

Hospital



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GOOD GOVERNANCE

Plus

- Infections
- Winners of the IT @ Networking Awards 2012
- Pharma Supplement
- Focus: Norway

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THE RECIPE FOR GOOD GOVERNANCE



Nikolaus Koller

Good governance is the goal of every hospital manager and should not just be discussed and debated but also implemented.

In my role as a hospital manager I am still challenged to reach this goal everyday. Many years of experience in a leadership position do not guarantee the mastering of a perfect management style. One of the reasons for this is the need for continuous change. You have to adapt

Good governance is like a dish prepared with local and national ingredients specified through the company's philosophy.

your leadership style and position as the values of staff members change constantly. Recent considerations have shown that achievements can not only be reached with financial incentives and rewards. It is much more important to create a culture of trust and motivate staff members by pushing their self-confidence which displays an increased will to perform.

Recent trends show that there are various aspects that lead to good governance: Giving staff members the opportunity to make choices promotes independence in their work as does lessening regulations and control systems and above all avoid- ing demotivating through pedanticism.

Recently we have also seen new models of service provision like national and international co-operations, outsourcing, public-private partnerships, networking and sectoral and departmental collaborations. These also play a role in good governance.

A vital trend that is reflected in all of the above is the necessity to provide challenging performances through collaborations across or-

ganisational borders in an environment that changes continuously.

Good governance is like a dish prepared with local and national ingredients specified through the company's philosophy. Whoever masters this recipe is able to reach goals more successfully and much more efficiently.

Our cover story highlights two important governance issues: Ethical governance and clinical governance. These are both important steps towards good governance.

This issue of (E)Hospital also includes a Norway country focus. Norway is known for its astonishing and diverse nature. There are so many fjords on the coastline in the west that reach far into the land and are confined by high mountains. This country once was the empire of the Vikings. From an economical view it is known and famous for its oil and fish exports. Like all the other Scandinavian countries Norway consists of a first class health-care system, which is financed from three different pots. It is also interesting to see the high equity contribution of patients and the famous general practitioner (GP) primary care system.

(E)Hospital will be distributed at the following congresses and events: EAHP, ISICEM, ECCMID (please contact Lee Campbell for further information). On behalf of the EAHM I would be very pleased to welcome you to one of the very interesting and informative events.

Nikolaus Koller

President of the Editorial Board

Note: The Presidential Letter

EAHM President, Mr. Heinz Kölking will announce the Board and Greek Association's decision concerning the 2012 congress in Athens in his 2012 Presidential letter.

This letter is available to all members on request. To receive the letter please visit, www.eahm.eu.org



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.



Good Governance

As Nikolaus Koller stated in his editorial, “good governance is the goal of every hospital manager”. This issue we look at two types of governance and discover what benefits good governance can bring for our hospitals. Our Italian colleagues focus on ethical governance; firstly defining the concept and then providing us with a step-by-step guide on how to implement it. Philip Crowley and Maureen Flynn from the Irish Health Service introduce us to clinical governance and how it can improve patient experience and outcomes in terms of quality and safety.

Pharma Special

This issue we have included a pharma supplement in which we tackle the important issues of prescribing efficiency, drug delivery systems and the safe handling of hazardous drugs. You will find the articles in two formats: One set inside the journal for you to keep and a second set as a pull out supplement. The second set is for you to pass on to your colleagues in the pharmacy department.

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Focus: NORWAY



Norway faces the same dilemma of many western European countries, as the standard of living improves and people's life expectancy increases, there are new challenges with an ageing population and a growing number of people with chronic diseases. To make further progress in the health of the population, it will be necessary to focus on the challenges of health promotion and illness prevention.



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41ST ORDINARY GENERAL ASSEMBLY 18/11/2011, DUSSELDORF, GERMANY

President of EAHM, Mr. Heinz Kölking welcomed members to the General Assembly and started by saying a few words about our dear colleague and long-standing EAHM member Asger Hansen who passed away in 2011. After a moment of silence the General Assembly got underway.

This year's agenda and the minutes from the 40th Ordinary General Assembly were unanimously approved. After this it was time for Mr. Kölking's EAHM activity report. The objective of this report is to highlight the most important issues and special developments since the last meeting in Zurich 2010.

Activity Report

Mr. Kölking informed members that the Presidium met five times in Brussels while the Executive Committee met twice (20th May and 18th November). He explained that the board has developed a strategy in view of the resource base and have forged partnerships with the healthcare industry. Partnerships with Ecclesia and BD are to be concluded soon. This is a key achievement for the association as the resources are greatly needed.

Looking back at the last General Assembly in 2010 and the congress in Switzerland Mr. Kölking thanked our Swiss colleagues for a very successful congress and encouraged members to show their appreciation. Looking ahead to Athens 2012, he stressed that the situation is not unproblematic due to the economic situation in Europe and recent developments in Greece. However, he is confident that EAHM and the Greek association will find a way to hold the congress successfully. Currently, this depends on funds. The Executive Committee discussed this matter at their meeting the following day and the final decision will be made in February. We must help and show solidarity to our colleagues in Greece.

The scientific subcommittee is dealing with the scientific component of the congresses as well as the key values of the hospital manager (shared identity, ethics etc.).

The EU Affairs Subcommittee has been looking at today's issues and has met twice, as have the Scientific Subcommittee. The Editorial Board has also met twice in Brussels to work out the editorial plan for *(E)Hospital*. Mr. Kölking stated that "this is a challenge to live up to. Everything we do will depend on how we handle these challenges with the right tools and actions and training of our staff."

Mr. Kölking thanked all three groups for their commitment and the hard work involved. This is important work and a prerequisite for the success of the organisation.

The reflection process was another key topic of the activity report. The president highlighted that at both the European and national association level, the environment in which we are working has changed. There have been major changes in terms of professionalisation and the structures we move in are also changing. This requires the re-shaping of organisations/hospitals and in this changing environment, managers need to adapt, hence the reflection process. The focal points so far are press liaison, Internet (through the website) and the IT Working Party with events in Vienna and Lithuania. These regional seminars set up a common language between management and IT professionals and received a very positive response. Mr. Kölking emphasised that the reflection process was not just a discussion, the results will be implemented and the Board and Executive Committee place it on the top of their agendas.

Regarding the membership, some national associations were unable to pay their fees. The Executive Committee decided not to exclude them, seeking solutions to maintain them without risking the financial base, which the association needs.

To close, Mr. Kölking asked, "where is Europe heading? We view ourselves as supporters of management but also contributing to a joint Europe. We need this joint Europe, especially in healthcare,

therefore it is important that the EAHM will only do the things that make sense."

Accounts 2010 and Economic Plan for 2012

Secretary General Mr. Willy Heuschen gave the financial reports. The 2010 budget was respected (106 euro overspending) with Mr. Heuschen specifically thanking the Swiss association for their profit from the 2010 congress in Zurich. Expenditure rose due to an increase in meetings and consequently higher travel expenses. In his summary Mr. Heuschen declared that despite the difficulties of the financial crisis, with the help of the successful Swiss conference, EAHM was able to implement the results of the reflection process without destabilising the budget.

The economic plan for 2012 contains no major changes. Again some national associations might not be able to pay their fees. It is hoped the world will look better in 2012 and we will see a recovery of part of the membership.

A key topic was the new partnership agreements. At the General Assembly Mr. Heuschen said there were six perspective partnerships at the present moment and urged members to help them find more. They are not easy to find as criteria dictates a true partnership and not simply a hit and run business. Partnerships will be concluded for three years.

From the audience an important question was raised regarding these partnerships, asking whether their expected revenue was included in the 2012 budget. Mr. Heuschen clarified that currently EAHM is two partners short but that spending is controlled in line with revenue. Only when the money from partnerships comes in will that money be spent. He did however admit that he is not ignoring the fact that the budget for 2012 is a challenge! Both the budget and economic plan were approved by the General Assembly. The auditors reported and were asked to continue their roles. It was also mentioned that the external audit report is available upon request.

The next General Assembly has been provisionally fixed for Athens on 27 September 2012.

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- > Need to reduce workload for pharmacists and nurses



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FIRST JOINT EUROPEAN HOSPITAL CONFERENCE

The 18th of November saw the first Joint European Hospital Conference take place in Dusseldorf, Germany. Organised by the three key associations in European Healthcare (EAHM, HOPE and AEMH), the aim of the conference was to gather together decision-makers and CEOs and to focus on the patient. The conference was designed to be used as a common platform to exchange knowledge and ideas and to try and resolve the problems we are facing.

The morning section focused on current European health policy with a keynote presentation by Mars Di Bartolomeo, Minister of Health and Social Affairs, Luxembourg. The afternoon was devoted to the EU Directive on Patients' Rights and its impact on hospitals. The key presentation was given by Annika Nowak, European Commission and was followed by comments from various European countries (UK, Hungary, France, Belgium, Sweden and Greece).

Current European Health Policy

Mars Di Bartolomeo took the opportunity to reflect on current European health policy and also the effect of directives on healthcare. He believes that equitable access, technology, cross-border, e-health and transparency of services are all important issues, which must be viewed through increasing costs/budget constraints for hospitals.

For Di Bartolomeo, European integration has become self-evident as a development, "we are no longer scared of European health policy." He did however admit that the European health market had provoked some heroic disputes. He confessed to resisting to health being restricted to market rules. Yes healthcare is a service but it is special, it is not just buying and selling based on contract but the services offered must also comply with high quality standards and there are also provider-beneficiary and reimbursement and social security systems to think about too.

EU policy should focus on first-rate medicine for everyone. This will cost more money but proven assets and values are worth being defended. The health minister also spoke of the need for comparable data and indicators for quality and benchmarking.

Long-term strategies are essential in overcoming crises and the minister spoke of the Europe 2020 strategy and how it

affects healthcare. The Europe 2020 strategy is about intelligent, sustainable growth and social cohesion. It is about investing in good health; each citizen is entitled to health promotion and care. The health sector constitutes a high cost factor but there is very high added-value: Quality of life cannot be expressed in Euros.

Di Bartolomeo continued with the following hypothesis: "Nothing deprives the welfare state of resources than poor health". He was realistic to the fact that medical progress will not make health cheaper; costs will not go down but you can get more for your money.

After this very informative speech the spotlight moved to the expert panel made up of representatives from each of the three European associations. George Baum, President of HOPE (European Hospital and Healthcare Federation) was the first to comment on current European health policy. Baum reiterated the fact that European integration is essential but that there must be limits on standards.

Baum believes that we, as Europeans, are far too unrestricted in our movement to be denied healthcare in another country when it cannot be treated at home. He emphasised the need for balance in the movement of health professionals and patients citing the worry that some regions will be under a greater burden than others.

Another key issue for HOPE is qualifications for healthcare professionals. They are worried that all care professionals will soon need 12 years of schooling to be qualified to do their job.

To speak on behalf of the EAHM Mr. Heinz Kölling took the floor. He stressed the value of these conferences in bringing Europe together. Mr. Kölling highlighted personnel issues including increased competition with other sectors and the scarcity of people willing to work in healthcare. This is not helped

by the new levels of complexity compared to ten years ago (ICU, IT) and the high pressure on staff. He believes that leading and supporting staff is a task for the management.

Kölling explained that the EAHM believes management on different levels is key to facing the current challenges in healthcare. For this reason EAHM is focusing on the professionalisation of management. Staff are key to the smooth running of a hospital and bad management can cause a lot of damage.

Last to take the stage before the lunch break was João de Deus, President of AEMH. He stressed that although different countries have different systems all hospital models hospitals across Europe are prime targets for cost-saving measures. For the AEMH the key goal is patient safety and quality. This includes risk management and improved pre- and post graduate medical training.

De Deus finished by stressing that hospital management should be based on quality and safety and he strongly believes there should be more doctors in hospital management.

EU Directive on Patients' Rights and its Impact on Hospitals

Annika Nowak, a representative from the European Commission (DG SANCO D2) was tasked with quite a responsibility: Explaining



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the directive on patients' rights in cross-border healthcare. Putting the longevity of this contentious issue into context, she explained how there have been 12 years of European Court of Justice rulings on patient mobility from Kohll and Decker in 1998 to Elchinov in 2010. The Commission proposal was adopted in July 2008 after which there was the first and second reading resulting in the formal adoption of the Council on 28 February 2011. The Directive entered into force on 24 April 2011.

The Directive has three aims:

- To help patients exercise their rights to reimbursement for healthcare received in another EU country;
- To provide assurance about safety and quality of cross-border healthcare;
- To establish formal cooperation between health systems.

The Directive is said to help patients access information through the national contact points, clarify the rules regarding reimbursement and provide procedural guarantees. The healthcare provider role includes provision of information to the patient, professional liability insurance, calculation of prices and medical records. The safeguards put in place for health systems include conditions for reimbursement, the maintaining of national rules and the prior authorisation system.

Quality and safety are promoted through transparency and accountability, Member State responsibilities and cooperation of Member States.

The transposition period for the Directive is 30 months (until 25 October 2013). This period will include bilateral discussions. The Commission questionnaire has been completed by all Member States in detail on patient rights and the Commission will also visit all 27 Member States to check on progress. The Committee on cross-border healthcare has also been set up.

Nowak concluded by praising all Member States for taking this process so seriously and reiterating that the European Commission is closely following all developments. After Ms. Nowak's informative presentation on the Directive itself it was time to hear from representatives of Member States and the effects of the Directive in their countries.

Elisabetta Zanon spoke on behalf of the UK NHS. The UK does not expect to see a

large increase in demand for healthcare from foreign patients but is concerned that longer waiting times in the UK could motivate patients to travel abroad for their care. The main challenge for the UK concerns tariffs and prices. In the NHS, 60 percent of care is not covered by tariffs and prices are often set at a local level. This is hard to define so the UK would like to see definitions of entitlements and worries about maintaining the ability to plan and prioritise.

Moving to France, Prof. Robert Nicodeme from the French Medical Chamber believes that healthcare personnel are missing from the Directive. This is an important issue as they are very active in healthcare mobility. Competence is another big issue here; everyone wants a competent doctor and each country must measure performance and ability with the same set of competences. This is not defined in the Directive.

The Hungarian perspective, given by Dr. Gyorgy Harmat, President of the Hungarian Hospital Federation, focused on the legal dimension of the Directive stating that there is a need for more legal provisions, especially regarding the use of e-health. Another key issue highlighted was the linguistic challenges of cross-border care. Patient mobility in Hungary is quite low but waiting lists are moderate and there is low level domestic cost meaning there is a fear that this could cause a flow into the country.

The Belgian representative, Dr. Miek Peeters explained that at the time of the conference, national planning and debate on the Directive had not yet started due to the government situation. Quality and safety are key concerns. Member States must impose certain standards and the Directive does push for Member States to improve this. It will be interesting to see how this will influence standards of quality of care. Non-discrimination on basis of nationality was highlighted, as were the high num-

bers of foreign patients in Belgian hospitals. Special mention was given to equal access with refusal as the exception not the rule and an end of higher tariffs for foreigners.

Dr. Thomas Zilling, Vice-President of AEMH spoke for Sweden, one of the more liberal countries in Europe. He explained that Sweden is strongly in favour of the Directive and indeed already demand no prior-authorisation for Swedish nationals to receive care in another country and be reimbursed at home. This does, however, depend on their ability to pay for the care before reimbursement and the government are working to change this process. Swedish medical doctors demand that the government establish an authority that protects the patients' rights regarding crossborder healthcare.

The final country to voice its opinion was Greece. Dr. D. Kremalis emphasised the difficult economic situation in Greece and that healthcare is not excluded from the cuts. Kremalis believes there is a need for further clarification on the Directive and the healthcare provided but is confident this is a step forward to the Europeanisation of healthcare. There are questions to be answered on a practical level (regulations, coordination of social security system) and dialogue must continue. He believes that the scope of the reimbursement system is significantly narrow and that although a step in the right direction, the Directive does not create a real European right to healthcare.

A lively discussion took place after the national perspectives with Ms. Novak taking questions from the floor. The conference, and the session on this Directive in particular, has shown that the issue of cross-border healthcare is far from resolved but that it is clear a level playing field needs to be established between all involved and all Member States must be involved to make it work. A sense of freedom for patients has been established as a right; political progress has been made.



Joao De Deus (AEMH), Willy Heuschen (EAHM), George Baum (HOPE) and Heinz Kolking (EAHM)

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THE BELGIAN ASSOCIATION TAKES A STUDY TRIP TO BOSTON

From the 19th to the 25th of September 2011, the Belgian Association of Hospital Managers organised a study trip to Boston, the capital of New England. Around 40 hospital managers took this great opportunity to visit a range of interesting hospitals.

On the programme: Tufts Medical Centre, a world-class academic centre. This medical centre is the principal teaching hospital for Tufts University School of Medicine. They offer outstanding patient care to both adults and children, teach generations of future physicians the most advanced medical science and break new ground with ongoing, innovative research.

Brigham and Women's Hospital, world-renowned in virtually every area of adult medicine. As a teaching hospital of Harvard Medical School, their leadership in patient quality and safety, development of state-of-the-art treatments and technologies, and robust research programmes have improved the health of people around the world.

Massachusetts General Hospital the third oldest general hospital in the US and

the oldest and largest hospital in New England continues its tradition of excellence today. The Hospital was designated a Magnet hospital, the highest honour for nursing excellence awarded by the American Nurses Credentialing Centre.

Newton Wellesley Hospital is a member of Partners Healthcare, a network founded by Massachusetts General Hospital and Brigham and Women's Hospital. This partner affiliation grants patients seamless accessibility to the finest community-based medicine as well as the most advanced specialty care in the world. The hospital offers patients access to various centres of excellence.

Beth Israël Deaconess Medical Centre have assembled surgical and clinical expertise second to none, have a state-of-the-art trauma centre, developed sophisticated minimally invasive techniques and called on innovative training and technology to ensure the highest level of patient safety and quality of care. Each year, more than a quarter of a million patients and their families count on Beth Israël Dea-

coness Medical Centre.

And last but not least the Massachusetts Institute of Technology. Research focuses on many topics – from biology and chemistry to political science, economics and linguistics – but when an issue is of global, immediate importance, MIT puts its effort where it is needed most.

Both the quality of the presenters, their presentations and the stakeholders gave us a better insight into the evolution of medicine in the United States and also the primary importance of quality in all their activities. The technologies used to achieve these quality objectives are very advanced and close to perfect. The desire to achieve these goals through these methods was omnipresent in all sites visited.

We can conclude that this study trip was for us one of the most successful that we have organised during the past ten years.

Jean-Pierre Vandervondelen

Vice-President, Belgian Association of Hospital Managers
Trip Organiser



Members of the Belgian delegation participating in a Q&A after a presentation



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ETHICAL GOVERNANCE

UL Aparo, A Aparo

We generally speak about ethical governance only when there are problems: Scandals, corruption, misbehaviours. When they occur, it does not matter how severe they are, we talk about ethical governance but we think in terms of adopting a code of ethics. The fact of the matter is that we like to think that ethical governance is not something that concerns us. We also show very little interest because it is not clear what we are talking about.

Therefore, what is ethical governance?

Definition

Ethical Governance refers to values and ethical behaviours, processes, procedures, culture, ways of doing and being that ensure high standards of performance, economy, effectiveness, efficiency, quality, satisfaction.

Governance is the set of processes and abilities needed to achieve the objectives and fulfill the responsibilities of whatever business or organisation, whether public, for profit or not-for-profit, in the healthcare sector or in any other field of economic activity.

The primary responsibility of those who, either elected or delegated power, have the task of managing governance, is to make decisions that must always be in tune with the values, identity, vision and mission of the organisation they work for. These decisions have to be ethical ones.

Health organisations are faced with a continuously changing environment in which profit seems, unfortunately, to have become more important than patient recovery and health. How can we meet the evolving expectations of an expert and demanding “customer”? How should moral dilemmas be addressed and solved? The expectations put on those working in healthcare are so high as the moral compass is pointing in different and mostly new directions. We have to rethink medical ethics.

Patients who only yesterday were obvious candidates for surgery or chemotherapy, can now decide how to approach the end of their life differently. These are decisions that do have a profound and immediate impact on the medical care to be provided. Decisions which generate new challenges for the healthcare system. Decisions which impose innovative thinking and competencies on health managers. But who decides what? Too often we take the easy

shortcut and throw the ball to the legal department. But does it make sense that a medical treatment should be decided by a lawyer? It does not matter how deeply expert, but can all the responsibility be on just one person? As good and knowledgeable he/she can be, is this the right thing to do?

These are questions that deserve careful consideration:

All ethical theories have two basic issues in common:

1. What good are we aiming at, and what is bad/negative that we should and must avoid?
2. What is the correct or desirable course of action and what is the inappropriate or prohibited one?

Ethics helps to decide between good and

Ethics helps to decide between good and bad,
between appropriate and inappropriate,
between right and wrong.

- What processes must be used?
- What is the role and importance of ethics and medical ethics in particular?
- In the healthcare world, what should be the optimal relationship between ethics and governance?

Let us try to find evidence that may help provide answers to these questions.

Ethics in Healthcare

Ethics is the branch of philosophy that deals with the moral aspects of human behaviour. Medical ethics, in the modern sense of the term, refers to the application of fundamental ethical principles to general situations of clinical practice, including medical research. Ethics has one basic question: “What must be done?” Ethics has no interest in common practices, in what is usually done, or in what could be done.

bad, between appropriate and inappropriate, between right and wrong. Ethics is different from science in a variety of ways. Ethical issues and ethical considerations cannot be studied through controlled experiments. Moreover, it is not possible to separate personal and subjective considerations, which are in turn strongly influenced by historical and cultural context. In physics, and in natural sciences, results are based essentially on objective observations and experiments. Science reaches conclusions. Ethics provides only recommendations.

The Declaration of Geneva of the World Health Organization in 1948 is –de facto– the first global code of ethics and was inspired by the Hippocratic oath. One of the greatest innovations in modern Western ethics has concerned the doctor-patient relationship, which has evolved from a paternalistic one to a relationship in which the patient has considerable au-

onomy. In recent years, different ethical principles have been formulated and adopted as a basis for discussion of ethics in healthcare. In particular, the principles of autonomy, do-no-harm, beneficence and justice.

Ethical theories closely resemble our gut-feeling decisions, they are instinctive. Every day we use ethics based analysis: When we decide to give way for someone, to stay longer at work, to help our children with their homework. The main ethical theories according to which we, citizens of a western industrialised country, base our instinctual decisions are:

1. Consequential: Look at the results;
2. Deontological: Look at the liability;
3. Value based: Look at the reasons.

There are also two other contemporary ethical theories that are worth recalling because of their implications for analysing the ethical problems that may be solved by hospital executives. The first one is the ethics of community that shows how we must take account of community values in which one is active, and how to operate in tune with its scope. The second is feminist ethics, which teaches that the social world was constructed permeating our communities and institutions with strong gender based preconceptions. Any form of prejudice, be it race, age, ethnicity, disability, gender, must be eradicated if we

Ethical Governance

That is why ethical governance is essential, and that is why the governance cannot and should not be limited to a single person or to a few with great powers. Open and democratic ethical discussion allows decision makers to manage a consensus generating process. This is the only process able to come up with creative solutions that the majority can accept and adopt. Decisions are no longer flat, conventional and taken behind closed doors by those who do not really know what they are talking about. Decisions are taken by a committee that listens to stakeholders through an ethical process and analyses the substance and not the form of an issue. The members of a committee, however intelligent and involved, will not be always in full agreement. However, it is important that the members of the committee are able to recognise and accept their own filters and ethical values sets, to attach different weights to different perspectives and ethical principles to justify their decisions.

The Ethical Committee

It must be clear to everyone that there can be no ethical governance without a board or committee in which the essential components of the organisation itself are represented. This entity should take into account the views expressed by the ethical committee. The governance ethical choice

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want to preserve the basic ethical principle of justice. Traditional ethical theories suggest that ethical decisions should be free from emotions and context independent. Feminist ethics said, however, that emotions serve as guides to identify what is morally relevant in a given situation.

is the outcome of dialogues and discussions among its members. The effect of the ethical committee is the governance. It is therefore necessary to develop an ethical committee that serves as a reference system, to be used whenever an ethical problem has to be solved. This is an approach that any-

one can use. How to implement it? Follow the instructions:

Step One:

Make sure that the committee or the council is duly informed of facts and situation. There must be understanding and sharing of relevant information about the patient (or employee) and his family, organisational aspects of medical care (including the facts on the diagnosis made, treatment administered, results) and other relevant circumstances.

Step Two:

Identify who is involved and what is at stake for each of them; address the demands and views of all the stakeholders; understand and respect the views and concerns of the patient, family members, health managers, of all those who have a legitimate interest in the case.

Step Three:

Define the relevant ethical issues. Has the respect for patient autonomy been taken into account? Which role is played by fairness, charity, justice and other ethical principles? Motivation, responsibility, consequences, power games, possible biases are relevant to the final decision? If so, what are they?

Step Four:

Identify the ethically relevant aspects of the possible solutions and give them a weight. To weigh the relative importance of different ethical dimensions of possible actions mutually exclusive is quite difficult and always time consuming. Differences of opinion emerge, each of which must be evaluated with due respect. Many ethical dilemmas are not perfect. You should always consider the human limitations in identifying the solution. The team must resist the temptation to jump to the conclusion. The risk of neglecting important aspects of the problem has to be accounted for, as the possibility of not looking for alternatives. Doing nothing is obviously a decision. Possible consequences must be analysed and evaluated. Intentionally delaying the decision to give the team time to find a solution is ethically acceptable and certainly preferable to a hasty choice. If you need to postpone, it is necessary to define the deadline for a decision. Postponing indefinitely is never a solution.

Step Five:

Monitor the results and then inform the committee or the council of the consequences of

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the decisions and relative choices. Solving a problem may leave unresolved issues or be a great relief, especially if the issue is highly visible and may have important consequences for the organisation.

One should adopt the good habit of taking time to reflect on the experience gained and to identify lessons learned. It is the only viable strategy to learn from experience. This learning and change allows, when a similar ethical issue appears in the future, to have a much faster and better solution. Ethics is closely linked to the conduct and behaviour. In order to be credible it must be consistent over time. Obviously change and evolution are always welcome, but always respecting the consistency with the basic values and attitudes.

Governance and ethics are not the Cahier de Charge of just one person. It is worthwhile to repeat and emphasise it: Quality, Governance and Ethics always affect the entire organisation. The complex, multidisciplinary and interdisciplinary nature of the matter is that it cannot be the responsibility of one person. It has to be delegated to a committee and the organisation's mission must be the first of the guiding principles of the ethics committee.

How to Improve the Analytical Skills and Perspective of your Committee

First of all, it has to be up and running. The ethics committee should not depend on anyone. It can be placed in staff at the Directorate-General level, but must have absolute autonomy. In the Committee three essential components of any governance in healthcare must be present:

1. He who makes the decisions in the name and on behalf of the company or organisation - the CEO or the Chairman of the Board of Directors.
2. He who is responsible for the production, i.e. the Medical Director.
3. He who represents the patient.

Nobody has to be hired. It is a responsibility assigned on a voluntary basis, or by selection, to someone within the organisation. People working in the medical care department, properly trained, are good candidates. The director of ethics must be part of the Board of Directors, which will report on the decisions taken by the ethical committee. His/her task is the implementation, monitoring, maintenance and continuous updating of the code of ethics and decisions taken, once they are approved by the

board of directors. At each regular meeting of the ethical committee the agenda for discussion will list the current ethical problems under scrutiny, and/or those that have emerged to public attention in the time period between the previous and the actual meeting. The Director shall always convene the ethical committee in an emergency or crisis generated by an ethical dilemma.

Governance uses ethics to solve problems that an organisation needs to solve. Healthcare always has an ethical dimension. The Ethical Committee, "wise men committee", board of trustees or how you may name it, should have clear responsibilities in deciding how the organisation delivers its healthcare services, how to resolve conflicts of interest and which strategic objective should be selected. These decisions will then be brought to the attention of the Board of Directors and the final decision-makers. So, where health organisations are managed by a single

judge, with a governing board that never meets or has no effective power, ethical governance does not exist and never will.

The health management authorities are able to act as catalysts for the different abilities servicing the ethical governance of healthcare organisations.

No health department jurisdiction? No Ethical Governance.

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How Ethical is Your Governance?

1. Leadership, behaviour and management style

Presence of a charismatic leadership, highly competent, able to suggest and share the vision of the organisation which means having the ability to answer or knowledge to answer the question: "for whom and for what do we exist". Able to create a culture of excellence and honesty. Able to promote and encourage high ethical standards.

2. Communication

Dissemination of relevant information, policies, procedures and ethical standards to all shareholders and stakeholders, encouraging dialogue and feedback. Using appropriate language, and monitoring the effective understanding. Regular communication with individuals and community groups, making sure that people are truly informed.

3. Relationships, their role and delegated responsibilities

Building positive relationships allows employees, patients and their families to feel respected and appreciated, making them partners to achieve the desired results. Everyone must have clear roles and responsibilities. The leader must act to support and monitor activities continuously and transparently.

4. Accountability, which means who is responsible for what, when and why. Roles and responsibilities, processes and their management must be clearly defined by senior management, in particular by the director general. Monitoring and reporting of decisions taken. Transparency of decision making and sharing of rules.

5. Definition and management of standards Systems, processes, risk management, ambiguities, conflicts, accusations, legal problems. Rules and their justification. Mechanisms of evolution, processes of change. Premium/ penalty logic. Relevant health management direction, which must guarantee the proper functioning of the hospitals, should be aware of the problem, in order to put in place the due activities needed to implement and monitor appropriate policies that reflect the ethical sensitivity towards patients, their families and health workers.

The health management authorities are able to act as catalysts for the different abilities servicing the ethical governance of healthcare organisations.

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SUPPORTING CLINICAL GOVERNANCE DEVELOPMENT

By Dr. Philip Crowley, Maureen Flynn

Over recent years the Irish health service has placed an important emphasis on quality and patient safety by developing an infrastructure for integrated quality, safety and risk management with the aim of achieving excellence in clinical governance. In summer 2011 the Health Service Executive established a renewed focus on clinical governance development in Ireland. A dedicated national lead was appointed and a steering group supported by an international reference panel and interdisciplinary working group was established.

As part of the communications strategy the need for succinct information on clinical governance was identified. This article provides an overview of the clinical governance development material prepared for this purpose. The objective was to inform the wider health community of the vision, benefits and guiding principles for clinical governance along with gaining momentum and support for implementation of the processes.

The Irish Example

Ireland, similar to many other countries, has experienced a number of high profile adverse incidents that clearly identified deficits in healthcare. A number of incidents resulted in commissions of enquiry, expert reviews or investigations, each identifying the impact of inadequate clinical governance arrangements. In 2010 the Health Service Executive signed the *Patient Safety First* declaration. Through participation in this initiative, those involved committed to play their part in improving the safety and quality of healthcare services. The current focus on clinical governance development arises from this commitment.

The Irish Government, elected in 2011, has committed to further changes to the governance and structure of the health system and therefore the reform programme continues. The plan is for the: Establishment of an integrated care agency and a hospital care purchase agency; introduction of trust boards for networks of hospitals; and a model of universal health insurance (UHI) to be implemented over a ten-year period. Similar to other European countries, Ireland is facing the most challenging financial conditions ever in the history of the State. In the current economic climate there is the possibility that the drive to restructure healthcare and cut health costs may compromise good governance. It is imperative that in a restructuring and cost containment environment the spotlight is equally placed on clinical governance which must form a central part of the corporate governance arrangements for the health system. In order to achieve this, organisational structure and process that support clinical governance must be clearly defined, implemented and monitored.

What is Clinical Governance?

Clinical governance is not a new term. It was first

introduced by the World Health Organisation in 1983 and widely adopted in the UK, Australia, New Zealand and Canada in the late 1990s. A key characteristic of clinical governance is a culture and commitment to agreed service levels and quality of care to be provided.

In Ireland clinical governance is described as a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver. It is built on the model of the chief executive officer or equivalent working in partnership with the clinical director, director of nursing/midwifery and service/professional leads. For healthcare staff this

means specifying the clinical standards you are going to deliver and showing everyone the measurements you have made to demonstrate that you have done what you set out to do.

Formalised governance arrangements ensure that everyone working in the health and personal social services are aware of their responsibilities, authority and accountability and work towards achieving improved patient outcomes. Effective governance recognises the inter-dependencies between corporate and clinical governance across the service and integrates them to deliver high quality, safe and reliable healthcare.

Patient First	Based on a partnership of care between patients, families, carers and healthcare providers in achieving safe, easily accessible, timely and high quality service across the continuum of care.
Safety	Identification and control of risks to achieve effective efficient and positive outcomes for patients and staff.
Personal Responsibility	Where individuals as members of healthcare teams, patients and members of the population take personal responsibility for their own and others health needs. Where each employee has a current job-description setting out the purpose, responsibilities, accountabilities and standards required in their role.
Defined Authority	The scope given to staff at each level of the organisation to carry out their responsibilities. The individual's authority to act, the resources available and the boundaries of the role are confirmed by their direct line manger.
Clear Accountability	A system whereby individuals, functions or committees agree accountability to a single individual.
Leadership	Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.
Inter-Disciplinary Working	Work processes that respect and support the unique contribution of each individual member of a team in the provision of clinical and social care. Inter-disciplinary working focuses on the interdependence between individuals and groups in delivering services. This requires proactive collaboration between all members.
Supporting Performance	In a continuous process, managing performance in a supportive way, taking account of clinical professionalism and autonomy in the organisational setting. Supporting a director/manager in managing the service and employees thereby contributing to the capability and the capacity of the individual and organisation. Measurement of the patients and staff experience being central in performance measurement (as set out in the National Charter, 2010).
Open Culture	A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events are embedded in everyday practice and communicated openly to patients. Staff willingly report adverse events and errors, so there can be a focus on learning, research, improvement, and appropriate action taken where there have been failings in the delivery of care.
Continuous Quality Improvement	A learning environment and system that seeks to improve the provision of services with an emphasis on maintaining quality in the future not just controlling processes. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results so that the improvement is ongoing.

Table 1: Guiding principles descriptor



Figure 1
Guiding principles for clinical governance

Clinical Governance Vision

It is anticipated that the further development, implementation and ongoing commitment to clinical governance in the Irish health system will create an environment where each individual as part of a team:

- Knows the purpose and function of leadership and accountability for good clinical care;
- Knows their responsibility, who they are accountable to and their level of authority;
- Understands how the principles of clinical governance can be applied in their diverse practice; and
- Consistently demonstrates a commitment to the principles of clinical governance in decision-making.

Clinical governance should create a culture of trust, openness, respect and caring and should be evident among managers, clinicians staff and patients and it should be embedded within the overall corporate governance arrangement for the statutory and voluntary health and personal social services in realising improved outcome for patients.

Benefits of Clinical Governance Development

Clinical governance helps ensure people receive the care they need in a safe, nurturing, open and just environment arising from corporate accountability for clinical performance. The benefit of clinical governance rests in improved patient experiences and better outcomes in terms of quality and safety. This has resulted in the clinical governance approach being widely adopted internationally.

Guiding Principles for Clinical Governance Development

To assist health services providers a suite of ten principles for good clinical governance, for the Irish health context, have been developed with a title and descriptor. The principles developed by an interdisciplinary working group were reviewed for comprehensiveness, clarity and usefulness by health managers, clinical directors, senior nurses and midwives, health and social care professionals and patient groups. It is proposed that the principles inform each action

Figure 2: Clinical governance development matrix

Structures (Organisation wide): Clinical governance committee with lead (member of the executive/senior management team) for each process										Outcomes
Principles	Processes	Quality and performance indicators	Learning and sharing information	Patient and public community involvement	Risk management and patient safety	Clinical effectiveness and audit	Staffing and staff management	Information management	Capacity and capability	
	Patient first									
Safety										
Personal responsibility										Patient Care
Defined authority										Patient Experience
Clear accountability										Staff Experience
Leadership										Service Improvement
Inter-disciplinary working										
Supporting performance										
Open culture										
Continous quality improvement										
Structures (Local): Local directorate/ department/ practice meetings reflecting the principles and processes of clinical governance										

Source: Adapted from *Towards excellence in clinical governance: a framework for integrated quality, safety and risk management across HSE service providers (HSE, 2009); Achieving excellence in clinical governance: towards a culture of accountability (HSE, 2010); Better quality better healthcare (Victorian Government Department of Health Services, 2005); The Magic Matrix of Clinical Governance (Lewis et al. 2002).*

and provide the guide for managers and clinicians in choosing between options, when making decisions. It is recommended that each decision (at every level) in relation to clinical governance development be tested against the principles set out in Figure 1 and described in Table 1.

Clinical Governance Development Matrix

The matrix is designed to assist discussions on clinical governance (see Figure 2). It is based on the principles, required structures, process and anticipated outcomes of good clinical governance. The matrix is surrounded by the structures. Across the top are the core processes (in blue) required to drive effective clinical governance. On the left side are the guiding principles (in red). On the right are the patient outcomes in terms of care, experience and service improvement. For each department or hospital directorate it is anticipated that the interdisciplinary team will discuss whether the principles are reflected in how the clinical governance structures and processes operate. It is not intended that text be inserted in each cell of the matrix as this is a guide to discussion.

Conclusion

A bottom up and top down approach is being used to further clinical governance development in supporting the national clinical programmes by providing a clinical governance checklist for use across the 32 programmes. The completion of the checklist assists the clinical leads in determining their clinical governance arrangements. At the same time

we are working closely with front line staff in the use of a assurance check as a means of determining their clinical governance arrangements. Further support documents are currently under development.

The mantra for clinical governance development is we are all responsible and together we can create a safer healthcare system.

Acknowledgement

With thanks to the members of the steering group, international reference panel and working group for clinical governance development. Their contribution is central in advising on the initiative, the preparation of the materials and piloting their use in practice.

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FIGHTING INFECTION WITH EUNETIPS

The European Network to Promote Infection Prevention for Patient Safety

By Silvio Brusaferrò

Last October in Venice, Italy, 16 European professional and scientific societies from 14 countries involved in infection prevention and control formed EUNETIPS- a European network to promote infection prevention for patient safety. The goal of EUNETIPS to promote better cooperation among nations, to share experiences, to promote and support initiatives in infection prevention for patient safety particularly at a European level, recognising and making the most of all single member societies.

EUNETIPS promotes:

- Activities to prevent and control infection risks including patient and staff movement throughout Europe;
- Engagement of politicians, caregivers and individuals in addressing:
 - public health implications, and
 - challenges and opportunities related to infection prevention.
- Exchange of experiences and harmonisation of activities for both professionals and 'customers';
- Active partnerships in promoting patient safety in Europe; and
- Formal links, inter alia, with World Health Organisation (WHO), European Centre for Disease Control and prevention (ECDC), International Federation of Infection Control (IFIC) and other institutions and professional and scientific associations.

European-Wide Collaboration

In Europe many scientific and professional societies exist to support research and to promote knowledge, attitudes, good practices and training on prevention and control of this risk. Although they have long history of successful initiatives, most of them are nationally based.

Indeed, there is certainly no shortage of HCAI prevention programmes developed by European countries. The

problem is they are not connected and there is a clear lack of homogeneity due to differences in histories, health-care systems, available resources and epidemiological settings. These differences are not easy to align, even if, in recent years, two European DG SANCO scientific initiatives (Improving Patient Safety in Europe (IPSE) and Hospital in Europe Link for Infection Control through Surveillance (HELICS)) developed a European consensus on standardisation or harmonisation of surveillance methods, standards, indicators and guidance on infection prevention and control and training.

Bringing Scientific and Professional Associations Together

National scientific and professional societies in many cases do not have regular formal contact with each other, with the exception of participation in international activities such as scientific projects and congresses. This is a critical point, as throughout Europe there is a consistent untapped resource of experiences, knowledge, scientific skills and training opportunities that could be known, shared, and finally become part of a common platform.

Scientific and professional societies play an important role in complementing and enhancing actions, initiatives or recommendations developed at the national or European levels. Whilst pro-

fessional and scientific organisations often serve different purposes for their respective membership, the unique opportunity to work together to develop, support and crucially implement and influence changes in practice through the network should not be underestimated. Medical, nursing and scientific network members can reach straight to a vast number of professionals both with meetings and publications, and have the ability to sense the climate in the field, giving them a unique opportunity to support programmes, to launch and monitor specific campaigns.

Recently, there have been some important EU institutional initiatives: The European Centre for Disease Control and Prevention (ECDC) set up a specific team on Healthcare Associated Infections (HAI) and in 2009 European Commission published a Council Recommendation on patient safety, including the prevention and control of healthcare associated infections where HAI risk and ways to control it are mentioned specifically.

A number of European scientific and professional societies involved in HAI prevention are convinced that the present epidemiological situation, the frequency of HAI, and cross-border movements of citizens, patients and healthcare staff needs international initiatives, particularly at a European level. They believe that it is necessary to cooperate and to share their expe-

periences in Europe considering it in a wider sense and not just on European Union political borders.

The Key Challenges in Infection Prevention in Europe

1. Patient safety

- Different infection prevention approaches throughout Europe;
- Patient and staff movement through Europe; and
- Compliance with infection prevention activities and education.

2. Public health implications of

- Individual clinical interventions; and
- National/regional policies.

3. Networking

- Exchange experiences and knowledge; and
- Defining priorities for action or research.

Initiating a formal network is considered the best way to start cooperation and collaboration because it requires members:

- To respect and to assume the value of histories, traditions, activities and specificities of the existing scientific and professional societies;
- To leave each country to evolve at its own pace and to respect local characteristics;
- To retain formal contact and to

share initiatives and experiences, to promote joint projects, etc.;

- To guarantee mutual support both for critical situations and for specific needs;
- To be more effective in lobbying and advocating HAI prevention at the different levels (regional, national, international);
- To be more visible for the media, for public opinion and for the professional and scientific arena; and
- To make a wide spread network able to support work programmes, guaranteeing expertise, channels of communication and feedback available to the EU, ECDC, international institutions and other stakeholders.

Full members are drawn from:

(a) Professional and/or scientific societies based in Europe with a strong commitment to infection prevention for patient safety ;

(b) A conglomerate (group) from a given European geographical area where no relevant European discipline or specialty association exists;

(c) Professional and/or scientific societies based in Europe that, among the others, have an interest in infection prevention for patient safety without a formal subgroup; and

(d) Regional, national or supranational

institutions financed and/or organised on a state or governmental level that have a commitment to infection prevention for patient safety.

The network also includes corporate supporters that may be admitted from organisations representing manufacturers of products and commercial enterprises offering services for infection prevention in healthcare organisations.

This is Only the Beginning

This is a start. Seventeen professional and scientific societies from Belgium, Bulgaria, Croatia, Denmark, France, Germany, Hungary, Kosovo, Italy, Malta, the Netherlands, Romania, Serbia, Spain and the UK signed the statutes but at least three other countries have expressed an interest and are likely to join in the next few weeks. We want to engage as many societies as we can. At the moment the network has its legal domicile in Italy (SIMPIOS, via Farini n.81. 30 Milano info@simpios.org) and the website is managed by the German Society of Hospital Hygiene.

www.infection-prevention.eu

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In 1972 Abbott developed the first hepatitis surface antigen test, AUSRIA-125, beginning our history as the world leader in hepatitis diagnostics.

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INTERVIEW: HEINZ KÖLKING

By Lee Campbell

This year we are including a new interview section in *(E)Hospital*. How better to kick off this new feature with an interview with Heinz Kölking, the President of EAHM. Managing Editor Lee Campbell caught up with Mr. Kölking to reflect on the main events of 2011 and to look ahead at what is to come for 2012.



2011 saw the start of your mandate of President of EAHM. How was your first year in charge and what did you accomplish?

As I have been active member of the association (Board and Executive Committee) for a long time now there is a certain continuity within the Presidency. The main activities of my Presidency focus on the implementation of the results of our reflection process; this is a prerequisite for the future success of our association.

In addition, we prepared a very successful conference with our like-minded European associations, HOPE and the AEMH.

In your opinion, what were the three most important developments in 2011 for European healthcare and hospital management and why?

The most important development in European healthcare was and is the European Directive on Patient Rights in Cross-Border Healthcare. Due to its significance, it was the main focus of the conference in Dusseldorf.

Demography is another huge issue for European hospital management. Increasing numbers of ageing patients require treatment and there are less young people available to provide this care. The average age of healthcare workers is also increasing. These developments require new management techniques.

Of course, debate on the future of the euro and the financial crisis was also an important issue in 2011. The effects of this crisis will also concern hospitals.

Looking forward to this year. What do you think will be the three most important issues in 2012?

The financial crisis will continue to affect our hospitals. Managers from across Europe are facing the challenge of securing healthcare delivery with ever tighter budgets.

A growing problem, in Germany at least, is the lack of specialists and skilled professionals. This requires new methods of recruitment, personnel management and organisation in our hospitals.

The first joint European Hospital Conference took place in November. What is the significance of this event? Will there be a similar conference in 2012?

The conference was a great success with informative presentations from experts and discussions focused on the impact of the new European Directive on cross-border health for European states and for hospitals in particular.

Of particular significance was the collaboration of hospital management and senior clinicians. Together with the policy representatives, the prospects for healthcare in Europe with regards to the new directive and European policy in general were discussed. Through this conference the great value of healthcare for European cohesion and development has become particularly clear and the health minister of Luxembourg set high standards for future developments.

This issue, our cover story focuses on "Good Governance". What is your idea of good governance?

Good leadership, or governance means to me to create particular conditions so that employees can have success in terms of the agreed targets. This includes, above all, trust. To achieve this, a culture that ensures trust must be created and maintained. Managers must set an example here.

In order to implement good governance it is good practice to make arrangements within the company and provide:

- A model with the business goals of the organisation;
- Principles of leadership and cooperation (e.g. error handling, conflict management); and
- Instruments for implementation (e.g. structured annual employee meetings, staff introductions, rules for meetings).

This issue we have included a pharmacy supplement. Undoubtedly one of the most expensive departments in the hospital, how important is it for hospital managers to keep up to date with developments in pharmacy?

With shrinking budgets, hospital managers are constantly being tasked to identify cost effective solutions whilst maintaining both the quality of the healthcare services and the performance and efficiency of their hospital. Pharmacy, being one of the major cost centres within the hospital, often finds itself under the microscope. Hospital medicine use has effects on ambulatory care, is difficult to manage and is frequently used in complex clinical situations. It is therefore, of paramount importance that the hospital manager is kept abreast of developments within the pharmaceutical field.

What is the most difficult management decision you have ever made and why? (Please explain the context and result)

I cannot name any individual one(s) here but the hardest are always personnel decisions. In order to make these decisions responsibly we must follow the rules of Good Governance.

Please pass on to your colleagues

(E)HOSPITAL PHARMA SUPPLEMENT



CRITICAL ROLE FOR CLINICAL PHARMACOLOGISTS AND HOSPITAL PHARMACISTS IN ENHANCING PRESCRIBING EFFICIENCY FOR NEW AND EXISTING DRUGS

By Brian Godman et al.

The rapid growth of pharmaceutical expenditure driven by changing demographics, strict clinical targets, rising patient expectations and the continued launch of new expensive drugs has become a contentious issue in the healthcare sector. New expensive drugs include new biological drugs marketed at considerably higher costs than previous standards, which now account for over 50% of in-patient drug costs among hospitals in Marseilles. This is causing concern with expenditure growing at approximately 20% annually leading to rationalisation of other hospital services.

If not addressed, this growth will compromise the European ideals of comprehensive and equitable healthcare exacerbated by the limited health gain of many new drugs, including new cancer drugs, despite high prices (Table 1). In their assessment of the value of new drugs between 2001 and 2007, the Transparency Commission in France concluded that only 13% had 'major' or significant health gain with the majority (78%) having only minor or no improvement. The Scottish Medicines Consortium, an HTA body established in Scotland to give rapid advice on the clinical and economic value of new medicines, in their analysis of 281 new products and indications between 2002 and 2008 also found limited health gain, with QALY (Quality Adjusted Life Year) gains averaging just 0.097 years and no more than 12% offering >1year.

Stakeholder Responses

These concerns led to activities among European stakeholders, including healthcare managers, to further improve prescribing efficiency. They include:

- Greater co-ordination of national, regional and local activities pre and post launch to improve

the 'managed entry' of new drugs;

- Raising concerns with 'risk sharing' arrangements (Table 2) as pharmaceutical companies seek new ways to enhance the value and/or reduce the budget impact of their new drugs;
- Formularies/ guidance in hospitals along with benchmarking of subsequent physician prescribing; and
- Greater co-ordination between hospitals and ambulatory care of drugs prescribed to maximise overall efficiency.

Improving the Managed Entry of New Drugs

Clinical pharmacologists and pharmacists are also playing an increasing role to optimise the managed entry of new drugs to ensure available resources are used wisely. These activities include:

- Undertaking early detection of new drugs likely to have a major budget impact. This process is known as 'Horizon Scanning', and is increasingly linked to all decision-makers in healthcare.
- Forecasting of drug expenditure in each major

ATC class. This includes an assessment of the likely role/ patient population for new drugs based on their anticipated net benefits in all/ sub-populations and possible prices, along with assessments of the financial consequences of new guidelines as well as current products likely to lose their patent during the coming years.

- Performing critical evaluations of new drugs pre-launch including development of guidelines/ guidance and protocols influencing post launch utilisation. Decisions incorporated into regional guidance/ hospital formularies. This includes assessment of comparators, doses and endpoints especially if concerns with unproven surrogate measures.
- Developing guidance for accepting/ assessing future risk sharing arrangements for new drugs (Table 3).
- Retrospective assessments of the benefit of new drugs in practice using observational data, typically registries. This is prevalent for new expensive biological products in Italy and growing for instance in France, e.g. natalizumab in multiple sclerosis, and Sweden.
- Continuous monitoring of prescribing and expenditure of new drugs in hospitals and primary care post launch with further educational activities if needed; acknowledging that it may be difficult to obtain accurate drug utilisation figures in hospitals.

Ongoing Activities with Existing Drugs

Best practices include:

- Providing clear updated recommendations for the treatment of common diseases, preferably valid for both primary and secondary care.
- Follow-up of prescribing guidance in practice with educational and other activities to enhance adherence. This includes continuous

Drug and amount used until disease progression	Total costs and estimated increase in survival for selected cancers
Cetuximab (6975mg)	<ul style="list-style-type: none"> • 59,879 euro • 1.2 months (Non-small cell lung cancer)
Bevacizumab (13200mg)	<ul style="list-style-type: none"> • 67,507 euro • 1.5 months (metastatic breast cancer)
Erlotinib (112 x 150mg tablets)	<ul style="list-style-type: none"> • 11,705 euro • 10 days (pancreatic cancer)
Sorafenib (682 x 200mg tablets)	<ul style="list-style-type: none"> • 25,542 euro • 2.7 months (renal cell carcinoma)

Table 1: Drug costs and health gain of selected recent anti-cancer biological drugs

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Table 2: Concerns with patient access schemes including outcome guarantee schemes (part of risk sharing arrangements)

Logistic concerns	Administrative concerns
<ul style="list-style-type: none"> Whether hospitals can cope with time scales for refunds, e.g. necessary time between monitoring disease progression and the next physician visit Whether hospitals can accept free goods/ rebates from pharmaceutical companies Whether refunds to hospitals are passed back to the 'payers' in practice, i.e. not happening in 47% of UK hospitals with the current bortezomib scheme 	<ul style="list-style-type: none"> Capacity to manage such schemes with current staff levels for those requiring considerable support, e.g. 73% of hospitals in the UK do not have the capacity to manage the bortezomib scheme Time taken to administer the schemes Communication between physicians and pharmacists to ensure refunds/ rebates, e.g. every missed claim for bortezomib loses 14,269 euro Transparency – whether schemes are open to all pertinent products for the patient population and whether distorts funding for other products in high priority disease areas

monitoring and subsequent feedback to prescribers and healthcare managers.

- Close working between counterparts in hospital and ambulatory care to optimise prescribing efficiency. This can include active therapeutic substitution.
- Aggressive contracting in hospitals.

Examples include University College Hospital, who recently instigated a drug substitution policy for ARBs. All admitted patients prescribed other ARBs than generic losartan for hypertension are automatically switched to losartan, unless intolerance concerns, as all ARBs seen as interchangeable. Any patient prescribed another ARB for heart failure also switched to generic losartan with doses increased if less than maximal doses currently prescribed. Similar switch programmes are in operation across all sectors in the UK saving an estimated £20mn/ month (24mn) if fully implemented.

Clinical pharmacologists, hospital pharmacists and pharmacists working for health authorities are increasingly working together to standardise common drugs to maximise prescribing efficiency across both sectors. This is driven by more standard drugs losing their patents, with estimated global sales of up to \$US100bn/ year of products likely to lose their patent between 2008 and 2013. Failure to co-ordinate activities increase costs and/ or limit potential savings in reality. Examples of the former include:

- In Scotland, contracts for hospitals increasingly take account of efficiencies across both sectors. This built on historic examples, e.g. Isosorbide Mononitrate MR tablets were heavily discounted in hospitals although costs in the community were approximately 11 euro/month/ patient higher than the lowest cost product (factor of 30). This resulted in some Health Boards working outside the contracting system to maximise whole system efficiencies until changes were made.
- The Ministry of Health in Lithuania endorsing

the continued prescribing of patients' medications in hospitals provided patients with chronic conditions have been on the medication for at least a month. This initiative was introduced to combat possible switching in hospitals to more expensive medications, which were typically donated by companies to enhance their prescribing post discharge.

- Separate guidance on suggested common drugs ("Wise Drug List") for out-patient hospital specialists (in operation since 2005), building on the guidance for primary care physicians. This includes for instance nutritional supplements, parenteral antibiotics and cytotoxics. The driving force being the recognition that hospital specialists heavily influence prescribing in ambulatory care.

Activities used by clinical pharmacologists and pharmacists working on behalf of health authorities to improve the quality and efficiency of ambulatory care prescribing include the 4Es (Education, Economics, Engineering and Enforcement). Recent research has shown that multiple and intensive interventions are more successful than single interventions (PPIs and statins), although prescribing restrictions can be successful on their own. Expenditures for PPIs and statins (/1000 inhabitants/ year) varied over tenfold between

patient populations depending on the extent and the intensity of initiatives undertaken. Concurrent with this, a recent ecological study has shown no appreciable impact on care whether patients are prescribed formulary drugs such as generic simvastatin or non-formulary drugs such as rosuvastatin; however, appreciable differences in expenditure.

Conclusion

Clinical pharmacologists and hospital pharmacists can appreciably enhance the quality and efficiency of prescribing of both new and existing drugs across all sectors. Failure to act and/or get involved will increase the prescribing of expensive patented drugs where less costly alternatives are available, without affecting care, and compromise the ability of European countries to continue to provide comprehensive and equitable healthcare.

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Potential criteria

- The objectives and scope are explicit and transparent
- The new drug is a novel treatment with envisaged health gain backed up by translational science and delaying treatment may not be in key stakeholders' interests
- There are few effective treatments currently available
- The new drug has long term safety concerns, which are difficult to fully assess in Phase III trials, which need to be factored into 'value' considerations
- The likely health gain can be determined within a limited time frame
- Patient access schemes improve reimbursement considerations having factored in all administrative costs including follow-up
- Price: Volume schemes help limit the possible budget impact for health authorities and health insurance agencies; especially important where currently limited demand side measures to optimise usage post launch

Table 3: Potential criteria for accepting future risk sharing schemes

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*Schmidt MG, Copper Touch Surface Initiative. Microbiology and Immunology, Medical University of South Carolina, Charleston, USA. BMC Proceedings 2011, 5 (Suppl 6):D53 [Oral presentation delivered at 1st International Conference on Prevention and Infection Control, June 29-July 2, 2011, Geneva, Switzerland].

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DRUG DELIVERY SYSTEMS

AN OVERVIEW

By Rajan K. Verma, Mitesh Nagar, and Purushottam Nagar

Today the pharmaceutical industry is caught between downward pressure on prices and the increasing cost of successful drug discovery and development. The average development cost of a new chemical entity (NCE) is approximately 0.5–1.5 billion US dollars and may take 10–15 years for development. It often costs substantially less to develop a new drug delivery system, which results in improved efficacy, reduced dosing frequency, and lesser side effects. Drug delivery systems are chemistry or biology based dosage forms intended to improve or control the exact amount and rate of drug delivery to the systemic circulation (e.g. Liposomes, osmotic pumps, transdermal patches, etc). By developing a new delivery system, an old drug molecule can get a “new life”, thereby, increasing its market value, competitiveness, and extended patent life.

To achieve marketing approval, a molecule undergoes different development phases and a variety of studies need to be carried out. A new molecule typically involves preclinical testing in animals followed by clinical trials in humans, after which the application is submitted to regulatory agencies for review. In case of new delivery system, since drug molecule is already known, there is no need to carry out full clinical trials.

Types of Drug Delivery Systems

Current drug delivery systems can be categorised as Oral, Pulmonary, Transdermal, Injectable, etc.

A. Oral Drug Delivery Systems

Oral route is one of the most extensively used routes of drug administration because of its obvious advantages of ease of administration, improved patient compliance, and convenience. In immediate release (IR) dosage forms, there is little or no control over release of drug from the dosage form, which most often results in constantly changing, unpredictable, and often sub- or supra-therapeutic plasma concentration. Modified release (MR) dosage form refers to a dosage form for which the drug-release characteristics of time course and/or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms. Extended release (ER) and delayed re-

lease (DR) dosage forms are two types of MR dosage forms.

ER dosage forms are formulated to make the drug available over an extended period after ingestion. This allows a reduction in dosage frequency compared to the drug presented as a conventional dosage form (e.g., an IR dosage form). These products typically provide numerous benefits, including greater effectiveness in the treatment of chronic conditions, reduced side effects, greater convenience, and higher levels of patient compliance due to a simplified dosing schedule. The term controlled release (CR) and extended release are often used interchangeably. A number of design options are available to control or modulate the drug release from a dosage form. Majority of the oral dosage forms fall in the category of matrix, reservoir, osmotic systems, or ion exchange resins. DR dosage forms release the drug at a time other than immediately following oral administration.

B. Pulmonary Delivery Systems

Pulmonary delivery has been until now primarily used for the treatment of respiratory disease. Recently, the lungs' natural ability to transfer molecules into the blood stream has been utilised for delivering drugs to the systemic circulation. This method is a noninvasive alternative to the painful injections and can lead to rapid onset of action and good bioavailability. Inhalation devices broadly fall into three categories: Pressurised metered-dose in-

halers (MDIs), nebulisers, and dry powder inhalers (DPIs). MDIs contain drugs as a solution or a suspension of fine particles in a liquefied propellant held under high pressure. The drug is emitted through an orifice from a metering valve. Nebulizers, on the other hand, do not require propellants and can generate large quantities of small droplets capable of penetrating into the lung. DPI is a device that delivers medication to the lungs in the form of a dry powder and requires some procedure to allow a measured dose of powder to be ready for the patient to take. The drug is typically held either in a capsule for manual loading or a proprietary form from inside the inhaler itself. Once loaded or actuated, the patient puts the mouthpiece of the inhaler into their mouth and takes a deep inhalation, thereby delivering the drug.

C. Transdermal Drug Delivery Systems

Systemic delivery of drugs via transdermal route has generated a considerable interest during the last decade. Transdermal drug delivery systems (TDDS) deliver drugs through the skin into the systemic circulation at a predetermined rate, thereby avoiding metabolism in the gastrointestinal tract and liver. Therefore, the amount of active ingredient required for transdermal delivery can be significantly less than that for oral systems. TDDS provide constant blood levels for one to seven days and increased patient compliance.

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D. Injectables

The research efforts in the field of genomics are expected to accelerate the discovery of new therapeutic biomolecules, placing an increased demand on the development of delivery systems for these drugs. This class of drugs are usually characterised by their large size, fragile nature, short biological half-life, and limited ability to cross cell membranes. These properties along with the methods of administration of biopharmaceuticals can limit their clinical applications to certain diseased states that warrant the expense and inconvenience of frequent injection. Several parenteral depot formulations based on biodegradable polymers such as microspheres and implants have become commercially available to improve the efficacy and prolong activity of several peptide and protein drugs.

Implants can be surgically implanted inside the body from where the drug release takes place at a controlled rate and the duration can be as long as 12 months. Another option is use of biodegradable implants that can be injected using a large gauge needle and they offer the advantage of a single procedure (no need to remove the implant).

Injectable MR dosage forms, typically a matrix is fabricated into an easily injectable form for administration at the desired tissue site (e.g., subcutaneously). The dosage form may be either a solid, gel, or liquid. Solid dosage forms such as biodegradable microspheres consisting of poly(lactic-co-glycolic acid) have been used as an injectable depot delivery system of small-molecule drugs, peptides, and proteins. The injectable gels usually consist of a solvent to dissolve the matrix and/or the therapeutic agent and they form an "implant-like" depot upon injection.

E. Ophthalmic (Ocular) Drug Delivery Systems

Recently, there has been increased attention for ophthalmic drug delivery as these delivery systems require less frequent administration than eye drops, allow continuous drug delivery, and extend the duration of drug action by enhancement of corneal absorption. Ocular delivery systems include viscous solution and hydrogel delivery systems, ocular inserts and contact lenses.

F. Vaginal Drug Delivery

The vagina has been studied as a favorable site for the local and systemic delivery of drugs and this route offers certain advantages, such as avoidance of gut and hepatic first pass metabolism, reduction in gastrointestinal and hepatic side effects, and local targeting of drugs to the reproductive organs. Vaginally administered agents and formulations are mainly being developed to provide "dual prophylaxis" for contraception and protection against microbial infections including AIDS and other sexually transmitted diseases (STDs). Drug delivery technologies that have been used for vaginal drug delivery include the intravaginal ring (IVR) and VagiSite bioadhesive technology.

Future Research and Conclusions

As discussed in this article, drugs can be delivered to a patient through many different delivery systems, including oral, transdermal, injection, pulmonary route, etc. With the sequencing of the human genome, biotechnology companies are rapidly developing a large number of peptide- and protein-based drugs and it is expected that in the next few years, this category will constitute a major portion of the new drugs. These biopharmaceuticals present drug delivery challenges because these are often large molecules that degrade rapidly in the blood stream. Moreover, they have a limited ability to cross cell membranes and generally cannot be delivered orally. The possibility of other routes of administration will be dictated by the drug, disease state, and desired site of action. Some sites are easy to reach such as nasal, buccal, vagina, etc, while others are more challenging to access, simplest example being the brain. Gene therapy is also likely to be one of the most exciting growth sectors as biotech companies become involved in drug delivery.

Nowadays, apart from the research in the technologies mentioned in this article, individualised dosing has emerged as one of the important focus areas. A recent article gives a very good overview of solid and liquid drug dosage forms used in personalized medicine. Solid dosage pen is such a device delivering a swallowable solid monolithic oral

dosage form containing individual doses. The device consists of a drug loaded rod (can be manufactured by an extrusion method) that can be fed forward.

Recent advances in the field of micro-fabrication have opened up the possibility of developing a new class of programmable drug delivery systems. One such device is microchip based delivery system. Chip consists of an electrolyte impermeable substrate, which separates the series of reservoir consisting of the component(s) to be released. Based on electrochemical reactions, the membrane disappears and the drug(s) are then diffused or release from the reservoir. Their small size and potential for integration with micro-electronics coupled with ability to store and release drug(s) on demand opens up a whole new world of possibilities in drug delivery.

In conclusion, the market for drug delivery systems has come a long way and will continue to grow at an impressive rate. Today's drug delivery technologies enable the incorporation of drug molecules into new delivery systems thus, providing numerous therapeutic and commercial advantages. A large number of companies are involved in the development of new drug delivery systems, which is evident by an increased number of products in the market and the number of patents granted in the recent past. Tomorrow's drugs will definitely be more challenging in terms of the development of delivery systems, and pharmaceutical scientists will have to be ready for a difficult task ahead.

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SAFE HANDLING OF HAZARDOUS DRUGS

Risk Management, Staff Training and Robots

Jill Davis, Interview by Lee Campbell

Firstly what are cytotoxic drugs and what do we use them for?

Cytotoxic drugs are drugs that kill cells. They are mainly used to treat cancer but can be used for other therapeutic indications e.g. rheumatoid arthritis, multiple sclerosis. Cytotoxic drugs mainly kill cells through their action on cell reproduction, affecting cell DNA division. They are indiscriminate in their effect and will kill any type cell that commences cell division to reproduce. Most cancers, especially in the early stages of the disease, are dividing rapidly and thus are the main target for cell kill. However, some cells within the human body also divide more often than others and it is these cells that are also affected by cytotoxic cells e.g. blood cells, the entire lining of the gastro-intestinal tract and skin and hair cells. Thus the most common toxicities we see in patients being treated with cytotoxic drugs are due to the death of non cancer cells. Low white blood counts leading to increased susceptibility to develop infections and less ability to fight infections, low platelets leading to less ability for blood to clot and an increased risk of bleeding and low red blood cells leading to anaemia and a need for blood transfusions.

What sort of danger do they pose for staff and patients?

As well as the general toxicities noted above, cytotoxic drugs have unique toxicities of their own. They may be carcinogenic, mutagenic and/or teratogenic. Thus patients receiving cytotoxic drug therapy have developed second cancers from their treatment (carcinogenic), have changes to their genetic DNA that increase their risk of developing cancer (mutagenic) and have increased foetal deaths and birth abnormalities (teratogenic). Second cancers do not appear for many years after treatment has ceased. These second cancers are not secondary cancer or metastases but totally new cancers. In the past, many patients did not live long enough after treatment to see the development of these second cancers but this is not the case today.

In addition to the direct toxicity of the drug, the administration of the drug can also pose a risk. Many cytotoxic drugs can damage/kill tissue if they are mistakenly injected into the tissue surrounding the vein instead of into the vein. Today's patients are advised of the possible toxicities of their treatments but as they expect to gain from the treatment (after all they have cancer) and their treatment is limited to a specific number of different drugs and to a certain time frame, the possible benefits outweigh the possible risks.

For staff it is a different matter. They can expect no benefit from being exposed to cytotoxic drugs. They handle many more drugs than a patient would receive and they do this over long periods of time, not a set course of treatment. So while a patient receives much higher doses, staff handling cytotoxic drugs may be exposed to low levels of many different drugs over a long period of time. Exposure may be via skin contact, inhalation of aerosols/drug particles or needle stick injuries. Adverse effects seen from this exposure include increase in mutagenicity, change in blood counts, foetal loss, foetal malformation and contact dermatitis. The main concern is the possibility of development of a cancer. It is impossible to quantify this risk, especially as there is rarely an immediate effect seen, but it is essential to minimise exposure. After all, employees are entitled to a risk free environment in which to work. Employers may have scoffed once at the possible toxic effects of asbestos exposure, again a problem with a long lag time and we do not want this delayed adverse outcome to happen with exposure to cytotoxic drugs.

Evidently the handling of these drugs is a huge safety issue for both pharmaceutical companies and also hospitals and health-care institutions. Could you tell us about the main safety precautions?

Pharmaceutical company employees have the biggest risk as they deal in very large volumes of drugs during the manufacturing process. However, they also have the best possible resources to ensure employees do not come into contact with the drug and re-

quire the use of 'space-suits' with external respiratory devices. Staff manipulating the drugs to create an individual dose are most at risk. Due to the requirement to individualise doses (based on patient parameters on the day of treatment) and the short expiry date of prepared doses, cytotoxic drug doses must generally be prepared on the day of treatment at the site of administration of the treatment. Many are provided as powders and must be reconstituted to be given as injections and even those provided as liquids must be handled to withdraw the correct dose and place it into an appropriate administrative format (e.g. into an IV infusion bag or a syringe or an ambulatory delivery device). Those administering the dose are also at risk although this risk is less as no actual manipulation of drug is required and the drug is often well diluted. Disposal of drug is also vital. All equipment such as used/partially used drug vials, used syringes, needles, empty IV infusion bags and IV giving sets, dressings and bandages must be appropriately segregated and stored prior to disposal. Waste must be identified as cytotoxic and transported and disposed of in a way to protect the environment from contamination. Incineration at over 1000°C is recommended.

What methods can hospitals use to reduce contamination as much as possible?

Institutions should review their need to create doses on site. If the use of cytotoxic drugs is limited, they should be purchased pre-prepared from an external source (such as a commercial company or a larger institution). If doses are required to be produced on site, their preparation should be centralised and done only by trained staff. Specific secure preparation areas are needed with clean rooms containing laminar flow cytotoxic drug safety cabinets or pharmaceutical isolators. Use of closed needleless systems further reduces possibility of exposure. Personal protective equipment is essential not only for those

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preparing the cytotoxic drug doses but also for those administering the doses, for staff unpacking purchased drug from suppliers (drug contamination has been found on the outside of newly purchased vials, glass vials may have broken) or for staff handling/moving waste. Other decisions can reduce the risk of exposure. Where there are choices always purchase vials not ampoules, liquids not powders, drugs packaged in plastic or plastic coated glass rather than glass alone. Staff transporting cytotoxic drugs must have training to ensure correct procedures are carried out should a spill occur. All of these require a substantial financial investment and on-going financial commitment.

Risk management for these processes must be key. In general what protocols and processes are put in place by the management?

Yes risk management is the key issue. If an institution is using cytotoxic drugs within its premises, such use crosses many departments and staff with different knowledge. Education is the key to risk minimisation. Written policies and procedures need to be developed, promulgated, implemented and evaluated throughout the institution. Effective planning and design of the workplace, 'best practice' control measures and specialised equipment, stringent safe handling procedures, training and education of employees (on commencement and at regular intervals), provision of personal protective equipment (and ensuring its use), instituting a staff health monitoring programme, ensuring specialised laundry of non-disposable equipment and arranging appropriate waste disposal of contaminated items are all vital.

Clearly successful staff training is essential. In general how are staff trained and is this a continuous process?

In general staff are trained on-the-job by experienced practitioners. Many institutions have developed their own in-house training modules. At a minimum, staff preparing cytotoxic drugs must be validated in aseptic technique (using broth manipulations) and in the specialist requirements for handling cytotoxic drugs. Validation is recommended to be performed yearly.

Prior to introducing any new techniques required for specific manipulations, time to provide full training to those handling the drugs must be available. Since staff preparing the cytotoxic doses are often 'isolated' in their secure cleanrooms, it is imperative that these training requirements are considered well in advance of the patient arriving at the hospital ready to receive their treatment. Communication is a key issue.

Many healthcare facilities are introducing robotics into the process. Can this really help with safety and prevent dosage errors?

The use of robots in drug dose preparation does certainly reduce the opportunity for exposure but does not eliminate it. The robot still has to be loaded and the final products handled and transported. Not all drugs are able to be handled by a robot. Robots are best used when large preparation runs are planned rather than for individualised doses. In addition, robots are very expensive. Robots do not replace the need for experienced staff but they can supplement preparation activities. Robots can work non-stop but they cannot operate unsupervised and are best utilised in very large operations such as a major institution supplying surrounding smaller institutions or in commercial operations. I am not familiar enough with the use of robots to comment on their ability to prevent dosage errors – however, as humans have to programme the robot, I do not see how human error would be totally eliminated.

In your opinion what does the future hold for the safe handling of hazardous drugs?

It is really pleasing that the current breakthroughs in cancer treatment are not reliant on cytotoxic drugs. Most new treatments involve targeted therapies, vaccines and monoclonal antibodies. The risks handling these drugs are much reduced compared to cytotoxic drugs. Even new forms of cytotoxic drugs such as liposomal forms are much less toxic to handle and administer BUT much more expensive to purchase and cannot be simply substituted for the parent drug. So while I think the percentage of patients requiring cytotoxic drugs is reducing, unfortunately the numbers of patients requiring treatment is increasing. Cytotoxic drugs are also becoming progressively cheaper compared to the newer treatments and they still remain the treatment of choice in many cancers.

In the foreseeable future I do not see an elimination of the use of cytotoxic drugs and as such it behoves us to create as risk-free as possible an environment in which these drugs can be prepared, administered and the contaminated waste disposed.

Interviewee:

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Top Tips for Hospital Managers

- Small institutions should eliminate the risk by outsourcing the preparation of cytotoxic drugs. Otherwise, centralise the preparation of cytotoxic drugs under the control of the pharmacy department.
- Involve the appropriate people within the pharmacy department in all aspects of planning and design and operation of cancer chemotherapy services.
- Ensure risk is minimised by i) separating people from the drugs by use of barriers (eg protective clothing, closed-systems, preparation in clean-rooms) ii) ensure containment equipment is well maintained (eg regular servicing of clean-room equipment) iii) only allow trained and validated staff to prepare drugs.
- Ensure written policies and procedures are developed, promulgated, implemented and evaluated throughout the institution.
- Communication is key.
- While protecting your employees from the hazards of cytotoxic drugs, and creating a safe work place for them will not be inexpensive, other hospital equipment is not cheap either e.g. compare to the cost of one radiotherapy machine.
- Finally, don't forget that you or a loved one may need their expertise one day.

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By Rosemary Foster, Ian de Vega

It is globally recognised that the only way to effectively support continuity of care is to implement an electronic health record (EHR) system on a large scale. The implementation of a national EHR is a high priority in the e-health strategies of most countries, regardless of whether they are first world or low- and middle-income countries. In South Africa, this has been successfully achieved in the Western Cape province.

Although South Africa has had some active health information systems implementations, only about a third of all public sector hospitals have some form of electronic medical record system. There is little or no integration between these systems and network and Internet access is not commonly found in public health facilities, especially primary healthcare facilities (community health centres and clinics).

Prior to 2004 in the Western Cape, none of these primary healthcare facilities were computerised. In 2004, there was an initiative to connect the fifteen largest community health centres to the provincial WAN. Computers were also installed but only provided email capability. For registry staff who were struggling to process more than 1,000 patients a day, for doctors who had to see up to 100 patients a day and for patients, who had queued outside from 4am, ill and often collapsing, this was of little help. Registry staff battled under chaotic circumstances, often using up to four different filing systems in the same facility.

PHCIS

A small team within the provincial government had designed and implemented a successful centralised system called CRADLE for use in the midwife obstetrics units (MOUs), public sector facilities where women receive ante-natal care and deliver their babies. It was proposed that CRADLE be adapted for use in all primary healthcare facilities, particularly making use of the patient registration functionality. The resulting system would be known as PHCIS (Primary Healthcare Information System). In 2003, the South African cabinet announced that anti-retroviral treatment (ART) for HIV/AIDS would be introduced in the public sector. It would be essential to monitor the roll-out of ART and to provide regular reports to the national Department of Health. The decision was taken to use the same CRADLE patient registration capability and to develop this ART module in-house, with guidance from the University of Cape Town Health Sciences

Faculty. The ART module, called eKapa, was therefore to be part of the PHCIS suite and the development was done in parallel.

The decision to enhance the CRADLE system was taken because it had the necessary foundations to suit the unique requirements and the cultural context. The CRADLE system had already been proven in the MOUs. Several commercially available systems were investigated but it was felt that, besides being very expensive, they were generally not suitable. There was considerable pressure at the time to use an open-source database and development tools. However, it was felt that the existing CRADLE team was skilled in the development language and it would be easier to find reliable skills in this language. The CRADLE system already used a commercial database management system and there were economies of scale in expanding this. From the outset the vision was to take a step-wise approach, i.e. not to proceed to the next level until the foundations were in place. This is illustrated in Figure 1.

Step 1. Connecting facilities to the WAN, giving staff basic computer literacy training and enabling them to use the computers to support administration of the facilities, e.g. email, access to the transversal financial system, BAS.

Step 2. Providing the capability of registering the patients on a centralised database, recording and updating demographic details, both on the PHCIS database and the provincial Patient Master Index (PMI) which is maintained in the Clinicom system (a centralised system used in provincial hospitals). At this stage staff could print labels that could be used by the pharmacy and to label specimen containers.

Step 3. Allowing more details to be recorded so that specialised registers could be maintained, e.g. for ART or TB treatment.

Step 4. Begin to add clinical details onto the patient record and proceed gradually until a comprehensive, longitudinal health record is maintained.

Step 5. Use the PHCIS database as a source for management reporting and business intelligence applications.

An Agile Tailor-Made Solution

The philosophy and methodology used for the design and development of PHCIS can be described as "agile". The development team worked very closely with the project manager and the business analyst, who in turn, dealt with the users on a daily basis. The roll-out began in 2006, using the approach

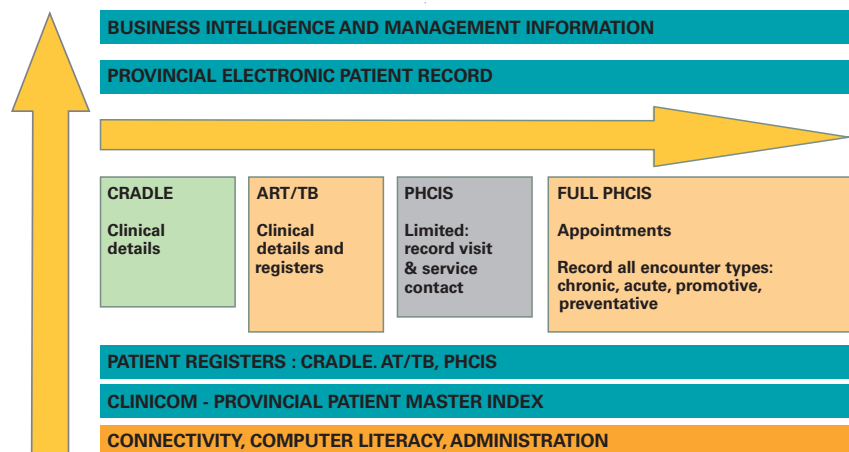


Figure 1: PHCIS development and implementation – a step-wise approach

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previously described. Two weeks after each “go-live” an on-site review was held where the users communicated openly about the system with the entire team, giving useful feedback to the developers.

Besides regular project meetings, the project manager and business analyst met regularly with facility staff and managers in a forum where they discussed the project, the system and its impact on clinic workflows. The team also spent a considerable amount of time visiting the facilities and speaking to staff and patients. This close relationship with the users and the patients continues and the result is that the “design reality gap” for PHCIS is very small, i.e. it is tailored to the needs of the users, the patients and the managers, closely fits the socio-cultural context, and has an improved chance of being adopted and retained.

The System

The hardware used for this system is very basic. All hardware procured must conform to the standards laid down for the provincial government, must be affordable as the budget is constrained and must be easy to support. Equipment used consists of standard network cabling for the LAN and WAN, compact workstations with flat screens, specialised high-speed label printers and laser printers for reports. In addition, bar-code scanners are used in the registry to scan the patient’s card on arrival in order to open the electronic record. Barcode scanners are also used to record details about a patient visit, with minimum effort on the part of the clinician or clerk.

One of the impressive features of the system is that it accesses a central PMI via web services. This PMI is used for all patient-based systems in the province – at hospitals, MOUs, ART clinics and 100 clinics serviced by the City of Cape Town. The City of Cape Town system has also been developed in-house by the city’s ICT services.

PHCIS has an SMS capability which allows reminders to be sent e.g. to patients who have missed appointments, or to parents to bring their children in for their next immunisation dose. On-going work with facility managers and users has ensured that PHCIS is an integral part of clinic workflows. Most facilities are not modern and were not built with computerisation in mind. It has been challenging to adapt workspaces, already cramped and ergonomically unsuitable, for the use of computer technology while at the same time taking into account high volume workflows.

Challenges

When roll-out of PHCIS began in 2006 the project team had to overcome several challenges:

- There was very little funding for this project;
- There was considerable resistance and lack of buy-in, especially at the outset. The behavioural patterns of staff and patients had to be changed. Staff were accustomed to chaotic workflows and facing long queues of frustrated patients. Patients were used to spending a full day in the facility each month in order to collect repeats of chronic medication;
- There was a shortage of skills for support of the system;
- The network infrastructure was not adequate and/or accessible;
- There was a lack of reliable and affordable connectivity;
- Processes for procurement of network infrastructure and hardware were complex and slow;
- Buildings were not designed for computerisation;
- Electrical supply to the facilities could be unstable;
- There were security and access issues. In some areas gang warfare raged outside the facilities at the time of “go-live”, several sites had all computers stolen, electricity supplies were disrupted when underground cables were stolen for their copper content, and on more than one occasion workers were involved in national strikes;
- The organisational structure did not include the roles necessary for the success of this project, i.e. information officers and data capturers.

Over the past five years these challenges have been overcome through innovation, teamwork and buy-in from the provincial department of health’s top management. The original goal of the project, to implement a patient management system in 33 community health centres, has far been exceeded. Today PHCIS has been implemented at 113 facilities and the roll-out continues. The aim is to include 126 more sites within the next year. The system tracks more than 5.6 million folders and the PHCIS database alone (apart from the provincial PMI) holds information for over four million patients.

Patients and Staff

This success has resulted in tremendous benefits for the patients, the users and the managers. Patients are benefiting from improved quality of care resulting from informational continuity, i.e. their records may be accessed at any PHCIS facility. Improved organisation and quicker throughput means that they do not have to queue for so long. They do not have to arrive early to secure a place in the line as those who must make repeat visits are given appointments. Patients who “walk in” for acute visits are also processed faster. Overall this gives the patients respect and dignity, the system knows them and recognises them,

their files are retrieved rapidly. Patients can plan their time better and do not have to lose a day’s work in order to pick up medicine.

The users can be divided into two groups – the clinicians and the administrative staff. The clinicians benefit because the environment is now generally less stressed. Their workload is better paced and, knowing their schedules ahead of time, they can plan their own time better. They are able to deliver a better quality of care because they have better information about the patient. The administrative staff has become empowered through computer literacy. The staff at the registry windows experience less stress as the patients are happier and the waiting room is less crowded. They have more job satisfaction as the job is more skilled and more is required of them.

Both user groups benefit from the simple but innovative use of barcode scanners to record visit details. By scanning three times – the patient’s barcode, the clinician’s barcode and the reason for the visit, the user triggers the rapid creation of an encounter within the patient’s electronic health record. The patient encounter holds the following essential information – which patient was seen, when the patient was seen, where the patient was seen, who attended to the patient and what was the reason for the visit (e.g. BCG first dose).

Managers are benefiting from the easy availability of high quality and accurate information. They are able to base strategic planning and decision-making on information reported or extracted from the system. Regular reports with the indicators they are required to provide are also easily obtained. They are able to monitor staff activities and workload as well as perform patient profiling for improved chronic disease management.

Conclusion

There is no doubt that PHCIS is a major success. In 2008 the PHCIS project won the African ICT Achiever’s Award for the best ICT project in Africa. In the same year the project won the silver award in the Premier’s Service Excellence Awards. In South Africa, the ART module of PHCIS has been mandated as the national electronic medical record system for the monitoring of treatment of HIV/AIDS in public healthcare facilities.

Work on PHCIS is ongoing and the team is always looking for ways to improve the system. In the words of Claudette Ruiters, the dynamic PHCIS project manager: “The question you have to ask yourself is ‘would you like to be a patient in this facility?’ And if the answer is ‘NO’ – then you have to do something about it!

INDIVIDUALISED PATIENT STRATIFICATION **USING WHOLE GENOME SEQUENCING**



2nd place

By Peter van der Spek

As the cost of sequencing the human genome falls, medical use of whole-genome sequencing in the clinic is rapidly approaching academic medical centres. In order to support the foreseeable flood of genomic information in the clinic an Oracle based database and business intelligence solution to detect genomic variants has been built at Erasmus University Medical Center (ErasmusMC), Rotterdam, the Netherlands.

Introducing Innovation in Healthcare

These advances in genomic medicine are only possible due to the equal progress in the information technology sector. The diagnostic opportunities also bring new challenges to medical centres regarding privacy in general and the necessary ICT infrastructure to secure this privacy at the individual patient level.

Clinical genetic testing in adults is at present typically done for a few patients who, as a result of family history or clinical indications, are considered at risk of carrying genetic variations that are linked to a particular disease or disease predisposition. This is going to change and in the near future, when at relative low cost, all variants in coding and non-coding DNA is mapped at once. The vast amount of knowledge that is offered by whole-genome sequencing means that informed consent for this procedure is more complex than that for existing genetic testing.

The ICT Solution

In order to facilitate this genomics project an Oracle Exadata server was installed as the initial component for the ErasmusMC Translational Research Center (TRC) personal cloud architecture. The aim of this next generation sequencing data storage and analysis project is being used as proof of concept to evaluate outsourcing of IT services.

Additionally, the bioinformatics team is using this environment to benchmark the

performance of the Exadata technology against an existing standard IT architecture. The project is a success in that the genomics solution started by the team of professor Peter van der Spek at ErasmusMC has attracted interest for adoption by organisations worldwide and now needs to be managed by an external company. To grow this solution to an international standard the support of Oracle is required.

Impact of the Project

As the focus in the clinic shifts from sequential testing of individual genes associated with a particular disease, to mapping all variants within an individual's whole genome to all known information on all diseases and traits, the consequence is the need for massive parallel processing and high volume data storage.

The added value to the clinic is for higher efficiency in diagnosis, with decreased time to delivery and a view of the whole genome not just the individual genes. Increased knowledge can result in medical or lifestyle changes that reduce risks, or it can affect the patient's life decisions or strategies for coping. Risks of genetic testing also centre on the accuracy of the knowledge that patients (or others) take away from the tests and how that knowledge is used. Over time our knowledge will rapidly expand and new ways to re-annotate the genome data will be developed. Historical data for both the clinician and patient, which has an updated diagnosis should be made available via a secure web based application.

Genome sequencing will have its major impact in three areas listed below:

- Genetic testing of inherited conditions;
- Cancer diagnostics; and
- Pharmacogenetics.

Every individual will learn that he or she is a heterozygous carrier of more than one serious or lethal autosomal recessive disease. This information might affect a patient's lifestyle decisions, and have implications for existing children or other relatives.

Education

This technological solution offers a platform for training medical professionals (physician scientists) to deal with large volumes of sensitive patient related data and learn to diagnose clinical relevant variants within the genome. These actionable items will help reducing costs by providing the right drug to the right patient in therapy. To make informed decisions about whole-genome sequencing, patients will need to have the opportunity to ask questions and get accurate answers from knowledgeable and trained professionals.

For more information on the IT @ Networking awards and pictures from this year's event, please visit: itandnetworking.org



EYESMART EMR

An intelligent IT Solution for Eyecare

By Anthony Vipin Das

The LV Prasad Eye Institute (LVPEI) was established in 1986-87 at Hyderabad as a not-for-profit, non-government, public-spirited, comprehensive eye care institution. From its very beginning, it set forth as its core values the "Three E's": Equity, Efficiency and Excellence. Equity translates as treating all patients (paying for services or not, rich or poor) with the same high-quality, no-compromise care. Efficiency means using the best available tools and technology, translating results of research into clinical practice, and evolving or changing policy as needed. Excellence is an ever-ascending goal that LVPEI attempts to achieve.

LVPEI operates out of 106 locations, 86 of them being primary eye care centres located in remote rural villages. For the past 24 years, it has served over 14 million people, over 50 percent of them entirely free of cost, irrespective of the complexity of care needed.

The LVPEI care model, called the Eye Health Pyramid encompasses service delivery at four different levels ranging from tertiary care to primary care in the villages. In the Village Vision Complex (VCC), ten Vision Centres connect to a Secondary Centre which then refers patients requiring further evaluation and management to the Tertiary Centres linked to them. This ensures a permanent infrastructure to deliver high quality eyecare services to the needy at all levels.

How it Works

eyeSmart is a revolutionary national award winning ophthalmic Electronic Medical Record (EMR) and Hospital Management System developed in-house by L V Prasad Eye Institute, India. We have embarked on networking the entire eye health pyramid of LVPEI on digitised medical records.

The goal is to enable electronic documentation for faster retrieval and research purposes, and to transform the entire network into a paperless eco-friendly environment. We have used an EMR concept of totally integrating all functions of a hospital from a common point, namely the patient. All functions, including clinical and administrative, are inter-linked in a single EMR and HMS system and through a single patient record. We have made use of different flash tools, document viewers, etc., to intelligently assist our doctors in managing patient data at the convenience of a click anywhere, anytime. Doctors can access case sheets on mobile phones, and have appointment details 24/7 365 days a year.

The application is enabled for various platforms like iPads, iPhones and tablets. The EMR has now evolved into an effective educational tool for our students and fellows who train at the institute. The standard procedures, classifications, evidence based medicine protocols integrated into the system help to deliver more effective care and also aid in teaching.

The project started as an in-house exercise with the task of building an application for a smaller urban centre at Madhapur, Hyderabad. The centre started on 16 August 2010 and since then has grown to be adapted for use in three other branches in three cities. We then moved on to upgrade the system and its functions in a tertiary centre that had sub-specialities in ophthalmology. We started our first tertiary centre on EMR at KVC Campus, Vijaywada. We then started our first secondary centre on EMR at Paloncha, which saw challenges in terms of connectivity and power but these were resolved. We then proceeded to connect the primary care vision centre to the secondary centre through EMR. Currently, our patients can move anywhere in the vision centre complex without having to physically carry their medical records with them.

Difficulties

Problems related to connectivity and power, as can be anticipated in rural hinterlands, have been addressed and alternative backup plans put into place. Training and monitoring the centres in real time has been made possible with the formation of an EMR Support and Installation Team (ESIT). The ESIT caters to live and remote support for the staff and users and gathers essential feedback on the application. It is also responsible for enforcing protocols of quality data documentation. ESIT members are currently based across four cities with 12 full-time employees catering to eight centres running on EMR. New centre installations, support and maintenance are also handled by the ESIT. We have a fully equipped office and simulated training centre based in Hyderabad, India.

A Unique Concept with Proven Results

The concept is unique as we are currently implementing a revolutionary connectivity solution with our vision centres located in remote rural villages. The broad framework of our operations is to seamlessly connect our care delivery and make our mod-

el digitally inclusive. In keeping with this mission, we have begun integrating all the 106 eyecare centres of LVPEI, spread across two states of India, in a phased manner, and hope to complete the task over the next two years.

EMR Statistics (from August 2010)

Total no. of Patients – 59,815 New Patients
Total no. of Appointments – 92,147 Appointments
> 150 unique users
No. of EMR Centres – 8
City Centre – Hyderabad
KVC Campus – Vijaywada
NBEC Secondary Centre – Paloncha
City Centre – Vizag
City Centre – Vijaywada
KAR Extension – Hyderabad
Secondary Centre – Cherukupalli
Vision Centre – Manuguru Village

Cost Savings

- Manpower costs for Medical Record Department
- Paper printing/ storage costs;
- Man hours saved in preparing elaborate reports; and
- View reports and status of any centre, anywhere, anytime!

Improving Customer Service

- Accurate, comprehensive medical reports in a single click;
- Digitised prescriptions for medicines and glasses;
- Shorter waiting time for patients;
- Online booking of appointments;
- Personalised SMS alerts; and
- Enabling better efficiency in patient flow in centres.

Employee Productivity

- Less time spent on written records (30 percent less time);
- Faster processing of information of patient statistics (90 percent less time);
- Reports at a click (100 percent time saved)
- LIVE patient status displayed dynamically to administrators (100 percent time saved)
- Faster entry of patient medical records;
- Faster printing of prescriptions, refraction records (90 percent time saved); and
- Assessment of employee specific functions (80 percent time saved).

ASSESSING THE "COST VERSUS BENEFIT" OF RADIOLOGY

By Jane Adam

All nations aspire to obtaining the best value for money for their population, achieving the maximum health gain for the money spent. Although a predominantly State-funded system like the NHS in the UK can look at these issues more readily than those with a mixed economy of healthcare, private insurers are also interested in value for money and are increasingly evaluating the evidence of benefit of treatments before funding them.

All licensed drugs have trial evidence that they work within their licensed indications, otherwise they would not have been granted a marketing authorisation by bodies such as the European Medicines Agency. Nevertheless they do not necessarily have to work particularly well or sufficiently well to justify their cost compared with other available treatments.

As the provision of healthcare has become more complex and expensive, health economics has emerged as an increasingly important discipline. There are three main ways in which the value for money of a health intervention can be assessed, as outlined here.

Cost effectiveness analysis. This looks at the costs of achieving a defined benefit. Examples might be cost per life saved, life year gained, hospital admission avoided, 5mm drop in systolic blood pressure, or 1% drop in HbA1c etc. Here the outcome itself is known to be of benefit either in health or societal terms, or associated with a monetary value.

Cost utility analysis. This uses a universal measure of 'wellness' or 'illness' on a scale of 0-1, where 1 is perfect health and 0 is death. Everyone will be somewhere on that scale and can be described in terms of their 'utility' (interestingly, it is possible to be in a health state worse than death). Utility declines with age and illness. A cost utility analysis looks at the average gain in utility against the cost of a treatment, allowing the success of any treatment for any condition to be judged using the same units. This is refined by the length of time for which the intervention works, to give a calculation of total health benefit gained as a result of the treatment. The unit is a quality

adjusted life year (QALY) which is a year of perfect health. When the cost of the treatment is known, a cost per QALY can be calculated. This represents what would have to be spent on that intervention to 'buy' the equivalent of a rise of 1 in the utility scale, lasting for one year in the treated population. This is looked at in relative terms i.e. in comparison with treatments already available. So in essence, an intervention which gives a big rise in utility and lasts a long time compared with alternative treatments will generate many QALYs in the treated population and may be a good investment even if it is relatively expensive.

Cost minimisation analysis. This is simpler, and can be used when two treatments are equally beneficial. It evaluates which is the cheaper, taking all costs related to the treatment into account. These calculations can

only be made on the basis of excellent evidence on the effectiveness of treatments, and the costs involved. Complex economic models are constructed to map the course of the disease in relation to the treatment(s) used, in order to calculate the value for money provided. This methodology is particularly widely used in the NHS in the UK by the National Institute for Health and Clinical Excellence (NICE) before being funded for use in the NHS.

Assessing the 'Value' of Radiology

These same principles can be applied to radiology. There are however several examples in relation to health screening, notably population screening for breast cancer, where similar analyses provided evidence that mammographic breast

Healthcare Spending Chart UK public Spending from FY1980 to FY 2011

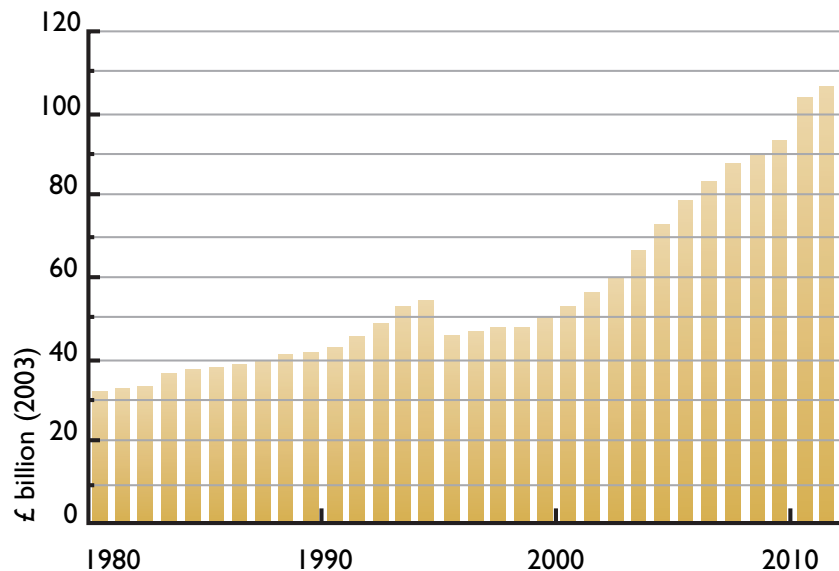


Figure 1: UK healthcare spending in real terms (inflation-adjusted) (Source: Public Spending UK)

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screening was a good investment in terms of cost versus benefit for the population in the selected age group.

Interventional procedures are also amenable to health economic evaluation, particularly comparing image guided intervention with open surgical techniques. It is perhaps surprising, and probably not to radiology's benefit, that these analyses have not been widely undertaken because the generally lower cost of interventional radiology might well work to its advantage in several areas of practice. It can be done; for example NICE evaluated the use of ultrasound guided central venous line insertion compared with 'blind' placement. The analysis found ultrasound guidance to be cost effective in cost per QALY terms on the basis of the number of complications avoided and the medical time saved by fewer attempts being required.

Evaluation of the health benefits of diagnostic radiology outside population screening is more problematic because here there

is a more indirect relationship between the diagnostic test and the utility gain of the patient. It would however be perfectly possible in theory to calculate for example the cost per QALY of using MRI to diagnose acoustic neuroma. Equally, in the case where two different imaging methods could be used to make the same diagnosis, it would be possible to evaluate which provides the better value for money based on their sensitivity, specificity and cost. In circumstances where a second test is used to confirm the finding of a first, a calculation of the additional information/ benefit gained relative to the cost of another investigation would give a measure of the incremental cost benefit of carrying out the second test.

The Future

As an expensive service, radiology will not be immune from scrutiny forever. In some cases, investigations are done for reassurance, for medico-legal reasons or to compensate for clinical uncertainty and might not be a good use of scarce resources. Cost

effectiveness evidence for the appropriate and effective use of radiology resources may not be a bad thing.

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Further Reading

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*Books in Review

Applied Methods of Cost-Effectiveness Analysis in Healthcare

Alastair M. Gray / Philip M. Clarke / Jane L. Wolstenholme / Sarah Wordsworth
 Oxford University Press, 2011



The third volume in the Handbooks in Health Economic Evaluation series, this book provides the reader with a comprehensive set of instructions and examples of how to perform an economic evaluation of a health intervention. It focuses solely on cost-effectiveness analysis in healthcare.

The book is developed out of the Advanced Methods of Cost-Effectiveness Analysis course taught at the University of Oxford and the four main sections mirror

the four principal components of the course: Outcomes, Costs, Modelling using decision trees and Markov models, and Presenting cost-effectiveness results.

Economic evaluation of health intervention is a growing specialist field, and this series of practical handbooks tackles, in depth, topics superficially addressed in more general economics books. Each volume includes illustrative material, case histories and worked examples to encourage the reader to apply the methods discussed, with supporting material provided online. The series is for health economists in academia, the pharmaceutical industry and the health sector, those on advanced health economics courses, and health researchers in associated fields.

About the Authors

Alastair Gray was appointed Director of the Health Economics Research

Centre, Division of Public Health and Primary Care, University of Oxford, in October 1996, and became Professor of Health Economics in 2002.

Dr Philip Clarke joined the School of Public Health, University of Sydney in February 2006 after spending six years engaged in health economic research at the University of Oxford. His health economic research interests include developing methods to value the benefits of improving access to healthcare, health inequalities and the use of simulation models in health economic evaluation.

Jane Wolstenholme joined the Health Economics Research Centre in December 1998, having previously worked at the University of Nottingham. Her main research interests lie in the areas of economic evaluation and health technology assessment from applied and methodological perspectives.



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HEALTHCARE IN NORWAY

AN INTRODUCTION

Geography

Norway is located in Northern Europe, bordering the North Sea and the North Atlantic Ocean. Half the country lies north of the Polar Circle. It borders Sweden, Finland and the Russian Federation. Norway is divided into 19 regional authority areas, counties, which in turn are divided into 430 local authority areas, municipalities. The capital is Oslo.

Demography	385,252 km ²
Population:	about 5 million
Age structure	
0-14 years	19%
15-64 years	66%
>65 years	15%
Population	0,38%
Birth rate	11,5 births/1000 inhabitants
Death rate	9,4 deaths/1000 inhabitants
Total fertility rate	1,78

Challenges, Plans and Solutions

Norway faces the same dilemma of many western European countries, as the standard of living improves and people's life expectancy increases, there are new challenges with an ageing population and a growing number of people with chronic diseases. An ageing society will be a challenge for the Norwegian healthcare system. To make further progress in the health of the population, it will be necessary to focus on the challenges of health promotion and illness prevention. From the end of the 1990s several reforms have been launched, designed to meet the main challenges that the Norwegian healthcare system will face in the next century. An overall challenge is to combine a decen-

tralised system with a regulatory environment that ensures equal access.

Health Services in Norway: Organisation and Financing

The system of healthcare provision in Norway is based on a decentralised model. The state is responsible for policy design and overall capacity and quality of healthcare through budgeting and legislation. The state is also responsible for hospital services through state ownership of regional health authorities. Within the regional health authorities, somatic and psychiatric hospitals and some hospital pharmacies are organised as health trusts.

The Norwegian healthcare system is tax-based and is formed around the principles of equal access to healthcare services, political decentralisation to local governments, and free choice of provider. Public expenditures consist of more than 80 percent of total health expenditure.

Special reforms in the late 1980s and early 1990s have contributed to the expansion of the range of services provided to meet the specific needs of the elderly, the handicapped and the mentally ill. In addition, an activity-based system of hospital financing, based on the DRG system, has been in place since 1997. The system has the aim of decreasing waiting lists through the expected expansion of capacity and utilisation. For inpatient stays, hospitals are paid by a combination of cost per case and global budgets.

Norway's 430 municipalities have responsibility for primary healthcare, including both preventive and curative treatment.

There are about 23,000 physicians in Norway. There are currently 230 citizens per physician under 67 years of age in Norway, or 4.34 physicians per 1,000 citizens, more than in the other Nordic countries (source: Physicians in the Nordic Countries 2008). Within the OECD, only Greece has clearly more physicians per head of population than Norway, while it is about equally high in Belgium, Italy, Spain and Switzerland (source: OECD Health Data 2010).

The Coordination Reform

The Government has introduced a Coordination Reform to ensure sustainable, integrated and coordinated health and care services that are of high quality, maintain a high degree of patient safety, and are tailored to the individual user. Greater emphasis will be placed on measures to promote health and prevent disease, on habilitation and rehabilitation, on increased user influence and on binding agreements between municipalities and hospitals. The municipal health and care services will be strengthened and the specialist healthcare services will be expanded.

Medical investigation and treatment of frequently occurring diseases and conditions will be decentralised when possible. Medical investigation and treatment of less frequently occurring diseases and conditions will be centralised when this is necessary to ensure a high quality of service and effective utilisation of resources.

If the Coordination Reform is to succeed, better balance and reciprocity between the specialist and municipal healthcare services must be achieved. The reform will be implemented over a period from January 2012. To achieve the reform's objectives, a wide array of instruments is required:

- **Legal instruments**, including the entry into force of the Act relating to public health efforts (Public Health Act) and the Act relating to municipal health and care services (Health and Care Services Act). The Public Health Act lays the foundation for long-term, systematic public health activities at all administrative levels: National, county and municipal. The Health and Care Services Act is designed to improve coordination within the municipalities and between the specialist and municipal health and care services. The municipalities' overall responsibility for the services offered is clarified, and the municipalities are given greater freedom to organise the services in accordance with local conditions and needs. The municipalities and regional health authorities/hospital trusts are required to enter into agreements at the local level.

– **Financial instruments** A scheme for limited municipal co-financing of somatic treatments within specialist healthcare services has been introduced. The ministry has stipulated that the regional health authorities, in conjunction with the municipalities, must chart the potential for cost-effective, local collaborative projects. The municipalities will be given financial responsibility for patients released from hospital. The municipalities must be able to provide 24 hour in-patient care for patients who require immediate assistance and monitoring from the health and care services, when the municipality has the capacity to investigate, treat or provide care. The municipalities have been given the opportunity to seek state investment funding to develop services in cooperation with other municipalities and hospital trusts.

– **Profession-oriented instruments** are designed to bring about a change in the practices used within the services, in keeping with the intentions of the Coordination Reform. Instruction material, guidelines and procedures and the introduction of national quality indicators are examples of profession-oriented instruments. New requirements on expertise will be needed. Education and training of personnel must be adapted to the objectives of the Coordination Reform. The municipalities must participate in and create a viable foundation for research on the municipal health and care services.

– **Organisational instruments** Appropriate arenas must be established for cooperation between various services and administrative levels. One example of this is the organisation of community medical centres as a collaborative effort between the specialist healthcare services and one or more municipalities. The services offered at a community medical centre may be designed on the basis of local needs, and may include a daytime clinic and possibly 24-hour care. Ownership and responsibility for the operation of such clinics should be regulated through agreements at the local level.

Patient Safety

In Safe Hands: The Norwegian Patient Safety Campaign 2011 – 2013

The Norwegian health and care system holds in general high standards. However, OECD and Commonwealth fund publications tell us that this picture is nuanced:

- Variation in clinical practice;
- Waiting time is unacceptable;

- Variation in health personnel qualification;
- Variation in user involvement; and
- Adverse events.

Financial Incentives

Today, there are no financial incentives for quality and patient safety. But in this context it is relevant to discuss how pay for performance (P4P) mechanisms can be considered as complementary tools for creating further incentives for achieving quality improvement and efficiency gains in the Norwegian health sector.

The Norwegian patient safety campaign, In Safe Hands, was launched in January 2011 by the Norwegian Ministry of Health. The three-year campaign aims to reduce patient harm and involves both specialist and primary healthcare services. The campaign aims to reduce patient harm, build pervasive structures and systems for patient safety and improve patient safety culture in the health services. In Safe Hands marks the beginning of lasting improvements in patient safety in Norway.

The campaign will introduce specific measures in several focus areas. As of now, three focus areas are ready to be implemented nationwide:

- Safe Surgery, with focus on post operative infections;
- Medication Reconciliation; and
- Drug Review.

In addition, the following areas are under preparation:

- Stroke Treatment;
- Mental Health;
- Central Line Infection;
- Fall;
- Pressure Ulcer; and
- Urinary tract infection.

Further areas will be developed in the course of the campaign. Measurements will be carried out within each priority area.

All focus areas are considered areas with great potential for improvement. They have been recommended by a special advisory board and have been considered by expert groups with expertise in the areas concerned. Because patient safety is a management responsibility, the campaign also promotes relevant leadership interventions. The interventions are piloted locally to ensure that the measures work in practice. Two of the five pilots concern leadership, such as Leadership WalkRounds.

Organisation

In Safe Hands was commissioned by the Ministry of Health. A steering group, led by the CEO of the National Health Directorate, is responsible for all key decisions in the campaign. The campaign secretariat forms part of the National Unit for Patient Safety, positioned in the National Knowledge Centre for the Health Services.

For more information, please visit:

<http://www.pasientsikkerhetskampanjen.no/no/+trygge+hender/In+English>

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The Norwegian Hospital and Health Service Association (NSH)

The Norwegian Hospital and Health Service Association (NSH, abbreviation in Norwegian) – is an interdisciplinary members' organisation for everyone who works in the healthcare sector in Norway. NSH will be celebrating its 75th anniversary in 2012. All healthcare companies and their employees are members, as are numerous local authorities, colleges, patient organisations, professional organisations, private companies and other operators in the health and social care sector.

NSH is an apolitical and independent organisation whose vision is to create interdisciplinary meeting places for healthcare professionals in the form of conferences, meetings and study trips. At these events, participants have the opportunity to develop new and improved knowledge and to exchange experiences with healthcare personnel and managers at various levels. By participating in contemporary and constructive debate and dialogue, the aim is to contribute to the creation of improved healthcare services for users. At the same time, NSH is striving to ensure equal healthcare availability for everyone, and is actively working to make generally accepted ethical principles the foundations of resource distribution, prioritisation and patient care at all levels.

NSH is a member of the European Association of Hospital Managers (EAHM) and the International Hospital Federation (IHF). In June 2013, NSH is hosting and organising the international World Hospital Congress "Oslo2013" on behalf of the IHF.

For more information, please visit: <http://oslo2013.no/org/nsh>



Nikolaus Koller

LA RECETTE D'UNE BONNE GOUVERNANCE

Une bonne gouvernance est l'objectif de chaque directeur d'hôpital. Elle devrait être non seulement discutée et débattue, mais également mise en application.

C'est un objectif que, en tant que directeur d'hôpital, je m'efforce d'atteindre chaque jour. De nombreuses années d'expérience dans un poste de direction ne garantissent aucunement la parfaite maîtrise du management. Une des raisons à cela est la nécessité dans laquelle se trouve un directeur d'adapter perpétuellement son style de management aux changements qui se jouent en permanence autour de lui, notamment au niveau du personnel dont les idéaux et les valeurs sont en constant renouvellement. De récentes observations ont montré que les incitations financières et les récompenses ne suffisent pas. Il est beaucoup plus important de créer une culture de confiance et de motiver les membres du personnel en soutenant leur confiance en eux, ce qui aura pour corollaire une plus grande volonté d'accomplissement.

On a récemment démontré que différentes configurations conduisent à la bonne gouvernance : Donner aux membres du personnel la possibilité de faire des choix favorise leur autonomie dans le travail, mais également la réduction des réglementations et des systèmes de contrôle, et surtout le fait de se garder de la démotivation par pédantisme.

Récemment, de nouveaux modèles de prestation de services sont apparus, ils jouent également un rôle dans la bonne gouvernance. Il s'agit des coopérations nationales et internationales, de la sous-traitance, des partenariats public-privé, du réseautage et des collaborations sectorielles et interdépartementales.

La tendance fondamentale qui se reflète dans tout ce qui précède est la nécessité, dans cet environnement en permanente mutation, de veiller à des performances stimulantes. Cela peut se faire grâce à des collaborations qui dépassent les frontières organisationnelles.

La bonne gouvernance est comme un plat qui se prépare avec des ingrédients locaux et nationaux qui seront déterminés par la philosophie de l'entreprise. Celui qui maîtrise cette recette est en mesure d'atteindre ses objectifs avec succès et beaucoup plus efficacement.

La « cover story » de ce numéro d'(*E*)Hospital met en évidence deux aspects importants de la gouvernance : la gouvernance éthique et la gouvernance clinique. Ce sont deux étapes importantes vers la bonne gouvernance.

Ce numéro d'(*E*)Hospital comprend également un « country focus » sur la Norvège. La Norvège est connue pour sa nature étonnante et diversifiée. Elle compte beaucoup de fjords sur la côte ouest qui remontent loin à l'intérieur des terres et sont entourés de côtes escarpées. Ce pays était autrefois l'empire des Vikings. D'un point de vue économique, il est connu et célèbre pour ses exportations de pétrole et de poissons. Comme tous les autres pays scandinaves, la Norvège possède un système de soins de santé de tout premier ordre, qui dispose de trois sources de financements différents. Il est également intéressant d'observer la grande équité qui régit les contributions des patients et le célèbre système de soins primaires des médecins généralistes.

Le magazine (*E*)Hospital sera distribué dans les principaux prochains congrès et conférences : Nous serons présents durant l'ECR, l'EAHP, l'ISICEM, l'ECCMID (pour plus d'informations, veuillez contacter Lee Campbell). Au nom de l'AEDH, je serai très heureux de vous accueillir au cours de l'un de ces très intéressants et instructifs événements.

Nikolaus Koller,
Président du comité de rédaction



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.

41ÈME ASSEMBLÉE GÉNÉRALE ORDINAIRE DU 18 NOVEMBRE 2011 À DÜSSELDORF, ALLEMAGNE

M. Heinz Kolking, président de l'AEDH, a accueilli les membres de l'Assemblée générale et a commencé par rappeler à notre mémoire notre collègue Asger Hansen, membre de longue date de l'AEDH et décédé en 2011. Un moment de silence a précédé le début de l'Assemblée générale.

Rapport d'activité

M. Kolking a tenu à informer les membres que le Bureau s'est réuni à cinq reprises à Bruxelles et le conseil d'administration par deux fois, les 20 mai et 18 Novembre derniers. Il a expliqué que les membres du Bureau ont élaboré une stratégie pour trouver des ressources et qu'ils ont noué des partenariats avec les milieux médicaux et les entreprises. Des partenariats avec Ecclesia et Becton Dickinson devraient être conclus prochainement. Nous considérons que c'est l'une des principales réalisations de l'association, les ressources devenant grandement nécessaires.

Revenant sur la dernière Assemblée générale qui s'est tenue en 2010 pendant le congrès organisé en Suisse, M. Kolking a remercié nos collègues suisses pour la grande réussite de ce congrès et a encouragé les membres à exprimer leur satisfaction. Se tournant vers l'avenir et l'organisation du congrès qui devrait se tenir à Athènes en 2012, il a souligné que la situation n'est pas sans poser de difficultés si on considère l'évolution de la Grèce et de la crise financière. Cependant, il est convaincu que l'AEDH et l'association grecque vont trouver un moyen pour organiser avec succès ce prochain congrès. Actuellement, nous nous efforçons de trouver les fonds nécessaires.

Alors que les ressources se font de plus en plus rares, les sous-comités scientifiques s'affairent autour de la composante scientifique du congrès et de la promotion d'une gestion efficace des hôpitaux. M. Kolking a déclaré : « c'est un défi auquel nous devons nous confronter. Nos réalisations dépendront entièrement de la façon dont nous négocierons ces challenges, du choix des initiatives et des outils adéquats, et de la formation de notre personnel. »

Le sous-comité aux affaires européennes s'est réuni par deux fois – tout comme le sous-comité scientifique – pour se pencher sur des questions d'actualité. Le comité de rédaction a également organisé deux rencontres à Bruxelles pour travailler sur le calendrier éditorial de *(E)Hospital*.

Le processus de réflexion a été un autre sujet important du rapport d'activité. Le président a souligné que l'environnement dans lequel nous travaillons tant au niveau européen que national de l'association a beaucoup changé. Il y a eu des changements majeurs en termes de professionnalisation et une grande évolution au niveau des structures qui nous poussent à concevoir une nouvelle organisation. Les gestionnaires doivent s'adapter à cet environnement en constante évolution, d'où l'importance du processus de réflexion. Il se penche en priorité sur les relations avec la presse, Internet (par l'intermédiaire du site web), le « IT Working Party » et les rencontres organisées à Vienne et en Lituanie. Ces séminaires régionaux ont permis de mettre en place un langage commun entre les directions et les professionnels de l'informatique et a reçu une réponse très positive. M. Kolking a souligné que le processus de réflexion engagé n'était pas uniquement une discussion et que ses résultats seront bientôt mis en application. Le Bureau et le Conseil d'administration le placent en tête de leurs priorités.

Parmi les associations membres, certaines associations nationales se sont retrouvées dans l'incapacité d'acquitter leurs frais. Le Conseil d'administration a décidé de ne pas les exclure et de trouver des solutions pour les maintenir sans faire courir de risques financiers à l'association.

Les comptes 2010 et le budget 2012

M. Willy Heuschen, secrétaire général, a donné les rapports financiers. Le budget 2010 a été respecté (dépassement des dépenses de 106 euros). M. Heuschen a

particulièrement remercié l'association suisse pour leur excédent lors du congrès qui s'est tenu à Zurich en 2010. L'augmentation des dépenses est à imputer à l'augmentation du nombre des réunions qui a occasionné des frais de voyage plus élevés. Dans son résumé, M. Heuschen a déclaré que malgré les difficultés dues à la crise financière et grâce au franc succès de la conférence suisse, l'AEDH a pu mettre en œuvre les résultats du processus de réflexion sans pour autant déstabiliser le budget.

Le budget 2012 ne prévoit pas d'importantes augmentations, seulement une petite contribution afin de palier à la situation difficile de certaines associations nationales. Encore une fois, si certaines associations nationales ne peuvent pas payer leurs frais, cela ne signifie aucunement qu'elles seront évincées. Nous espérons être les témoins d'une amélioration en 2012 et qu'ainsi nous pourrions regagner une partie des cotisations.

Les nouveaux accords de partenariat sont un sujet de tout premier ordre. Au cours de l'Assemblée générale, M. Heuschen a déclaré que six partenariats étaient actuellement prévus et a exhorté les membres à les aider à en découvrir d'autres. Ce n'est pas chose facile car les critères imposent un véritable partenariat et non pas simplement une opération rapide avec une entreprise. Nous espérons que ces partenariats pourront nous accompagner sur une durée de trois ans.

Christoph Pachlatko a soulevé une question importante concernant ces partenariats. Il a demandé si le chiffre prévisionnel avait été inclus dans le budget 2012. M. Heuschen a précisé que, pour le moment, deux partenariats font encore défaut, mais que les dépenses sont contrôlées et coïncident avec les recettes. L'argent ne sera dépensé qu'une fois qu'il aura été effectivement perçu. Il a toutefois admis que le budget 2012 représentait un véritable challenge.

La prochaine Assemblée générale aura lieu à Athènes le 27 Septembre 2012.



Première « Joint European Hospital Conference »

Le 18 Novembre dernier, la première « Joint European Hospital Conference » s'est tenue à Düsseldorf, en Allemagne. Organisée par les trois principales associations de soins de santé européennes (l'AEDH, HOPE et l'AEMH), les thèmes de l'actualité politique, médicale et économique ont pu y être abordés.

La conférence a été divisée en deux parties. La session de la matinée portait sur la politique de santé européenne actuelle et a débuté avec une présentation de Mars Di Bartolomeo, ministre de la Santé et des Affaires sociales du Luxembourg. Elle a été suivie par les commentaires de chacune des associations européennes. L'après-midi a été consacrée à la directive européenne sur les droits des patients et à son impact sur les hôpitaux. La présentation principale a été donnée par Annika Nowak, de la Commission européenne, et a été suivie par des commentaires des représentants de différents pays européens comme le Royaume-Uni, la Hongrie, la France, la Belgique, la Suède et la Grèce.

Cette conférence a obtenu un franc succès auprès de tous ceux qui y ont assisté, et a illustré la volonté de chacun d'apprendre des expériences vécues dans les autres pays européens. Elle a également souligné l'importance de la coopération et de la collaboration pour faire face aux défis croissants qui s'imposent aux soins de santé actuellement.



La gouvernance éthique

Par UL Aparo, A Aparo

La gouvernance éthique renvoie à des valeurs et à des comportements, processus, procédures, à la culture, et à des façons de faire et d'être éthiques qui garantissent des standards élevés de performance, d'économie, d'efficacité, d'efficience, de qualité et de satisfaction. Qu'il soit clair pour tout le monde qu'il ne peut pas y avoir de gouvernance éthique sans une équipe responsable, soit une « direction de la commission santé » ou un « comité de directeurs » composés des représentants des principaux composants de l'organisation, cette entité étant chargée de prendre en considération les vues exprimées par le comité d'éthique. Le comité d'éthique, quant à lui, devrait être composé de personnes dûment informées des faits et des circonstances. Il doit pouvoir répondre aux demandes et aux remarques de toutes les parties prenantes et être en mesure de comprendre et de respecter les opinions et les préoccupations du patient, des membres de sa famille, des gestionnaires, des professionnels et de tous ceux qui trouvent un intérêt légitime à cette question.



Soutenir le développement de la gouvernance clinique dans les soins de santé irlandais

Par Philip Crowley, Maureen Flynn

En été 2011, la direction du système de santé irlandais s'est attachée à développer la gouvernance clinique. La nécessité d'une information succincte sur la gouvernance clinique est apparue dans le cadre de la stratégie de communication. L'objectif est d'informer la communauté de la santé dans son ensemble à propos de cette notion, des avantages et des principes directeurs en matière de gouvernance clinique ainsi que de profiter de leur élan et de leur soutien pour la mise en œuvre des changements.

La gouvernance clinique permet de s'assurer que les personnes reçoivent les soins dont ils ont besoin dans un environnement sécuritaire, stimulant, ouvert et juste. L'avantage de la gouvernance clinique réside dans l'amélioration du vécu des patients et dans de meilleurs résultats en ce qui concerne la qualité et la sécurité. Le mantra correspondant au développement de la gouvernance clinique est « nous sommes tous responsables, et ensemble nous pouvons créer un système de santé plus sûr ».



La lutte contre les infections avec EUNETIPS

Par Silvio Brusaferrero

En octobre dernier à Venise, en Italie, seize sociétés européennes de professionnels et de scientifiques de quatorze pays engagés dans la prévention et le contrôle des infections ont formé l'EUNETIPS, un réseau européen visant à promouvoir la prévention des infections pour la sécurité des patients. Le but d'EUNETIPS est la promotion d'une meilleure coopération entre les pays, le partage des expériences, la promotion et le soutien des initiatives concernant la prévention des infections pour la sécurité des patients, en particulier au niveau européen.

Les sociétés nationales scientifiques et professionnelles, si l'on excepte leur participation à des activités internationales comme les projets scientifiques et les congrès, n'ont le plus souvent aucune occasion officielle de se rencontrer. Nous ne pouvons que le regretter car dans toute l'Europe elles sont le creuset d'expériences inexploitées, de connaissances, de compétences scientifiques et de possibilités de formation qui pourraient être connues, partagées, et enfin faire partie d'une plate-forme commune. EUNETIPS fournit cette plate-forme.



Le rôle crucial de la pharmacologie clinique et des pharmaciens hospitaliers dans l'amélioration de l'efficacité des prescriptions pour les médicaments nouveaux ou déjà existant

Par Brian Godman et al.

Les nouveaux médicaments les plus onéreux sont créés à partir de substances biologiques commercialisées à des coûts considérablement plus élevés que les substances précédentes. C'est à elles que l'on impute une augmentation des dépenses d'environ 20% par an, qui serait responsable de la limitation d'autres services hospitaliers.

Si cette dépense reste élevée, elle compromettra les idéaux européens de soins de santé complets et appropriés. Tout cela se trouve être exacerbé par le fait que les bénéfices en terme de santé que procurent de nombreux nouveaux médicaments, y compris les nouveaux médicaments anticancéreux, sont parfois limités en dépit de leurs prix élevés.

Ces préoccupations ont poussé de nombreux acteurs européens à prendre part à des activités afin d'améliorer l'efficacité de prescription. Des efforts de coordination nationale, régionale et locale, des accords de partage des risques et de benchmarking ont vu le jour. La pharmacologie clinique et les pharmaciens hospitaliers ont la possibilité d'améliorer sensiblement la qualité et l'efficacité de la prescription des médicaments nouveaux ou déjà existants dans tous les secteurs. S'ils refusent d'agir ou de s'impliquer, nous pouvons nous attendre à une plus grande croissance encore de la prescription de médicaments brevetés et onéreux, ce qui compromettrait la capacité des pays européens à fournir dans le futur des soins de santé complets et appropriés.

► Un aperçu des systèmes de délivrance de médicaments

Par Rajan K. Verma, Mitesh Nagar, Purushottam Nagar

Aujourd'hui, l'industrie pharmaceutique est prise entre la pression pour une diminution des prix et le coût croissant de la recherche et du développement pour obtenir un médicament. Le coût moyen de développement d'une nouvelle entité chimique (RCE) est d'environ 0,5 à 1,5 milliards de dollars et le développement peut prendre de 10 à 15 ans. Le financement du développement d'un nouveau système de délivrance d'un médicament est souvent beaucoup moins dispendieux et son application se traduit par une meilleure efficacité, une réduction de la fréquence de la prise, et une diminution des effets secondaires. Les systèmes de délivrance de médicaments sont des formes de dosages chimique ou biologique destinées à améliorer ou à contrôler la quantité exacte et le taux de délivrance d'un médicament dans la circulation systémique (par exemple les liposomes, les pompes osmotiques, les dispositifs transdermiques, etc.). En développant un nouveau système de délivrance, une ancienne molécule peut décrocher une « nouvelle vie », ce qui permet d'augmenter sa valeur sur le marché, sa compétitivité et la durée de vie du brevet.

► Évaluation du coût versus avantages de la radiologie

Par Jane Adam

Les interventions pour les soins de santé devenant de plus en plus complexes et coûteuses, l'économie de la santé s'impose comme une discipline importante. Trois moyens principaux permettent d'évaluer le rapport qualité-prix d'une intervention dans le secteur de la santé : l'analyse coût-

efficacité, l'analyse coût-utilité et l'analyse de minimisation des coûts. Ces principes peuvent être appliqués à la radiologie. Par exemple, il a été prouvé que le dépistage par mammographie du cancer du sein est un bon investissement en termes de coût par rapport aux avantages pour la population dans le groupe d'âge choisi.

Comme tout service coûteux, la radiologie n'échappe pas toujours au contrôle. Dans certains cas, les examens semblent uniquement réalisés pour rassurer, pour des raisons médico-légales ou pour suppléer à une incertitude clinique, ce qui n'est probablement pas la façon la plus appropriée d'utiliser ces ressources rares.

► Focus sur la Norvège

Par May Britt Buhaug, Erik Kreyberg Normann



La « Norwegian Hospital and Health Service Association » (NSH) est une organisation interdisciplinaire qui s'adresse à tous les professionnels du secteur de la santé en Norvège. En 2012, elle fêtera son 75ème anniversaire. Organisation apolitique et indépendante, elle s'efforce de créer des lieux de rencontre interdisciplinaires pour les professionnels de santé sous la forme de conférences, de rencontres et de voyages d'études. Lors de ces événements, les participants ont la possibilité de développer de nouvelles connaissances et d'améliorer l'échange d'expériences entre les personnels de santé et les gestionnaires à différents niveaux. La NSH s'efforce d'assurer l'égalité de tous devant les soins de santé. Elle s'emploie activement à faire des principes éthiques les plus communément reconnus, les fondements sur lesquels s'appuient la répartition des ressources, le choix des priorités et la qualité des soins effectués auprès des patients.



Nikolaus Koller

GUTE FÜHRUNG UNTERLIEGT DEM TREND DER ZEIT

Gute Führung ist das Ziel, welches von jedem Krankenhausmanager nicht nur anvisiert, sondern auch aktiv umgesetzt werden soll.

In meiner Funktion als Krankenhausmanager werde ich nach wie vor jeden Tag herausgefordert, dieses Ziel zu erreichen. Viele Jahre an Erfahrungen im Bereich der Führungsposition sind noch lange nicht die Garantie für die Beherrschung des perfekten Führungsstils. Denn die Werte der Mitarbeiter und damit auch die Trends der Führungsstile ändern sich mit der Zeit. Nach neuesten Überlegungen ist so zu beachten, dass Leistungen nicht alleine mit finanziellen Anreizen erreicht werden können. Viel wichtiger ist es eine Kultur des Vertrauens zu schaffen und die Mitarbeiter durch Selbstbewusstsein zu motivieren, ihre Leistungsbereitschaft zu erhöhen.

Vor allem zeigen Zukunftstrends, dass die Wahlmöglichkeiten, die Selbstständigkeit und Entscheidungskraft, die Deregulierung weniger Richtlinien und Kontrollsysteme sowie die Vermeidung von Demotivation durch Pedanterie klare Ziele der guten Führung sind. Aber nicht nur diese sondern auch bereichs-, amts- und departmentsübergreifende Zusammenarbeiten, nationale und internationale Kooperationen, Auslagerungen, Outsourcing, Public-Private Partnerships, Networking und andere gemeinsame Formen der Leistungserbringung werden an Zahl und Komplexität zunehmen.

Zentraler Trend, der sich in allen anderen reflektiert, ist die Notwendigkeit, durch Zusammenarbeit über die eigenen organisatorischen Grenzen hinweg anspruchsvollere Leistungen in einem sich rascher und diskontinuierlich verändernden Umfeld zu erbringen. Gute Führung ist wie ein Gericht, welches durch regionale, nationale und von der Unternehmensphilosophie vorgegebenen Zutaten zubereitet wird. Wer diese Rezeptur beherrscht, kann Ziele in Zukunft rascher und besser erreicht werden.

Diese (E)Hospital Ausgabe zeigt Ihnen weitere wichtige Inhalte und Schritte der guten Führung.

Der Länderfokus der (E)Hospital Ausgabe richtet sich auf Norwegen. Norwegen ist besonders für seine erstaunliche und abwechslungsreiche Natur bekannt. Die vielen Fjorde an der Küste im Westen rei-

chen weit in das Land hinein und werden von hohen Bergen begrenzt. Das Land war einst ein Wikingerreich. Wirtschaftlich ist es vor allem wegen seiner Öl- und Fischexporte bekannt. Wie alle skandinavischen Staaten hat Norwegen ein qualitativ hochwertiges Gesundheitssystem, welches aus drei verschiedenen Quellen finanziert wird. Interessant ist auch die hohe finanzielle Eigenbeteiligung der Patienten und das in Norwegen bekannte Hausarztssystem der Primärversorgung.

Die EVKD konzentriert sich auf die bevorstehenden Kongresse und Events des IT@, ECR, EAHP, ISICEM, ECCMID (Bitte an Lee Campbell für weitere Informationen). Im Namen des EVKD würde es mich sehr freuen, Sie bei einer der für sie interessanten Veranstaltungen begrüßen zu dürfen.

Nikolaus Koller

Präsident des Redaktionsbeirat



Leitartikel in (E)Hospital werden von Führungspersonlichkeiten der EVKD verfasst. Die hier veröffentlichten Beiträge geben dennoch ausschließlich die Meinung der Autoren wieder und sind nicht als offizielle Stellungnahme der EVKD zu werten.

41. ORDENTLICHE GENERALVERSAMMLUNG 18/11/2011, DÜSSELDORF, DEUTSCHLAND

Zu Beginn der Generalversammlung begrüßte EVKD-Präsident Heinz Kölking die Mitglieder und erinnerte im Anschluss an den liebenswerten und langjährigen EVKD-Mitglied Asger Hansen, der 2011 verstorben ist. Nach einer Schweigeminute wurde die Generalversammlung fortgesetzt.

TÄTIGKEITSBERICHT

Herr Kölking informierte die Mitglieder, dass sich das Präsidium im abgelaufenen Jahr fünfmal und der Vorstand zweimal in Brüssel getroffen haben (am 20. Mai und 18. November). Er erklärte, dass der Vorstand in Hinblick auf die Ressourcen eine Strategie entwickelt hat und Partnerschaften mit medizinischen Fachkreisen und Unternehmen forcieren. So sollen die Partnerschaften mit Ecclesia und BD bald abgeschlossen sein. Das sei eine wichtige Errungenschaft der Vereinigung, da Ressourcen dringend benötigt werden.

Rückblickend auf die letzte Generalversammlung im Jahr 2010 und den Kongress in der Schweiz dankte Kölking den Schweizer Kollegen für die sehr erfolgreiche Veranstaltung. Mit Blick auf die Versammlung 2012 in Athen betonte Herr Kölking, dass die Situation aufgrund der Entwicklungen in Griechenland und der Finanzkrise nicht unproblematisch sei. Dennoch sei er zuversichtlich, dass die EVKD und die griechische Vereinigung einen Weg finden werden, einen erfolgreichen Kongress abzuhalten. Derzeit hänge dies, so Kölking, von der Finanzierung ab.

Der wissenschaftliche Unterausschuss beschäftigt sich mit der wissenschaftlichen Komponente des Kongresses und mit der Förderung einer erfolgreichen Krankenhausführung in Zeiten immer knapper werdender Ressourcen. Herr Kölking betonte, dass dies eine Herausforderung sei, die es zu bewältigen gilt. „Alles, was wir tun, wird davon abhängen, dass wir diesen Herausforderungen mit den richtigen Werkzeugen, Aktionen und Mitarbeiterausbildung entgegenreten.“

Der Unterausschuss für EU-Angele-

genheiten sowie auch der Wissenschaftliche Unterausschuss sind in Vorbereitung auf die Tagesordnungspunkte im Vorfeld zweimal zusammengetroffen. Auch der Redaktionsausschuss traf sich für die Ausarbeitung des Redaktionsplans für *(E)Hospital* zweimal in Brüssel.

Ein weiteres zentrales Thema des Tätigkeitsberichtes war der Reflexionsprozess. Der Präsident hob dabei hervor, dass sich das Arbeitsumfeld, in dem man tätig ist, sowohl auf europäischer als auch auf nationaler Ebene der Vereinigung verändert habe. So gab es größere Veränderungen in Bezug auf die Professionalisierung und auch die Strukturen. Dies erfordere eine neue Organisation und in dem sich veränderndem Umfeld müssten sich die Manager für den Reflexionsprozess anpassen. Die bisherigen Anlaufstellen dafür waren die Presseverbindungen, das Internet (über die Webseite), die IT-Arbeitsgruppe und die Veranstaltungen in Wien und Litauen. Diese regionalen Seminare bauten eine gemeinsame Sprache zwischen dem Management und den IT-Professionalisten auf – wofür es positive Reaktionen gab. Herr Kölking betonte, dass der Reflexionsprozess nicht nur diskutiert wurde, sondern dass die Ergebnisse implementiert werden und dass der Vorstand und der Exekutivausschuss dies an die Spitze ihrer Agenden gesetzt haben.

Hinsichtlich der Mitgliedschaft waren einige nationale Vereinigungen nicht in der Lage ihren Mitgliedsbeitrag zu zahlen. Das Geschäftsführung hat entschieden, diese nicht auszuschließen und wird Lösungen finden, diese zu unterstützen ohne die finanzielle Basis, die die Vereinigung braucht, zu gefährden.

JAHRESABSCHLUSS 2010 UND WIRTSCHAFTSPLAN 2012

Generalsekretär Willy Heuschen legte die finanziellen Berichte vor. Mittlerweile konnte das Budget 2010 eingehalten werden (mit 106 Euro Überschuss) und Herr Heuschen dankte vor allem der Schweizer Ver-

einigung für deren Gewinn aus dem Kongress 2010 in Zürich. Die Ausgaben erhöhten sich wegen der Zunahme von Sitzungen und den damit verbundenen Reisekosten. Zusammenfassend erklärte Herr Heuschen, dass trotz der Schwierigkeiten im Zuge der Finanzkrise, die EVKD mit Hilfe der erfolgreichen Schweizer Konferenz, die Ergebnisse des Reflexionsprozesses implementieren konnte, ohne das Budget zu destabilisieren.

Der Wirtschaftsplan 2012 sieht keine größeren Zunahmen vor. Es gibt einen kleinen Beitrag zu der schwierigen Situation nationaler Vereinigungen. Wieder können einige nationale Vereinigungen nicht ihre Gebühren bezahlen, aber das bedeutet nicht, dass sie ausgeschlossen werden. Man hege die Hoffnung, dass die Welt 2012 besser aussehen wird und ein Teil der Mitgliedsbeiträge wieder eingebracht werden können.

Ein weiteres zentrales Thema waren die Partnerschaftsabkommen. Bei der Generalversammlung sagte Herr Heuschen, dass man derzeit sechs Partnerschaften in Aussicht habe. Er appellierte an die Mitglieder dabei zu helfen, mehr solche Partnerschaften zu finden. Diese seien nicht einfach zu finden, da die Kriterien eine echte Partnerschaft vorschreiben und nicht nur ein „Blitzgeschäft“. Man hofft, dass jede diese Partnerschaften mindestens drei Jahre dauert.

Christoph Pachlatko stellte in Hinblick auf diese Partnerschaften die wichtige Frage, ob deren erwartete Einnahmen im Budget 2012 berücksichtigt werden? Herr Heuschen stellte klar, dass die EVKD erst zwei Partner habe, dass aber kontrolliert wird, dass die Ausgaben im Einklang mit den Einnahmen stehen. Es werden nur Gelder, die aus einer Partnerschaft reinkommen, ausgegeben. Herr Heuschen aber betonte aber gleichzeitig, dass er die Tatsache, dass das Budget 2012 eine Herausforderung ist, nicht ignoriere.

Die nächste Generalversammlung wird am 27. September 2012 in Athen stattfinden.

▶ Erste Europäische Krankenhauskonferenz

Am 18. November 2011 fand die erste Europäische Krankenhauskonferenz in Düsseldorf, Deutschland, statt. Organisiert wurde diese von den drei wichtigsten Vereinigungen im Europäischen Gesundheitswesen (EVKD, HOPE und AEMH). In der Konferenz ging es um die heutigen politischen, medizinischen und wirtschaftlichen Themen. Die Konferenz war in zwei Teilen gegliedert. Die Vormittagssitzung konzentrierte sich – mit einem Hauptvortrag von Mars Di Bartolomeo, Gesundheits- und Sozialminister in Luxemburg – auf die derzeitige europäische Gesundheitspolitik. Darauf folgten Anmerkungen jeder der europäischen Vereinigungen. Die Nachmittagsitzung war der EU-Richtlinie über Patientenrechte und ihren Auswirkungen auf die Krankenhäuser gewidmet. Den Hauptvortrag hielt Annika Nowak von der Europäischen Kommission. Es folgten Stellungnahmen verschiedener Europäischer Staaten (Vereinigtes Königreich, Ungarn, Frankreich, Belgien, Schweden und Griechenland).

Alle Teilnehmer bestätigten den großen Erfolg der Konferenz, denn dort wurde nicht nur eine große Bereitschaft gezeigt, von den Erfahrungen anderer europäischer Staaten zu lernen, sondern auch die Wichtigkeit einer Kooperation und Zusammenarbeit hervorgestrichen, um die wachsenden Herausforderungen im Gesundheitswesen heute bewältigen zu können.

▶ Ethische Führung Von UL Aparo, A Aparo

Die ethischen Führung bezieht sich auf Werte und ethisches Verhalten, auf Prozesse und Verfahren, auf Kultur und Wege des Handelns und Seins, sowie auf die Sicherung hoher Standards im Bereich der Leistung, Wirtschaft, Effektivität, Effizienz, Qualität und Zufriedenheit. Dabei müsse jedem klar sein, dass es kein ethisches Handeln geben kann, ohne dass dessen Grundsätze nicht von der „Leitung des Gesundheitskomitees“ oder im Vorstand, die die wesentlichen Bestandteile der Organisation darstellen, gelebt werden.

Diese Organisationseinheiten sollen die Ansichten der Ethikkommission berücksichtigen. Die Ethikkommission sollte sich aus Personen zusammensetzen, die die über Tatsachen und Umstände gut informiert sind und die in der Lage sind, Bedürfnisse und Ansichten aller Beteiligten zu erkennen und zu verstehen. Dabei sollten die Ansichten und Anliegen des Patienten, seiner Angehörigen sowie der Führungskräfte und aller jener, die ein berechtigtes Interesse haben, respektiert werden.

▶ Unterstützung für die Entwicklung „Clinical governance“ im irischen Gesundheitssystem Von Philip Crowley, Maureen Flynn

Im Sommer 2011 hat die Leitung des irischen Gesundheitsdienstes neuerlich beschlossen, einen Schwerpunkt auf die Entwicklung der „Clinical governance“ zu setzen.

Als Teil der Kommunikationsstrategie wurde die Notwendigkeit einer prägnanten Informationen zum Thema „Clinical governance“ festgestellt. Das Ziel ist eine breitere Gemeinschaft des Gesundheitswesens über die VisioL, um über die Vorteile und Leitsätze „Clinical governance“ zu informieren und daraus Dynamik und Unterstützung bei der Umsetzung der Prozesse zu gewinnen.

Die „Clinical governance“ hilft sicherzustellen, dass die Menschen die notwendige Betreuung in einer sicheren, pflegeorientierten, offenen und richtigen Umgebung erhalten, welche sich aus den Organisationsprinzipien für die klinische Leistung ergeben. Der Vorteil der „Clinical governance“ liegt in der Verbesserung der Erfahrungen von Patienten und auf besseren Ergebnissen in Sachen Qualität und Sicherheit. Das Mantra für die Entwicklung der „Clinical governance“ ist, dass alle gemeinsam Verantwortung wahrnehmen und gemeinsam ein sichereres System der Gesundheitspflege verwirklicht wird.

▶ Kampf gegen Infektion mit EUNETIPS Von Silvio Brusaferrò

Vergangenen Oktober gründeten in Venedig, Italien, 16 europäischen Berufs- und Wissenschaftsverbände aus 14 Ländern, welche mit Infektionsvorbeugung und –kontrolle befasst sind, das Netzwerk EUNETIPS – eine Europäisches Netzwerk zur Förderung von Präventionsprogrammen für die Sicherheit von Patienten. Die Ziele von EUNETIPS sind: Die Förderung einer besseren Zusammenarbeit zwischen Mitgliedsländern, die Teilung von Erfahrungen, die Förderung und Unterstützung von Initiativen betreffend Präventionen von Infektionen für die Sicherheit der Patienten insbesondere auf europäischer Ebene, sowie das gegenseitige Kennenlernen von Mitgliedern, um so einen Mehrwert für jedes Mitglied zu erreichen.

Auf nationaler Ebene agierende wissenschaftliche und professionelle Gesellschaften haben in vielen Fällen keinen regelmäßigen, formalen Kontakt mit Gesellschaften aus anderen Mitgliedstaaten, abgesehen von jenen Kontakten, die sich bei Teilnahmen an internationalen Aktivitäten wie wissenschaftliche Ausschüsse oder Projekte ergeben. Dies ist ein entscheidender Punkt, da es in ganz Europa eine große Anzahl ungenutzter Ressourcen von Erfahrungen, Wissen, Qualifikationen und Ausbildungsmöglichkeiten gibt. Diese Ressourcen sollten bekannt gemacht, geteilt und schließlich Teil einer gemeinsamen Plattform werden. EUNETIPS stellt eine solche Plattform bereit.

▶ Klinische Pharmakologen und Krankenhausapotheker spielen entscheidende Rolle in der Förderung der Verschreibungseffizienz für neue und bereits vorhandene Arzneimittel Von Brian Godman et al.

Zu den neuen, kostenintensiven Medikamenten zählen beispielsweise die Biologika, die mit wesentlich höheren Kosten vermarktet wer-

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den, als dies bisher üblich war. Ein besorgniserregender Trend – die Ausgaben steigen jährlich um etwa 20%, was zu einer Rationalisierung anderer Krankenhausbereiche führt. Wird dieses Problem nicht rechtzeitig angesprochen, könnte das europäische Ideal einer umfassenden und gerechten Gesundheitsversorgung gefährdet sein. Verschärfend kommt hinzu, dass viele der neuen Wirkstoffe, einschließlich neuer Krebsmedikamente, trotz ihrer hohen Preise einen nur begrenzten Vorteil für die Gesundheit erbringen.

Diese Bedenken waren für viele Europäische Interessensgruppen der Ansporn, sich aktiv um eine bessere Verschreibungseffizienz zu kümmern, einschließlich nationaler, regionaler und örtlicher Koordinierungsbemühungen, Absprachen zur geteilten Risikoabdeckung und Vergleichstests.

Klinische Pharmakologen und Krankenhausapotheker können in einem beträchtlichen Ausmaß die Qualität und Effizienz beim Verschreiben neuer und bereits bestehender Arzneimittel in allen Bereichen verbessern. Untätigkeit auf diesem Gebiet wird zu einem vermehrten Verschreiben teurer, patentierter Arzneimittel führen, und die Fähigkeit europäischer Länder gefährden, auch weiterhin eine umfassende und gerechte Gesundheitsversorgung zu bieten.

▶ **Medikamentenversorgungssysteme: Ein Überblick**

Von Rajan K. Verma, Mitesh Nagar, Purushottam Nagar

Bezüglich einer erfolgreichen Medikamentenforschung und -entwicklung ist die pharmazeutische Industrie heute gefangen zwischen Preisdruck und steigenden Kosten. Die durchschnittlichen Entwicklungskosten für eine neue chemische Einheit (NCE) betragen ca. 0,5 -1,5 Milliarden US-Dollar und nehmen 10 bis 15 Jahre für die Entwicklung in Anspruch. Die Entwicklung eines neuen Verabreichungssystem für Medikamente verursacht oft wesentlich weniger Kosten, führt aber gleichzeitig zu einer Verbesserung der Wirksamkeit, Reduzierung der Anwendungshäufigkeit und Verringerung der Nebenwirkungen. Verabreichungssystem für Medikamente basieren entweder auf chemischen oder biologischen Elementen und haben den Zweck, die Dosierungen zu verbessern oder die genaue Menge des Medikaments im systemischen Kreislauf (z.B. Liposomen, Osmotische Pumpen, transdermale Pflaster, etc) zu kontrollieren. Durch die Entwicklung neuer Verabreichungssystem für Medikamente kann einem alten Medikamentenmolekül "neues Leben" eingehaucht und damit der Marktwert gesteigert werden, sowie die Wettbewerbsfähigkeit erhöht und der Patentschutz verlängert werden.

▶ **"Kosten-Nutzenanalyse" der Radiologie**

Von J. Adam

Da die Gesundheitsversorgung komplexer und teurer geworden ist, hat sich die Wirtschaftsanalyse des Gesundheitswesens als zunehmend wichtige Disziplin etabliert. Es gibt vor allem drei Wege, wie der

Geldwert bei Gesundheitsinterventionen beurteilt werden kann: Kosteneffizienzanalyse, Kosteneinheitenanalyse die Kostenminimierungsanalyse. Diese Prinzipien können auch im Bereich der Radiologie angewandt werden. So ist beispielsweise erwiesen, dass das „Mammographie-Screening“ eine gute Investition in punkto Kosten-Nutzen Verhältnis darstellt.

Als teure Untersuchungsmethode wird die Radiologie auch in Zukunft nicht immun gegen die Hinterfragung der Kosten sein. In einigen Fällen werden Untersuchungen zur Beruhigung, aus medizinisch-rechtlichen Gründen oder als Ausgleich für eine klinische Unsicherheit gemacht – und diese bedeuten dann möglicherweise keine gute Verwendung der knappen Ressourcen.

▶ **Focus: Norwegen**

Von May Britt Buhaug, Erik Kreyberg Normann



Die norwegischen Krankenhaus- und Gesundheitleistungsvereinigung (NSH) ist eine interdisziplinäre Organisation für alle, die im Gesundheitswesen in Norwegen tätig sind. NSH feiert 2012 sein 75-jähriges Jubiläum. Als eine unpolitische und unabhängige Organisation hat NSH das Ziel, ein interdisziplinärer Treffpunkt für Berufstätige im Gesundheitswesen zu sein – durch die Bereitstellung von Konferenzen, Tagungen und Studienreisen. Bei diesen Veranstaltungen haben die Teilnehmer Gelegenheit neues und verbessertes Wissen zu erwerben und einen Austausch von Erfahrungen mit Führungskräften im Gesundheitswesen auf allen Ebenen zu führen.

NSH ist bestrebt, eine gleiche Gesundheitsversorgung für jedermann zu gewährleisten und arbeitet aktiv an allgemein anerkannten ethischen Prinzipien, welche die Grundlagen der Ressourcenverteilung, Prioritätensetzung und der Versorgung für die Patienten auf allen Ebenen sicherstellt.

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¹CLSI. Surveillance for methicillin-resistant Staphylococcus aureus: principles, practices and challenges: a report. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

²Screening, isolation, and decolonisation strategies in the control of methicillin resistant Staphylococcus aureus in intensive care units: cost effectiveness evaluation. Robertson et al. BMC 2011; 14(2):25591 doi: 10.1185/bmj.d15594

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