jeder Vereinigung genau aussehen?

Es wurde ein Überblick über die Auswahl der derzeit verfügbaren Kompetenz-Tools vorgenommen und eine Diskussion bezüglich ACHE, MSH, kanadischen LEADS und Australischen LEADS (angepasst vom kanadischen Rahmen) sowie über den NHS Rahmen geführt. Es kam zu einer Vereinbarung bezüglich der Kernkompetenzen in folgender Priorität:

1. Führungsstärke
2. Professionelle und gesellschaftliche Verantwortung
3. Kenntnisse bezüglich Gesundheit und des Umfeldes der Gesundheitsversorgung
4. Kommunikations- und Beziehungsmanagement
5. Unternehmerische Fertigkeiten und betriebswirtschaftliches Wissen.

Obwohl akzeptiert wird, dass die Grundlagen-Ausbildung über Kern-Kompetenzen unerlässlich für die Entwicklung von „Wissen und Können“ sowie Fertigkeiten ist, muss es eine Phase experimentellen Lernens geben, bevor die Bewertung durchgeführt wird; z.B. fordert ACHE, dass ein Manager vor seiner Bewertung zumindest zwei Jahre gearbeitet hat. Die Fragestellung der Validierung jeglichen Werkzeugs erfordert weitere Erwägung, da jede bestehende Evaluierung von Werkzeuge größtenteils empirisch erscheint. Es könnte einen Bedarf für die Definition und po-

tentielle Ausweitung des Kompetenzrahmens für jedes Land geben – eine zentrale Untereinheit sollte jedoch vereinbart werden, mit möglicher gegenseitiger Anerkennung.

Weitere Diskussionen fanden darüber statt, welche dieser Kompetenzen WHO-genehmigt sein könnten. Jedoch dauert so ein Prozess von zwei bis fünf Jahren. Das hat zu der Entscheidung geführt eine eigene IHF Arbeitsgruppe zu gründen. Diese Gruppe wird die eigenen Fragestellungen bearbeitet unter der die Zusammenarbeit fortschreiten kann. Zusammen mit der WHO hat die IHF eine Absichtserklärung verlautbart. Dies ist eine gute Voraussetzung für die weitere Zusammenarbeit mit der WHO.

Nächste Schritte

Zu den nächsten Schritten in dieser Zusammenarbeit zählen:

- Eine webbasierte Projektseite (mit Basecamp Software) soll für die online-Diskussion erstellt werden; Uploaden von Entwürfen und Referenzmaterial (unerlässlich für das Management der Logistik der geographischen Verteilung der Teilnehmer)
- Aufgabenbereich für Kapitel erstellen und verbreiten
- MSH/PAHO: Identifizierung von Organisationen / Vereinigungen zur Repräsentation von Afrika
- Aufstellung von Subgruppen zur Arbeit an Prinzipien/Charta, Kompetenz-Dokument, Oslo Konferenz Session (90minütiger Programmplatz verfügbar für Beispiele von Kompetenz-Rahmen und für die Rückmeldung hinsichtlich der Konsultations-Dokumentation).
- Vereinbarung über nächstes Meeting: im Rahmen der IHF Konferenz in Oslo, Juni 2013.

▶ Rollentausch des Krankenhauses

Von Roland Ollivier, Emilie Hericher, Cedric Arcos

Ende des letzten Jahrhunderts befanden sich Krankenhäuser in einer Übergangsphase zwischen dem stabilen Modell mit teilweise voraussehbaren Veränderungen und dem neuen Schema des Gesundheitswesens und Krankenhausmanagements, das wir heute kennen. Krankenhäuser entwickeln sich innerhalb dieses neuen Rahmens – die Herausforderung für das Management liegt im Definieren einer relevanten Strategie, die von allen Teams verstanden wird, und gleichzeitig im Umgehen mit der Unsicherheit und der konstanten Anpassung an innere und äußere Veränderungen. In einer Welt mit unsicherer Zukunft sind die Jahre 2010 bis 2020 paradoxerweise die Vorboten einer integrierten Sicht des Managements von Gesundheitsorganisationen.

Hinsichtlich einer Gesundheitsstrategie wird der Krankenhausdirektor von morgen gezwungen sein, eine umfassendere Sichtweise zu entwickeln und Aktivitäten in Zusammenarbeit mit anderen Einrichtungen in einem definierten geographischen Gebiet durchzuführen. Die Definition dieser Tätigkeitsbereiche ist daher wichtig – seien sie geteilt oder verbunden –, um sowohl die Kontinuität der Pflege als auch die Ressourcenverteilung zu gewährleisten.

▶ Die "Saint Jean Philosophie"

Von Jos Olbrechts

Seit mehr als 800 Jahren bietet das Saint-Jean Krankenhaus im Herzen von Brüssel medizinische Betreuung. Der Mitarbeiterstab spiegelt die kulturelle Vielfaltigkeit der Patienten wider, und zeigen das Ergebnis eines klar strukturierten Ziels: In jedem Team sind gleichermaßen Frankophone, Niederländisch-sprachige sowie ausländische Angestellte vorhanden. Dieser Fokus auf die kulturelle Diversität, die fröhliche Atmosphäre der Klinik und deren vielfältige Vorteile – wie etwa leichter Zugang oder flexible Arbeitszeiten – machen St. Jean zu einer attraktiven Arbeitsstelle. St. Jean führt ein „Krankenhaus-zentriertes Management“, anstelle des in den meisten anderen Kliniken üblichen Fokus auf ein Finanz- oder Medizinmanagement. Ein Krankenhaus-zentriertes Management gibt jedem Arbeitnehmer die Gelegenheit zur Teilnahme und damit zu Beeinflussung der Entscheidungen des Managements.

Das Krankenhaus besteht auf Sicherheit und Fürsorge auf allen Ebenen der Organisation; wir machen unsere Philosophie, „die Saint-Jean Philosophie“ allen Patienten zugänglich, die aus unserer insgesamt positiven Einstellung gegenüber den Angestellten die Vorteile ziehen. Tatsächlich konnten wir nach Einsatz interner Benchmarking-Tools sowie aufgrund von Patientenfragebögen mit externer Auswertung feststellen: Die Belegschaft reflektiert die Qualität ihrer Arbeitsbedingungen und die Berücksichtigung, die sie im Team erfahren, in der Betreuung unserer Patienten.

▶ Der Francis-Report: Weckruf für die Britische NHS

Von Lee Campbell

Der Bericht einer unabhängigen Untersuchungskommission über die Betreuung durch den ‚Mid Staffordshire NHS Foundation Trust‘ hat im Vereinigten Königreich Schockwellen durch die gesamte NHS geschickt. Die Kommission untersuchte die Behörden für Aufsicht, Regulierung und Beauftragung, die für die Überwachung des Mid Staffordshire Krankenhauses zwischen Januar 2005 und März 2009 zuständig waren. Die Untersuchung ergab eine Geschichte von furchtbaren und unnötigen Leiden von Hunderten von Menschen, bei denen ein System versagte, das die Warnzeichen der schlechten Betreuung ignorierte und das unternehmerische Eigeninteresse sowie die Kostenkontrolle höher bewertete als die Interessen der Patienten und deren Sicherheit. Premierminister David Cameron entschuldigte sich in aller Form bei den Patienten und deren Angehörigen für die schlechten Betreuungsstandards. Staatsanwalt Robert Francis QC, Vorsitzender der Untersuchungskommission, stellte 290 Empfehlungen auf, um diese Kultur zu verändern und um zu gewährleisten, dass Patienten an erster Stelle der Prioritätenlisten stehen, indem für die gesamte NHS eine gemeinsame, patientenzentrierte Kultur gelten soll. Zu den Empfehlungen des Vorsitzenden zählen:

- Eine Struktur grundsätzlicher Standards und Messungen der Compliance;
- Offenheit, Transparenz und Freimütigkeit im Bereich des gesamten Systems, diese seien satzungsmäßig zu untermauern. Ohne diese Voraussetzung könne sich eine Kultur der Offenheit und Ehrlichkeit mit Patienten und Regulatoren nicht durchsetzen;
- Mehr Unterstützung für mitfühlende, fürsorgliche und engagierte Pflege; und
- Starke Führungskräfte im Gesundheitswesen.

▶ Multidisziplinärer Ansatz der Finanzplanung

Von Wilhelm Frewer, Hans-Peter Busch

Der Wettbewerb am Gesundheitsmarkt wird sowohl die Krankenversicherung als auch die Niveaus der Dienstleistungen beeinflussen. Als Konsequenz gibt es einen anhaltenden Bedarf für die Erhöhung von Effektivität und Effizienz, um somit Vorgänge zu verbessern – generell auf dem Gesundheitssektor und im speziellen in der Organisation von Krankenhäusern und Arztpraxen. Das erfolgreiche Management von Krankenhausabteilungen und Arztpraxen erfordert daher die entsprechend Strukturen und Optimierungsmaßnahmen auf den Gebieten der medizinischen Qualität, der Qualität der Dienstleistungen sowie der Effizienz.

Die Optimierung der Organisationsstruktur hat einen direkten Einfluss auf die Wertekette der bildgebenden Abteilungen. Im DRG Kontext wird der gesamte Behandlungspfad im Krankenhaus kompensiert; die kontinuierliche Optimierung der Vor-

gänge in den Bereichen Gebieten der medizinischen Qualität, der Qualität der Dienstleistungen sowie der Effizienz ist daher erforderlich, um Einnahmen zu erzielen. Auf diesen drei Säulen ruhend muss das Zentrum laut den Regeln eines Unternehmens gemanagt werden.

▶ **Optimierung Bildgebender Abteilungen: neue Wege gehen** Von Bernd May

Sowohl Manager von Bildgebenden Abteilungen (Medical Imaging Department, MID) als auch Krankenhausmanager suchen nach neuen Wegen, einen optimierten Service anzubieten – und dies in Zeiten schrumpfender Gesundheitsbudgets, Wettbewerb von privaten Bildgebenden Zentren und erhöhtem Bedarf für evidenzbasierte medizinische Leistungen.

Die folgenden Faktoren sind der Schlüssel für das optimierte Kostenmanagement:

- Auswahl geeigneter Untersuchungen zur Verkürzung des Krankenhausaufenthalts;
- Erkenntnis, dass Arbeitskräfte einen der hauptsächlichen Kostentreiber darstellen
- Krankenhausmanager müssen die Einfluss der hohen Kosten für Betrieb und Wartung der Geräte erkennen; und
- Alle Formen der Bildgebenden Einrichtungen würden von der Erwägung einer öffentlich-privaten Zusammenarbeit für das Anbieten von bildgebenden Dienstleistungen profitieren.

▶ **Blockbuster, biotechnologische Arzneimittel und Biogenerika** Von F. Braidò, F. Balbi, D. Bagnasco, G.W. Canonica

Wir stehen derzeit am Anfang eines Umlagerungsprozesses in Patientenbetreuung und in der Arztpraxis. Im derzeitigen Szenario bewegen wir uns hin zu einer gezielten Therapie – der erste Schritt hin zu einer personalisierten Therapie –, wo der richtige Wirkstoff in der richtigen Dosierung an die richtige Person verabreicht wird, zum richtigen Zeitpunkt. Dieser Vorgang wird durch die Grundlagenforschung und die Forschungs- und Entwicklungspläne der pharmazeutischen Unternehmen ermöglicht. Wir erleben einen Switch von vornehmlich chemischen Modellen, entwickelt, um möglichst große Patientenpopulationen zu behandeln (sogenannte Blockbuster-Arzneimittel) hin zu einer neuen Generation von Wirkstoffen, vor allem biotechnologischer Natur, die zur Modifizierung eines spezifischen pathogenen Mechanismus entwickelt wurden. Genauso, wie das Auslaufen der Patienten von chemischen Produkten mit der Entwicklung von Generika zusammenfiel, sieht das Auslaufen der neuen biotechnologischen Produkte das Auftreten von Biogenerika. Letztere beziehen sich auf Biopharmazeutika, die von Nicht-Urhe-

ber Pharmazieunternehmen hergestellt werden, nach Ablauf der Patentperiode, mit ähnlichen Eigenschaften bezüglich Qualität, Sicherheit und Effektivität. Dies impliziert spezifische Forschung, klinisches Überwachen, und die Aktualisierung von Ärztwissen, für die sichere und geeignete Anwendung dieser Produkte.

▶ **Fokus: Irland**

Mehr tun mit weniger – das ist eines der größten Mantras im Management. Jedoch: kann in diesen Zeiten eingeschränkter Ressourcen die Dienstleistungsqualität wirklich verbessert und gleichzeitig Kosten eingespart werden? In den letzten beiden Jahre hat das irische Gesundheitssystem gezeigt, dass dies tatsächlich möglich ist; wobei ein Großteil des Gesamtprozesses auf bessere Manager und besseres Management zurückzuführen ist.



Einige der Zahlen sprechen für sich. Im Jahr 2012 wurde ein 98%iger Rückgang in der Anzahl der erwachsenen Patienten gesehen, die länger als neun Monate für stationäre und ambulante chirurgische Eingriffe warten mussten. Die Anzahl der Kinder, die länger als 20 Wochen für stationäre oder ambulante chirurgische Eingriffe warten mussten, sank um 95%. Die dazu nötigen Management-Vorgänge sind keine Hexerei. Sie beruhen auf vernünftigen, grundsätzlichen Prinzipien des Managements: Dazu zählen unter anderem multi-disziplinäre Teams, die Strategien entwickeln und bereit sind, aus althergebrachten Sichtweisen auszubrechen. Ressourcen konzentrieren sich auf kritische Problembereiche, und gut aufgestellte Pläne mit einem soliden System aus Überwachung und Rückmeldung werden unerbittlich umgesetzt. Eine gut sichtbare Führung und die Kommunikation mit zentralen Interessensvertretern sind unerlässlich.

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