Chronic disease management and remote patient monitoring

Chronic disease management in Europe and the US
Clinical and economic perspectives on remote patient monitoring
Adopting mainstream telecom services: lessons from the UK

Cross-border health care: implications for NHS • Norway: improving child and adolescent mental health services
Promoting a sustainable workforce • Pharmaceutical sector in Srpska • South Korea: long term care insurance
Chronic disease management and the use of remote patient monitoring

Chronic diseases, such as heart disease and diabetes, have substantial health and economic impacts. Routine consultations to monitor these conditions place a considerable strain on health service resources. Consequently, there has been an increased interest in utilising information technology to help manage patients. One such innovation – the use of remote monitoring – allows for the collection of routine information on the health status of individuals outside the doctor’s office and is the focus of much of this issue of Eurohealth.

Chronic disease management (CDM) encompasses the ongoing management of chronic conditions over a period of time using evidence-based care. In an article on CDM in the US, Kenneth Thorpe highlights the huge burden of chronic disease in terms of mortality and health care spending. He calls for prevention efforts directed at patient education, improved coordination among practitioners and better patient-doctor collaboration. In their article on CDM in Europe, David Scheller-Kreinsen and colleagues, present key strategies used to manage chronic diseases, summarising existing evidence on their effectiveness and describing common obstacles to effective CDM.

Four articles specifically address remote monitoring. In their article on the clinical perspective, Jillian Riley and Martin Cowie contrast traditional models of CDM with the inclusion of remote monitoring in a heart failure population, presenting both the clinical benefits and patient perspective. Paul Trueman tackles the economic perspective, describing the potential benefits of remote monitoring and commenting on the growing body of evidence on the clinical and cost effectiveness of such interventions. Michael Palmer and colleagues look at the European Commission’s adoption of a Communication to support the deployment of telemedicine for the benefit of patients, health care systems and society. Finally, James Barlow and Jane Hendy use the case of the UK to present the challenges of adopting integrated mainstream telecare services. A common thread running through these contributions is the challenges in providing appropriate incentives for health care professionals to implement changes to improve chronic care, including the use of telemedicine.

Other features in this issue include two perspectives from the European Commission. One discusses the EU Directive on patients’ rights in cross-border health care and its implications for the National Health Service in the UK. The second focuses on the EU Green Paper on the health care workforce, which is intended to support Member States as they confront an ageing but increasingly mobile population.

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Contents

Chronic disease management
1 Chronic disease management in Europe
   David Scheller-Kreinsen, Miriam Blümel and Reinhard Busse
5 Chronic disease management and prevention in the US:
   The missing links in health care reform
   Kenneth E Thorpe
8 Adopting integrated mainstream telecare services
   Lessons from the UK
   James Barlow and Jane Hendy
10 Economic considerations of remote monitoring in chronic conditions
   Paul Trueman
13 European Commission perspective: Telemedicine for the benefit of
   patients, health care systems and society
   Michael Palmer, Christoph Steffen, Ilias Iakovidis and Flora Giorgio
15 A clinical perspective on remote monitoring of chronic disease
   Jillian P Riley and Martin R Cowie

Health Policy Developments
18 EU cross-border health care proposals: implications for the NHS
   Helena Bowden
20 Promoting a sustainable workforce for health in Europe
   Elizabeth Kidd
23 The pharmaceutical sector in the Republic of Srpska, Bosnia and
   Herzegovina
   Vanda Markovic Peković, Ranko Skrbić and Nataša Grubiša

Snapshots
26 Improving child and adolescent mental health services in Norway:
   Policy and results 1999–2008
   Marian Adnanes and Vidar Halsteinli
28 The introduction of long-term care insurance in South Korea
   Soonman Kwon

Evidence-informed Decision Making
30 “Bandolier” Value of vision
32 “Risk in Perspective” An overview of “Science and decisions:
   advancing risk assessment”

Monitor
37 Publications
38 Web Watch
39 News from around Europe

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Policy makers across Europe increasingly recognise that chronic disease management (CDM), the ongoing management of conditions over a period of years or decades, is one of the most important challenges that European health systems face. Chronic conditions and diseases are the leading cause of mortality and morbidity in Europe and research suggests that complex conditions, such as diabetes and depression, will impose an even larger health burden on societies across Europe in the future. The World Health Organization ‘Global Burden of Disease’ study estimated that, as of 2002, chronic or non-communicable conditions accounted for 87% of deaths in high income countries. By comparison, 7% of deaths were attributed to communicable conditions and nutritional deficiencies, and 6% to injuries. Worldwide, the proportion of deaths due to non-communicable or chronic diseases is projected to rise from 59% in 2002 to 69% in 2030.1

CDM embraces not only the ‘classical’ conditions such as cardiovascular disease, diabetes and asthma, but also many types of cancer and HIV/AIDS (as survival rates and times have visibly improved), mental disorders (for example, depression, schizophrenia and dementia) as well as certain disabilities (for example, visual impairment). CDM is a complex response over an extended period with coordinated input from a wide range of health professionals, as well as access to drugs and equipment and patient empowerment going beyond medical care into the social care setting. This is in contrast with most health care today, which is structured round acute, episodic models of care.

It has been shown that the economic implications of chronic diseases and conditions are severe from both the macro- and microeconomic perspectives. Chronic diseases impact on wages, workforce participation, labour productivity and hours worked. Often, chronic conditions contribute to early retirement, high job turnover and disability. Overall, disease-related impairment of households’ consumption and educational performance affects the gross domestic product (GDP) negatively. In addition, expenditure on chronic care is rising across Europe and consumes increasing portions of public and private budgets. Suhrcke and Urban2 demonstrated that the cost of chronic diseases and their risk factors, as measured by cost-of-illness studies, is sizeable, ranging up to 6.77% of a country’s GDP.

Policy makers across Europe have developed heterogeneous CDM strategies, such as disease management programmes (DMPs) or prevention and early detection interventions. However, research suggests that many of these current approaches to CDM face substantial structural problems and hence have failed to fulfil hopes and promises.3 This article briefly outlines the principal CDM strategies and summarises existing evidence on their effectiveness. We also highlight common obstacles impeding successful CDM and outline a series of steps that policy makers need to take to improve the conditions for effectively managing chronic diseases in Europe.4

**CDM strategies**

*Disease prevention and early detection interventions* aim to reduce the burden of chronic disease through activities that avoid impairment to health or reduce the likelihood of chronic conditions developing. Prevention includes primary,
secondary, or tertiary approaches that differ in aims and target groups. Primary prevention targets the prevention of illness by removing the causes, especially in periods of increased risk. Secondary prevention aims to treat disease at an early stage, when first observable and perceivable pathophysiological changes occur, so that people can be cured early or be prevented from further deterioration. Tertiary prevention activities intend to cure, alleviate or compensate for the impacts of a disease up the point where it can no longer be influenced.6

The specific prevention approaches adopted in a country vary according to the health care system and dominant political opinions. European countries place different emphasis on the responsibility of the community and the individual, depending on culturally anchored views about the role of the state and the autonomy of the individual.5 Overall, the effectiveness of prevention and early detection interventions is relatively well documented for risk factors such as hypertension, obesity or alcohol and tobacco consumption. In particular, research indicates that comprehensive approaches, combining several interventions are most effective. Compared to curative and acute treatment, a high proportion of prevention interventions have proven to be more effective. Even though prevention is a promising strategy for managing chronic diseases, it still plays only a secondary role in European health systems. Most countries have not yet reacted to the need for prevention of chronic diseases at a programmatic level.

New professions, qualifications and settings were designed to meet the challenge of CDM in Europe. For instance, nurse practitioners, liaison nurses and community nurses have been introduced in several countries. In addition, the tasks and responsibilities of existing professional groups have shifted and expanded. For example, the UK and Scandinavian countries have implemented a ‘collaborative methodology’ as an instrument for managing chronic diseases by training physicians to have a guiding role through chronic disease management (CDM) in Europe. For instance, nurse practitioners, liaison nurses and community nurses have been established over the last decade depending on culturally anchored views about the role of the state and the autonomy of the individual. In addition, the tasks and responsibilities of existing professional groups have shifted and expanded. For example, the UK and Scandinavian countries have implemented a ‘collaborative methodology’ as an instrument for managing chronic diseases by training physicians to have a guiding role through CDM. However, these approaches often suffer from fragmentation and a lack of coordination between different actors in the health system. Disease management programmes have been implemented in many European countries. While no universal definition of DMPs exists, most definitions share three main features: a knowledge base, a delivery system with coordinated care components, and a continuous improvement process for a specific disease among a defined population.7 Further key elements of DMPs are presented in Figure 1.

In summary, DMPs can be regarded as a means to coordinate care, focusing on the whole clinical course of a disease. Care is organised and delivered according to scientific evidence and patients are actively involved in order to achieve better health outcomes. Structured DMPs for selected conditions were originally developed in the United States and subsequently adopted by a number of European countries, including Germany and the UK. The effectiveness of European DMPs has not been sufficiently evaluated. Large-scale population-based evaluations with rigorous research design are lacking. In part, this is due to the relatively short time period that has elapsed since DMPs have been established across Europe.8 Small-scale studies suggest that DMPs may have a positive impact on the process of care for congestive heart failure, coronary heart disease, diabetes and depression, while the evidence for asthma and chronic obstructive pulmonary disease is inconclusive. With regard to medical outcomes, the existing evidence is also inconclusive.

Most small-scale studies suggest that DMPs are hampered by a lack of coordination between professional groups, the absence of well-targeted financial incentives, as well as fragmentation in the health care sector. Finally, integrated care models respond to the fact that chronic diseases can rarely be treated in isolation. Often patients suffer from several chronic diseases or conditions. Hence, while DMPs focus on one single disease, integrated care models are organised to achieve better integration of services across the whole continuum of care for various diseases. Integrated care models developed in the US have been influential in informing chronic care policies in Europe and elsewhere. European countries such as England, Germany and Spain have invested considerably to develop integrated care models inspired by experience in the US. Other countries, such as the Netherlands or France, have established provider networks which bridge the gap between ambulatory and inpatient sectors to achieve better integration of services across the whole continuum of care. The effectiveness of integrated care models is controversial. Large-scale population-based studies are lacking. Preliminary results from pilot studies suggest that some positive results may be generated, but given the complexity of integrated care models, again implementation, coordination and fragmentation are key challenges. Moreover, studies fail to indicate which components of integrated care are responsible for positive and negative results.

**Key challenges to successful CDM**

The broad set of policy instruments to meet the challenge of CDM in Europe indicates that policy makers have invested considerable energy and resources. Never-
Financial flows and incentives

Common problems in the effective management of chronic diseases are financial flows and incentives, which do not motivate health professionals to engage in CDM. The importance of financial incentives is intuitive: however motivated some health care stakeholders may be to implement changes to improve chronic care, few will operate counter to their economic interest.9 Table 1 summarises examples of the use of financial incentives in CDM across Europe.

Different types of financial incentives are used in CDM to motivate providers and health professionals: they tend to focus either on the structure or processes of care.10 Only the UK general practitioner (GP) contract specifically includes a range of incentive payments focused on the delivery of particular outcomes. In general, there has been a gradual shift of focus from approaches that simply take into account the presence of patients with chronic disease for funding towards incentives designed to encourage specific kinds of structural and process responses at the provider level.11

The impacts of these incentives are rarely scrutinised. However, the US experience offers some insights: designs that set a few narrow goals may lead to an excessive focus on incentivised versus other tasks or areas of quality, as well as more gaming or better reporting, but without any improvements in quality.

Moreover, financial incentives influence various subgroups of providers or health professionals differently. Those with high, average or poor performance prior to the intervention react differently to financial incentives. Thirdly, mixed approaches, combining different payment schemes such as fee-for-service (covering all expenditures after a medical intervention retrospectively irrespective of the total amount and the quality of the service) and case fees (covering only a predefined fixed sum for a specific intervention) may mitigate negative effects of either approach applied alone.

Finally, Peterson et al.12 find that the size of the incentive clearly matters: a significant percentage of income has to be variable before providers or health professionals can be expected to change their behaviours. Overly large incentives on the other hand may motivate health professionals to concentrate excessively on incentivised goals at the expense of other implicit targets.

Some evidence has also been generated about the Quality and Outcomes Framework (QOF) for GPs in the UK. This established pay-for-performance at the GP practice level by monitoring outcomes and quality variables. Typically about 25% of practice income is dependent on quality rewards.

While some controversy exists about the impact of the programme, positive outcomes with regard to quality of care, especially chronic care, have been identified.13 In particular, patients seem to benefit from the provision of more systematic care. In addition, structures are important since improvements in the quality of care tend to generate (measurable) benefits only in the long-term. Hence, health professionals and providers can only be effectively incentivised to improve chronic care, if a certain ‘continuity of care’ is ensured.

Coordination

Enhancing coordination is another critical dimension that must be achieved to fully unveil the potential of CDM in Europe. Research suggests that one of the central obstacles to improved care for patients with chronic diseases is the lack of coordination in health care provision. As noted earlier, structured CDM approaches such as DMPs and integrated, multi-disease care models suffer from fragmentation between the different tiers of increasingly differentiated health systems. Often in chronic care multiple actors are involved in service provision over an extended period of time.

Common reasons for coordination problems include:

- Different modes of operation across sectors (primary vs. secondary; public vs. private).
- Providers incentivised to compete rather than to cooperate.

Table 1: Financial incentives in European health systems

<table>
<thead>
<tr>
<th>Financial incentives targeting the individual</th>
<th>Financial incentives targeting structures of care</th>
<th>Financial incentives targeting processes of care</th>
<th>Financial Incentives targeting outcomes of care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piloting ‘year of care’ payments for the complete package of CDM required by individuals with chronic conditions, For example, based on validated ‘care pathways’ for diabetes (DK; UK)</td>
<td>Per patient bonus for physicians both acting as gatekeepers for chronic patients and setting care protocols (FR)</td>
<td>Points for reaching process targets (UK: GP contract)</td>
<td>Points for reaching outcome targets (UK: GP contract)</td>
</tr>
<tr>
<td>Additional services (for example, patient self-management education) only reimbursable if physicians and patients participate in DMP (GER)</td>
<td>Bonus for DMP recruitment and documentation (GER)</td>
<td>1% of overall health budget available for integrated care (GER)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Points for reaching structural targets (UK: GP contract)</td>
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<td></td>
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</tbody>
</table>

Note: DK = Denmark; FR = France; GER = Germany; UK = United Kingdom
Source: Authors’ own table based on Busse and Mays, 2008.10
- Individuals or professional groups compensated for separate activities rather than for cooperation.
- Rivalry over resources and power between professional groups.
- Overlapping responsibilities and non-transparent accountability between divisions within providers and between different providers.

In addition, high levels of professional concern among physicians with regard to shifting competencies to other professional groups, such as nurses or general practice, can pose considerable challenges to the coordination of chronic care. Finally, the absence of training for staff meant to perform these new roles is a serious problem.

**Information and communication technology**

Another obstacle to the effective management of chronic diseases in Europe is the lack of efficient use of information and communication technology (ICT). Expectations with regard to the former were high. Abstract models and a number of small-scale pilot studies suggested that multiple benefits could be generated through the employment of computerised data collection and decision support systems and data collection. In particular, the use of evidence-based medicine, supported by electronic protocols and clinical pathways, was considered attractive since improvements in the quality of medical outcomes and efficiency gains seemed to be achievable.

However, experience to date does not suggest that ICT has generated large benefits. In many European countries, ICT initiatives suffer from unexpected difficulties, budget-overruns and high costs. In addition, no well-grounded empirical evidence of the benefits of ICT has been generated. Pilot studies have however identified a number of common problems: functional interoperability within health systems is not given; no practical tools are offered on how the vast amounts of data which modern information technology is able to store, can be translated into meaningful information for health professionals; and public concerns about data protection are not adequately addressed.

**Evaluation**

Furthermore, many aspects of CDM are not properly evaluated. The effectiveness and cost-effectiveness of various preventive and treatment interventions are not well established. Policy makers are therefore not optimally equipped to make informed decisions to shape the future of CDM.

**Pharmaceutical and medical innovation**

It is essential that the important role of pharmaceutical and medical innovation continues to be recognised. A new type of pharmaceutical, for example, personalised medicine, may lead to better medical outcomes, adherence and improvement in patients' quality of life. At the same time, the development of innovative pharmaceuticals, especially pharmaceuticals and therapies targeting rather small population groups effectively at high costs, poses huge challenges with regard to authorisation and reimbursement.

**Conclusion**

Given these structural and organisational problems with CDM, policy makers in Europe can clearly contribute to improving the conditions for effective CDM.

With regard to financial incentives, making the payment schemes of different professional groups compatible is a prerequisite to the facilitation of cooperation in multidisciplinary teams. Different financial incentives for members of the same medical team may frustrate common efforts, as economic interests may motivate demands for different approaches to treatment. Moreover, continuity of care needs to be one of the key preconditions for payer or provider investment in CDM programmes, since any net returns from up-front investments tend to be made five years after installation while the benefits of avoiding severe complications tend to be collected only five to ten years after prevention.

As a consequence, health systems with a traditional focus on 'patient choice' of providers, little enrolment with particular providers and/or payment using fee-for-service as the key approach for reimbursement, all of which lead to relatively low continuity of care, face the greatest difficulties in aligning financial incentives with the goal of promoting better CDM. Given the former, policy makers should consider strengthening or introducing financial incentives conducive to 'continuity of care'.

To enhance coordination, policy makers need to decide early on whether a radical departure from the given structure is needed for more effective coordination, or whether reform can be built on established norms, institutions and practice. Structurally, policy makers need to map out both clearly shared and clearly separated responsibilities of the actors involved in the delivery of chronic care. Moreover, the balance between local autonomy and central authority during reform and routine operation needs to be defined. Operationally, there is a need to provide sufficient funding to enable reform, while at the same time compensation schemes conducive to cooperation rather than emphasising professional separation need to be established. Finally, the workforce needs to be prepared to fulfil their new roles; hence adequate training and mutual learning and communication need to be initiated.

In the face of globalisation and the European common market for goods and services, which increasingly penetrates health care markets, policy-makers need to ensure that standards and methods of evidence-based evaluation are internationally accepted and possibly harmonised. There is also a need to increase the transparency of procedures and policy decisions. Moreover, to overcome ICT problems connected to functional interoperability within health systems and to address public concerns on data protection, policy makers need to take the lead in introducing adequate technical standards and regulatory frameworks.

Finally, policy makers need to develop a clear position on the market authorisation and reimbursement of highly effective but costly personalised medicines. Furthermore, new criteria may be needed to assess interventions and treatments in CDM, since cure is rarely the medical goal. Hence incorporating concepts such as 'quality of life' more explicitly into marketing authorisation and reimbursement decisions should be considered.

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Chronic disease management and prevention in the US: The missing links in health care reform

Kenneth E Thorpe

Summary: In the United States (US), chronic diseases are among the most prevalent and costly health care problems, as well as the most preventable. This article examines chronic disease as the missing link in health care reform in the US; candidly discusses the particular impact chronic diseases and the lack of prevention have on quality of life, on escalating health care costs, and on the overall US economy; and recommends population health improvement programmes to reach and support citizens with chronic diseases in varied settings.

Key words: Chronic Disease, Population Health Improvement Programmes, Prevention, USA

The burden of chronic disease

Chronic diseases account for seven out of ten deaths in the United States, and consume 75 cents of every dollar spent on health care. Nearly half of all people in the US – of all ages, race, and socio-economic background – live with a chronic condition, such as high blood pressure, diabetes, or asthma.1 More than two-thirds of all deaths are caused by one or more of five chronic diseases: heart disease, cancer, stroke, chronic obstructive pulmonary disease and diabetes.2 Many chronic diseases are lifelong conditions, and their impact lessens the quality of life, not only of those suffering from the diseases, but also of their family members, caregivers and others. Chronic diseases not only affect health and quality of life and reduce economic productivity by contributing to increased absenteeism and poor at-work performance, but they also drive rising health care costs and threaten health care affordability.

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In 2007, the US spent over $2.2 trillion on health care, and three-quarters of this went to treat patients with one or more chronic diseases. In public programmes, treatment for chronic diseases constitutes an even higher portion of spending: 83 cents of every dollar in Medicaid and more than 95 cents in Medicare.3 From 1987 to 2000, health spending for non-institutionalised populations doubled from $314 billion to $628 billion per year; fully $211 billion of that increase was attributable to the increase in treated disease.3 Those figures represent just the direct costs. By some measures, indirect costs actually dwarf money spent on treatment. A groundbreaking study in late 2007 by the Milken Institute reported that treatment costs for the seven most common chronic illnesses – cancers, diabetes, heart disease, hypertension, stroke, mental disorders, and pulmonary conditions – ran to $277 billion in the US in 2003. That figure does not include treatment costs for secondary conditions and complications. But indirect costs were nearly four times as high: totalling more than $1 trillion.4 The same analysis estimates that modest reductions in unhealthy behaviours could prevent or delay forty million cases of chronic illness per year. Despite these significant and growing expenditures, research shows that chroni-
Evidently ill patients receive only 56% of clinically recommended health care. While the US is spending a staggering amount on chronic disease care, objective measures indicate it may not be spending wisely or well to treat chronically ill patients. This discrepancy results chiefly from systemic inadequacies: the American health care system was built to deliver health care services to acutely ill patients requiring episodic care, not to patients who are chronically and persistently in need of medical care. Additionally, the US spends more on health care than any other industrialised nation, but by many measures, its spending is not achieving the results wanted or needed.

A study comparing the trends in deaths considered amenable to health care before age 75 between 1997/98 and 2002/03 in the US and 18 other industrialised countries should give the US pause. On average, preventable deaths account for 32% of total mortality among women and 23% among men under age 75. The majority of the conditions responsible for preventable deaths are chronic conditions: cancers, diabetes, ischemic heart disease, and other circulatory disorders. The average decline in amenable mortality in developed countries was 16%. But the US was an outlier, with a decline of only 4%. If the US could have reduced amenable mortality to the average in the three top-performing countries – France, Japan, and Australia – there would have been 101,000 fewer deaths per year. In addition, a recent study indicates that life expectancy in the US has dropped for the first time in a hundred years, which may be attributed to chronic disease resulting from smoking and obesity.

The rates of amenable mortality and life expectancy are indicators of overall health system performance. America’s significant performance gap is a worrisome signal that the health care system is not performing well against a set of relative health measures. On its current trajectory, cases of chronic disease will significantly increase, along with their associated direct and indirect costs. The truth is, though, the vast majority of chronic disease could be prevented or better managed.

Discussions regarding health care reform in the US are incomplete if they do not consider the role that chronic disease plays in driving preventable ill-health, increasing costs for care, and decreasing American competitiveness. Transforming the US health care system to better meet the needs of people with chronic conditions will require a renewed focus on preventing disease when possible, identifying it early when it occurs, and implementing evidence-based secondary and tertiary prevention strategies that slow disease progression and the onset of activity limitations, as well as save money for the patient and the health care system.

Evidence in support of prevention and chronic disease management

Over three-quarters of American adults are candidates for at least one health prevention activity which, if fully adhered to, would decrease heart attacks by 63% and strokes by 31%. The US medical community has developed consensus recommendations on the clinical treatment and appropriate preventive measures for patients with diabetes, hypertension and other chronic conditions.

Aggressive secondary and tertiary prevention in the present system have the appearance of insurmountable time and cost requirements. Education in professional medical programmes nationwide should frame the discussion on preventive medicine as one of needed and lasting benefit to patients and populations. If such actions were to be adopted nationally, the aggregate results have the potential to decrease demand for treatment, freeing both time and resources for targeted care provision. These savings will not only be enjoyed by the individual, but by the entire US health care system.

Evidence-based research suggests that well designed prevention and primary care focused chronic disease management programmes can both improve health and provide financial value, including cost savings. Investments in high-impact, cost-effective population prevention and health improvement programmes can increase the affordability of health care, while helping Americans live longer, healthier lives, thus contributing to higher productivity and increased economic performance.

Prevention programmes must be appropriately tailored to specific populations; targeting people who are at higher risk is more effective than programmes that screen large segments of the population for a particular illness or condition without regard to risk. When directly tied to particular interventions or population groups, prevention can be cost-effective, even in the short term.

Following the diagnosis of a chronic disease, disease management interventions can also have a positive effect. Chronically ill populations, particularly those suffering from multiple diseases and conditions, or receiving services from multiple health care providers, might require appropriate and ongoing management and intervention to ensure adherence to high-quality care and, ultimately, to improve health outcomes.

Implementing community health improvement programmes

Effective population health improvement strategies consider the range of physical, environmental, and socioeconomic factors that contribute to health. Recognising both the significant problems of chronic disease and the opportunities for population health improvement, groups across the US are developing sustainable, adaptable programmes that work to improve health and lower costs.

Well-designed, community-based lifestyle interventions can produce dramatic reductions in the incidence of chronic diseases like hypertension and diabetes. A recent analysis found significant reduction in total health care spending linked to these programmes: savings ranged from a short-term return on investment of $1 for every $5 invested, rising to more than $6 over the longer term. Though limited in scope, community-based programmes provide instructive models for design of federal health care policy that could capture substantial health care savings through disease prevention and care coordination on a national scale.

American businesses are also investing in prevention and wellness initiatives as they see costs associated with obesity and smoking-related illness increase. According to the National Business Group on Health, employers are paying 100% more for health care since 2000. Recognising the negative impact on their competitiveness and profit margin, employers are increasingly embracing workplace health promotion (WHP) programmes.

Several scientific reviews report that WHP programmes reduce medical costs and absenteeism and produce a positive return on investment. For example, at Citibank, a comprehensive health management programme showed a return on investment of $4.70 for every $1 in cost. A similar comprehensive programme at Johnson & Johnson reduced health risks including high cholesterol levels, cigarette smoking and high blood pressure, saving the company up to $8.8 million annually.
Reforming care delivery

An estimated 90% of the care chronically ill patients require must be self-managed, outside the health system.18 But the US health care system is hospital and physician-centric, which means chronically ill patients are rarely educated to manage their conditions effectively outside physicians’ direct care. Few have community-based support systems that can reinforce active disease management and help them stay out of the hospital. Reorienting the US health care system toward effective chronic disease care will require reform of many aspects, including payment structures to encourage coordination of care, patient incentives for healthy behaviours, broader use and adoption of health information technology and development of the primary health care workforce. In the meantime, state and local initiatives have been able to achieve remarkable changes within the existing system. Exemplary among them is an effort by the state of Vermont.

Vermont has been first in launching a state-wide collaborative system of care for chronically ill patients. The Vermont Blueprint for Health creates ‘medical homes’ for patients with chronic diseases, bringing together:

- patients, who learn how to manage their health conditions;
- primary care physicians, who oversee patients’ care;
- health care teams, to provide individualised support to the patient, including one or two health providers (typically nurses), a public health specialist, and community health workers; and
- patients’ local communities.

To support the medical home model, the legislature changed how providers are paid for care. Participating providers receive normal fee-for-service reimbursements plus a care management fee. This fee is tied to the competencies measured in the National Committee for Quality Assurance’s (NCQA) patient-centred medical home model. Under the NCQA criteria, specific points are assigned for different capabilities, such as the adoption of evidence-based guidelines for care, active patient self-management support and systematic tracking of test results and identification of abnormal results. As a practice’s skills and competencies increase, payments increase along a sliding scale.19

Conclusion

Chronic disease management and prevention, as well as health improvement initiatives, can contribute to changing unhealthy behaviours, improving health and mitigating costs in the US. Health improvement initiatives reach people through a variety of settings, where they work, where they live, where they study, and within the health care system itself.

Care delivery clinically must include prevention, and prevention must include action outside the physician’s office. Patients need to be educated about health conditions, empowered to maintain health and assisted in managing chronic disease. Providers must work within a coordinated system of practitioners, collaborating with the patient to deliver the care that is needed. Those in the US medical community must learn from past attempts, advocate for responsible change, focus on preventing what can be prevented and, in the end, have enough resources to meet the most basic health care needs of Americans nationwide.

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Adopting integrated mainstream telecare services
Lessons from the UK

James Barlow and Jane Hendy

Summary: ‘Telecare’, the use of Information and Communication Technology (ICT) to support health and social care remotely, has been around for many years. Its potential has been recognised in health policy in many countries and there have been numerous pilot projects and technology trials. However, implementation is generally characterised by a failure of pilot projects to develop into sustainable services. This paper argues that this is due to the quality of the evidence base for its benefits, problems in integration with existing care services and responsibilities for payment and reimbursement.

Keywords: Telecare, Telemedicine, Innovation, Implementation, UK

‘Telecare’, the use of Information and Communication Technology (ICT) to support health and social care remotely, often in a patient’s own home, has been around for many years. Its development has been driven partly by technological advances in sensing equipment and data processing, as well as a policy concern with the costs of an ageing population and a rise in the number of people with chronic long-term conditions. There are also growing public expectations: increasingly we expect to receive a more personalised package of care at a convenient time and place of our choosing. These factors have made the introduction of mainstream telecare attractive to governments and care providers. Its potential is increasingly recognised in health policy in the UK, US and Europe. Around the world there have been numerous pilot projects and technology trials.

The UK government’s position certainly supports this. Since 1998, over twenty government reports have called for telecare. These have now resulted in around £175m of finance over the period 2006–2011 via a number of initiatives to support uptake.* This support is needed. While an increasing number of people have received telecare as part of a pilot project, it still cannot be described as a mainstream part of care delivery: implementation is characterised by a failure of pilot projects to develop into sustainable services.

Using evidence to stimulate uptake
Part of the problem is the quality of the evidence base for the benefits of telecare. Almost 9,000 studies reporting on telecare trials and pilot projects have been published in scientific journals, yet within this wealth of information very little strong conclusive evidence has emerged. For some specific applications, for example telecare aimed at patients with diabetes or heart disease, there is evidence of benefits in terms of individual patient outcomes (i.e., clinical or quality of life improvement). However, the evidence for benefits in terms of economic impact or impact on care delivery processes is limited, although there is some simulation modelling based on limited data.

Building an evidence base for the individual and system-wide impacts of telecare is now felt to be critical for convincing those making telecare investment decisions and those who have to use it. With this in mind the English Department of Health is funding the largest randomised control trial (RCT) of telecare so far undertaken, based on its Whole System Demonstrators programme. This was launched on 1 June 2008 and is designed to test the benefit of whole-system redesign of services for those with long-term health conditions and social care needs. Three contrasting sites in England have been chosen, with a variety of demographic and geographical contexts. Each site is putting in place integrated packages of personalised health and social care, including systematic chronic disease management programmes. It is anticipated that the demonstrator sites will involve approximately 7,500 telecare users.

* Comprising £80 million for the Preventative Technologies Grant and £31m for the Whole System Demonstrators programme in England, £9m for the Telecare Capital Grant programme in Wales, £8m for the Telecare Development Fund in Scotland, and Northern Ireland’s £46m telecare investment programme.
The government views the Whole System Demonstrators as a way of meeting the challenge of providing credible evidence that integrated care, combined with the use of telecare, benefits individuals and delivers improvements. It will also test whether telecare is a cost-effective means of future care delivery.

The availability of evidence certainly plays a part in influencing the uptake of health care innovations. However, in many areas of health and social care, the credibility of evidence is subject to interpretation and negotiation. A number of commentators have argued that RCTs are an inappropriate model for gathering evidence for the benefits of complex service delivery interventions such as telecare. Evidence gathered through an RCT approach may help to convince sceptical physicians, but such evidence alone is unlikely to be equally valued and applied across all the relevant stakeholders involved in the mainstream implementation of telecare.

Arguably, the main beneficiaries of telecare are patients and family carers, through the provision of independence, security, confidence, quality of life, and the ability to stay in one's own home. These benefits are hard to quantify, but RCT measures such as admissions avoidance are unlikely to convince telecare users and their families.

The context into which telecare is implemented will also be different from area to area. Future telecare services may involve unique sets of interventions and users that will not be comparable. The evidence gathered has to fit with these demands. So part of the challenge is not to just produce more evidence, but to produce evidence that convinces different stakeholders across professional boundaries and different familial and organisational contexts.

The professional autonomy of care professionals, especially within the NHS, has proved problematic, especially in relation to general practitioners’ hegemony and difficulties in engaging this group. Physicians need to be persuaded that telecare is useful to both their practice and the health of their patients. In the UK this issue is partly being addressed by the growing role of specialist community nursing, which is being used to underpin some telecare services for patients with long term chronic conditions and help demonstrate that this approach can help physicians manage their case loads more effectively. But even without the problem of an adequate evidence base, there are still enormous challenges which relate to the redesign of care service models to accommodate telecare, and to payment and reimbursement for services.

Integration with existing services
Telecare requires different levels of integration between health and social care depending on the type of services being offered. The introduction of mainstream telecare must recognise this complexity, with the development of responsive, flexible service structures that can work equally well across different agencies. Achieving this will not be easy. A review of public sector management by Ferlie and colleagues illustrates the difficulties of achieving fundamental change and cautions against over-optimistic hopes of reform associated with new ways of working in the public sector. The joint activities resulting from increased implementation of telecare are more likely to produce a series of incremental changes than complete system change.

The most important parts of a new telecare service are the models for assessment, installation, monitoring and response. Identification of appropriate clients and assessment of their needs in relation to available telecare technology and services has proved hard due to a lack of awareness by different groups of health and social care professionals and the slowness in introducing a national ‘single assessment process’. Installation is particularly important as it moves telecare from being a purely technical service to becoming part of the care service with installers helping users to understand the system. However, developing suitable supply chain arrangements, involving equipment manufacturers and local authority social or housing services, has not always proved easy. Finally, while there is already an infrastructure for monitoring and response in the form of several hundred local community alarm centres, these are not necessarily equipped or have the expertise to take on health, as opposed to social, monitoring of clients.

To move away from the small pilot projects of the past to mainstream integrated services, health and social care organisations will need to think carefully about the way they plan, commission, procure, deliver and install telecare. The technologies and processes on which telecare are based need to be a catalyst for new levels of collaborative working because of the many stakeholders from health and social care that need to be involved. Identifying all these stakeholders, engaging everyone, aligning their respective agendas towards telecare and maintaining momentum takes time and effort. Similarly, training operational staff and raising awareness amongst other staff is time consuming.

A key challenge for achieving integration is data sharing and the use of statutory standards. The availability of a shared health and social care record keeping service and an electronic single assessment process would make telecare much easier to implement and operate. This was promised in the introduction of the UK National Programme for IT, yet shared patient records remain elusive five years after inception of the programme. With data sharing amongst NHS staff proving this difficult, it is hard to envisage that the added involvement of social and community care services will be any easier, and currently very little progress is being made.

Payment and reimbursement
Another challenge in the UK, and in many other countries, is the way health and social care services are currently funded. Telecare demands true partnership working because costs and benefits lie with different stakeholders. ‘Silo thinking’ about budgets and future investment slows down the process of implementation. In the UK most health care services are free to the users, whilst many social care services are means tested. This is particularly problematic for the introduction of telecare, where the boundaries between the ‘health’ and ‘social’ aspects of monitoring may be blurred.

This complexity is combined with the uncertain impact of implementing telecare on costs and benefits. For example, the current policy initiative in England made local authority social services departments primarily responsible for telecare investment costs, having directly received part of the Preventative Technologies Grant. However, exactly how the different organisational elements of the health and social care system benefit from this expenditure, and in what ways, is currently very unclear. This, in turn, makes it hard for commercial suppliers of telecare equipment to develop suitable business or charging models.

Conclusions
Despite limited evidence on its benefits, in the UK a combination of central government policy and funding, a belief in its potential by certain ‘champions’ in local social services and health authorities is
sustaining the current momentum, however, will require constant attention and reinforcement of existing initiatives – it is essential that the current wave of trials and pilot projects do not slip back once government funding ends.

Scaling-up from existing schemes will require care providers to understand how telecare can be integrated into existing and new care pathways. This means that the cultural differences between different care organisations need to be addressed, and the right incentives for innovation are put in place.

While there are examples of telecare schemes in some other countries, the major initiatives in the four countries of the UK, including the Preventative Technologies Grant and the Whole System Demonstrators, represent the most important concerted effort by government to stimulate innovation in this field. The next few years should provide many useful opportunities for learning about the potential and pitfalls of telecare.

The increasing prevalence of chronic conditions, such as diabetes and heart disease, places an enormous burden on health service resources. Routine consultations to check the health status of patients with such conditions consume significant resources in both primary and acute care. The demand on the health service for routine consultations to monitor chronic conditions is one of the reasons that there is increased interest in harnessing technology to help manage these patients. Technological solutions have developed rapidly and there has been a significant growth in the application of information technologies to health care over the last two decades.1

Terms such as telemedicine, telehealth and telecare have been used, often synonym-

**Economic considerations of remote monitoring in chronic conditions**

Paul Trueman

Summary: Remote monitoring systems allow for the capture of routine information on the health status of individuals with chronic conditions. The potential benefits of remote monitoring include reduced demand on scarce health care resources and more intensive monitoring of an individual’s health, which may ultimately result in improved long-term outcomes. Evidence on the economic benefits of remote monitoring remains equivocal. Further research of the cost effectiveness of remote monitoring in practice is warranted.

Key words: Remote Monitoring, Telemedicine, Economics, Chronic Conditions

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**REFERENCES**

mously, to describe the application of modern information and communication technologies to health and social care. These broad definitions capture a range of technologies, from patient operated alarm systems often used in residential care, to technologies designed to allow for a virtual consultation with a health care professional, particularly in remote geographical areas, to technologies designed to allow health care professionals to monitor the health status and vital signs of individuals in real time.

Remote monitoring (sometimes referred to as telemonitoring) of chronic conditions is one of the most widely used applications of technology in health care. Remote monitoring involves capturing information on vital signs or clinical indicators to monitor a patient’s condition. Remote monitoring can take many forms. In some cases, patients may be required to manually input data into a device and then transfer the data, through a telephone or computer interface (often referred to as ‘store and forward’ systems). Data can then be stored on a secure server and accessed by a health care professional able to interpret the findings. More advanced technologies include automated data capture, often in real-time, and communication through the use of advanced information systems comprising wireless communication.

Such technologies have been widely used in investigative studies in common chronic conditions, including diabetes and heart disease. The rationale for adoption in chronic conditions appears to be based on several hypotheses:

- Firstly, remote monitoring can reduce the need for routine consultations with a health care professional by providing regular information on an individual’s health status;
- Secondly, by providing more regular or continuous information on vital signs, remote monitoring can allow for more intensive management of an individual’s condition which has the potential to reduce acute exacerbations and improve long-term outcomes;
- Thirdly, patients are expected to find remote monitoring more convenient and accessible than direct consultations with a health care professional.

In chronic conditions such as diabetes and heart disease, these benefits might manifest themselves in the form of tighter control of blood glucose levels or blood pressure and ultimately reductions in serious adverse outcomes, such as hypoglycaemic events or heart attacks. The potential benefits have both clinical and economic implications for patients and the health service. The challenge is to generate evidence to show that these theoretical benefits can be realised in practice.

The economic evidence on remote monitoring

There is a growing body of evidence on the clinical and cost effectiveness of telemedicine interventions, including remote monitoring technologies, in the management of chronic conditions. However, empirical analysis of the evidence on the cost effectiveness of telemedicine interventions has raised concerns about the quality of evidence available to support these technologies.

Roine and colleagues conducted a systematic review of the evidence on telemedicine interventions in 2001. The review included several studies of remote monitoring interventions, the majority of which were intended to contribute to the management of diabetes and heart disease by monitoring vital signs. Whilst the majority of these studies produced improvements in clinical indicators (for example, HbA1c levels, blood pressure), evidence to support an economic benefit of remote monitoring was limited. Where economic analyses were included in studies these tended to focus only on costs. Only one study was identified which reported cost effectiveness ratios for an intervention designed to assist in managing blood pressure.

Whitten and colleagues conducted a systematic review of cost effectiveness studies of telemedicine interventions, published in 2002. The review identified fifty-five studies of telemedicine that captured cost data. Over 50% concluded that telemedicine saves money/time and money whilst only 7% concluded that telemedicine does not save money. However, these positive findings need to be considered with some caution and the authors noted that the economic evidence tended to be derived from small-scale, short-term studies that were often characterised by poor design and inadequate technical quality. The majority of studies included only partial analysis of costs and no examples of full cost utility analysis were identified. The authors concluded that there was only limited persuasive economic evidence to support the routine adoption of telemedicine.

A further review paper published by Paré and colleagues in 2007 examined the evidence specifically related to home telemonitoring for four chronic conditions, namely diabetes, cardiovascular disease, pulmonary disease and hypertension. The review included a total of sixty-five empirical studies across the four disease areas. The authors reported that the research indicated that home telemonitoring was largely safe, efficacious and acceptable to patients. However, as per the earlier reviews, the authors noted the absence of an unequivocal economic case. Of the studies included, 26% included some form of cost analysis. The authors were unable to make any recommendations based on the findings of these studies, mainly due to limitations in the methodologies used and heterogeneity across the studies. The authors did though make a strong case for future studies of home monitoring to focus on examining issues associated with patient outcomes, quality of life and the economic implications for health services. This evidence is seen as being important to securing more widespread adoption and coverage by payer bodies.

Discussion

These reviews highlight the equivocal nature of the economic evidence on remote monitoring in chronic conditions. However, these findings need to be interpreted in context. Home monitoring remains a relatively novel health care intervention, having only been introduced into mainstream practice over the last two decades. As such, the evidence base remains in development and largely derived from small-scale pilot studies. The reviews considered above suggest that the volume of economic evidence on these technologies is increasing over time, although there is still some concern over the quality of studies, particularly with regard to their short-term nature and the widespread use of partial economic analysis.

It should be acknowledged that the evaluation of such technologies is challenging for a number of reasons. First, remote monitoring is a disruptive technology that requires changes to treatment pathways and the attitudes of health care professionals, all of which take time. For example, despite the more intensive nature of remote monitoring, health care profes-
sionals may continue to adhere to their usual referral patterns for some time following its introduction. Care needs to be taken in designing studies of remote monitoring technology to ensure that the benefits are fully realised in trial settings.

Second, the evaluation of remote monitoring technologies is highly context specific. That is, the effectiveness of the technology is also heavily dependent on local treatment pathways, health care professional’s attitudes and patient populations. As a result, much of the research published to date has been characterised by poor external validity, meaning that more widespread adoption may be restricted due to the limited generalisability of study settings.

These factors suggest that more pragmatic, observational, in-use research on remote monitoring technologies is required. Such studies should take care to ensure that they are designed to allow for an assessment of the effectiveness of remote monitoring relative to current practice, and also capture the impacts of novel technologies on organisational and financial outcomes. Ideally, studies should incorporate full economic evaluations as opposed to the partial analyses that characterise the majority of evidence published to date. Frameworks for the evaluation of telemedicine have been made available.12

The absence of robust economic evidence on remote monitoring systems, and telemedicine interventions more generally, is a concern. However, it is worthwhile considering the primary intention of many remote monitoring systems. Such systems are often developed with non-financial objectives, including improving access to care, patient satisfaction and health outcomes. Whilst these systems have the potential to lead to more efficient use of health service resources, they will not necessarily lead to reductions in health care expenditure. Indeed, it has been suggested that whilst technology offers the potential to reduce the demand for less complex consultations it should be considered as an adjunct to direct consultations with a health care professional, rather than as a substitute.13 If this is the case then technologies such as remote monitoring may require increased investment in return for improvements in patient outcomes and access.

The absence of an unequivocal argument to support the cost effectiveness of remote technologies means that coverage and payment remain barriers to adoption in many countries. Whilst remote monitoring systems may offer potential efficiencies in the use of health care resources, it has long been acknowledged that reimbursement systems need to change to incorporate innovation.14 Indeed, many reimbursement systems, particularly those based on fee-for-service, actually disincentivise the use of telemedicine by providing coverage for direct consultations but not for remote monitoring. The result is an incentive to rely on unnecessary consultations, many of which could be managed more efficiently using technologies that permit remote monitoring.

There are signs of expanding reimbursement and coverage for remote consultations and monitoring, particularly in the United States.15 However, many routine monitoring technologies find themselves in something of a vicious circle. Payer bodies are reluctant to provide widespread access, as the evidence that is available for the technologies is derived from small scale studies which are criticised on the grounds of their limited applicability to a larger population. However, generating evidence in a larger population demands that such technologies are more widely available which requires some form of coverage and reimbursement to be in place.

Appropriate financial incentives for remote monitoring need to be put in place. These should ensure that the efficient use of remote monitoring, instead of direct consultations, is incentivised where this is clinically justified. Systems also need to be put in place to ensure that patient care is not compromised through any reduction in direct contacts with health care professionals. Finally, it is vital that information is captured prospectively on the use of these systems to determine whether they offer improvements in patient outcomes, access to care and health service efficiency. Only by generating further evidence can payer bodies make a rational decision about the appropriate use of remote monitoring technologies.

References
European Commission perspective: Telemedicine for the benefit of patients, health care systems and society

Michael Palmer, Christoph Steffen, Ilias Iakovidis and Flora Giorgio

Summary: In November 2008, the European Commission adopted a Communication to support the deployment of telemedicine for the benefit of patients, health care systems and society. Telemedicine can support better quality, safer and more efficient health systems that empower patients throughout the EU. Actions proposed aim to improve confidence and acceptance of telemedicine services amongst users (professionals and patients), clarify legal aspects, solve technical issues and support market deployment.

Keywords: Telemedicine, Chronic Disease Management, Telemonitoring, Teleradiology, European Policy

For twenty years the European Commission has funded research on eHealth systems and tools, including telemedicine. Since the adoption of the eHealth Action Plan in 2004,1 the Commission’s role has broadened to include policy support to the deployment of eHealth, supporting better quality, safer and more efficient health systems that empower patients throughout the EU.

Telemedicine is the latest focus of this support to deployment. While research in telemedicine-related areas (for example, Personal Health Systems) continues through the Research and Development Framework programmes, support to deployment is co-funded by the Commission through the Competitiveness and Innovation programme as well as through cohesion and structural funds.

Following extensive consultation in 2007 and 2008 with Member States, health professionals, patients associations and industry representatives, where it received strong support from all parties, a Commission Communication on Telemedicine for the Benefit of Patients, Healthcare Systems and Society was published in November 2008.2

Supporting patients and health professionals alike

Telemedicine comprises ICT (Information and Communication Technology)-enabled health care services that are provided to patients in situations where one or more health care professionals and the patient are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients. Supporting telemedicine deployment, as advocated in the new Communication, could lead to concrete benefits for patients and health professionals (Box 1).

At the launch of the initiative, Viviane Reding, EU Commissioner for Information Society and Media commented that “telemedicine can radically improve chronically ill patients’ quality of life and give people access to top medical expertise. It is our duty to make sure patients and health professionals can benefit from it.”

At the same time she noted that “the provision of remote health care services through Information and Communication Technologies can optimise the use of scarce human and financial resources in the medical field.” EU Health Commissioner Androula Vassiliou, also at the launch, added that “the key to success is the full involvement of citizens, patients and health professionals.”

An ageing Europe with chronic illnesses needs new solutions

In an ageing Europe, where more and more citizens live with chronic diseases, telemedicine is an important tool. For instance, it allows the monitoring of...
Telemedicine not only can benefit patients. Medical images, such as radiographs (X-rays) or if Computed Tomography (CT) scans are performed at a distance. Furthermore, it can contribute to a reduction in waiting times, for example in hospital. It can improve the availability of specialised care in remote areas where access to health care is difficult. It can also contribute substantially to the growth of the European economy. Small and medium-sized enterprises (companies with no more than fifty employees), in particular, can tap into the financial and clinical benefits from this expanding market, provided that some of the barriers to development can be addressed. Telemedicine not only can benefit patients. It can also contribute substantially to the growth of the European economy. Small and medium-sized enterprises (companies with no more than fifty employees), in particular, can tap into the financial and clinical benefits from this expanding market, provided that some of the barriers to development can be addressed.

Box 2: Actions to support Members States achieving large-scale and beneficial deployment of telemedicine services

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<tr>
<th>Building confidence in and acceptance of telemedicine services</th>
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<tr>
<td>The Commission will support the development by 2011 of guidelines for consistent assessment of telemedicine services’ impact, including effectiveness and cost-effectiveness. This will be based on the work of experts in the field, Commission supported studies, large scale pilot schemes and relevant research projects.</td>
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<tr>
<td>In 2010, the Commission, via its Competitiveness and Innovation Programme, will support a large-scale telemonitoring pilot project. This will include a network of procurers and payers of health care services.</td>
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<td>The Commission will continue to contribute to European collaboration between health professionals and patients in key areas with potential for greater application of telemedicine in order to make concrete recommendations on how to improve confidence and acceptance of telemedicine, also taking into account ethical and privacy related aspects.</td>
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<td>Member States are urged to assess their needs and priorities in telemedicine by the end of 2009. These priorities should form part of the national health strategies to be presented and discussed at the 2010 eHealth ministerial conference.</td>
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<td>The Commission will support the collection of good practice on deployment of telemedicine services in the different Member States.</td>
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<th>Tackling legal and regulatory obstacles</th>
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<td>In 2009, the Commission will establish a European platform to support Member States in sharing information on current national legislative frameworks relevant to telemedicine and proposals for new national regulations.</td>
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<tr>
<td>In 2009, the Commission, in cooperation with Member States, will publish an analysis of the European legal framework applicable to telemedicine services.</td>
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<td>By the end of 2011, Member States should have assessed and adapted national regulations enabling wider access to telemedicine services. Issues like accreditation, liability, reimbursement and data protection should be addressed.</td>
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<th>Solving technical issues and facilitating market development</th>
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<tr>
<td>By the end of 2010, industry and international standardisation bodies, with the support of the Commission, shall issue a proposal on interoperability of telemonitoring systems, including existing and new standards.</td>
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<tr>
<td>By the end of 2011, the Commission, in cooperation with Member States, will issue a policy strategy paper on pan-European conformance testing of interoperability, functionality and security of telemonitoring systems based on existing, newly adopted or emerging standards at European level.</td>
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Important health parameters, such as blood sugar levels or blood pressure within the patient’s home, avoiding troublesome and, particularly in the case of older people and those with severe health problems, potentially exhausting trips to a doctor or hospital. It can improve the availability of specialist care in remote areas where access to health care is difficult. Furthermore, it can contribute to a reduction in waiting times, for example in radiology, when reading and interpreting medical images, such as radiographs (X-rays) or if Computed Tomography (CT) scans are performed at a distance. Awareness of the benefits of telemedicine by users (patients, health professionals and payers) and acceptance of the technology by health professionals are crucial elements for the success of telemedicine. Only the buy-in of users will allow a seamless integration of these technologies into the normal health care delivery processes and allow the progressive changes in medical practices to take place.

2. Gaining legal clarity

The right of establishment for health professionals exercising telemedicine, accreditation and authorisation schemes to provide telemedicine services, as well as issues on liability, the recognition of professional qualifications or protection of personal data related to health, are among the areas which require legal clarity, both at EU and national level.

3. Overcoming technical issues and supporting market development

Issues linked to infrastructure, such as access to broadband and the ability of the provider to enable full connectivity ranging from urban, densely populated communities to remote, rural, sparsely populated areas still represent a major challenge. Evidence on large scale benefits needs to be presented to political leaders and payers to enable further investment in telemedicine processes that not only improve access to quality care but also promise to achieve more for less in a sector traditionally constrained by resources and unequal geographical coverage of skills.

Proposed actions to accelerate deployment and use

The Commission proposes three sets of strategic actions to be carried out either jointly or at Community or Member State level alone which appear to be most urgent and could provide maximum added value (see Box 2). The first group focus on increasing confidence and acceptance of telemedicine services among users, mainly through the provision and dissemination of scientific evidence of effectiveness and cost-effectiveness, particularly if implemented on a large scale. In the case of the telemonitoring pilot project, the aim is to validate, in real-life settings on a large scale, the use of existing Personal Health Systems for innovative
A clinical perspective on remote monitoring of chronic disease

Jillian P Riley and Martin R Cowie

Summary: Chronic disease management programmes have developed rapidly in an attempt to provide high quality evidence-based care to an increasing number of people living with chronic medical conditions. Such programmes are frequently based on regular home or clinic visits that limit their ability to match demand. Innovative methods to extend the reach of such programmes are urgently required. This article discusses the use of remote monitoring as part of chronic disease management and draws upon the authors’ experience in a heart failure population.

Key words: Technology, Remote Monitoring, Chronic Disease Management, Delivery of Care

The number of people living with chronic disease, particularly cardiovascular disease, is increasing rapidly across the world, largely due to the unprecedented ageing of the world’s population. This provides a major challenge to health care systems, particularly where access to optimal evidence-based care is poor. There is a need for innovative strategies to provide support for high quality chronic disease management. Telehealth has been proposed as one such strategy.

In theory, such technology should enable the limited number of health care professionals to interact with a larger number of individuals with chronic health problems. This facilitates the early identification of problems requiring health care intervention (such as hospital admissions, doctor office reviews, or change in medication), whilst empowering individuals to continue living in their own environment, with higher levels of self-care.

The remote monitoring of patients (telemonitoring) is challenging, not least because of the change in working practice for health care practitioners, but the evidence is accumulating that such an approach can be an effective component of high-quality care. There is a large degree of heterogeneity in the structure of telemonitoring programmes, and it remains unclear as how best to employ both technology and staff, and how to integrate new programmes into existing health care practice. The most robust evidence applies to diabetes, chronic lung disease and heart failure. In many health care communities, telemonitoring has been introduced without much consideration of how it should best be employed or how it fits into the usual information flow about patients. An early review of the technology concluded that although feasible, such technology had yet to prove its clinical benefit. Professional disease guidelines remain largely silent on how best to use this technology. This article reflects on the authors’ own experience in using telemonitoring for patients whose predominant medical problem is heart failure.
Traditional models of chronic disease management

Chronic diseases are, almost without exception, characterised by acute exacerbations. It is during one of these acute events that the patient is likely to present either to their primary care physician feeling generally unwell or to the emergency department of the local hospital. The trajectory of chronic illness then becomes marked by increasingly shorter periods of stability between acute exacerbations. To assist in the early recognition of the often subtle signs and symptoms of deterioration regular follow-up with a health professional is encouraged. In primary care based health services (such as in the United Kingdom) this regular follow-up is provided by the general practitioner, with secondary care clinic visits only at six to twelve month intervals. The effectiveness of this model relies upon good communication between the patient, primary and secondary care, and the many other professionals involved (primary care physician and practice nurse, community pharmacist, and the hospital specialist medical consultant and nurse).

Multidisciplinary disease management programmes, frequently led by a specialist nurse in secondary care, have developed to optimise management of chronic conditions such as diabetes, chronic airways disease, or heart failure. Such programmes provide education to facilitate self-care (including monitoring), ensure appropriate up titration (dosage raising) of drug therapy, and facilitate collaboration within the multidisciplinary team. This approach is recommended in current international clinical guidelines.2–4

Many patients are elderly and their decreased mobility and lack of social support is likely to impact upon clinic attendance. Home-based models of care can circumvent this problem but are costly in terms of travelling time for the health care professional. This reduces the number of patients that can receive care. Telemonitoring offers the promise of enabling such professionals to extend the reach of disease management programmes, ensure more appropriate use of health care resources, and provide care at a time and place more convenient to the patient.

What is telemonitoring?

Telemonitoring (‘remote monitoring’) refers to patient monitoring where the patient and health care professional are separated by geographical distance. The information is transmitted from the patient (usually in their home) to the health professional. The transmission can be relayed in real time (synchronous), or asynchronously where the information is stored and forwarded for review later. In most cases, data are transmitted using the domestic telephone line, although within the home, data may be transmitted wirelessly from the monitoring device to a unit plugged into the telephone line.

The monitoring technology can vary in complexity from simple monitoring of such physiological data such as blood pressure, pulse, blood oxygen level, blood sugar or body weight, to implantable devices (such as heart pacemakers or defibrillators) whose functions can be monitored remotely, and in some cases also reprogrammed remotely. Very sophisticated implantable monitors that can measure the pressure within heart chambers or large blood vessels, or the amount of water in the lungs, can also be monitored remotely. This adds to the physiological data that can be provided to a health care practitioner to facilitate better management of the underlying heart condition.

Figure 1 shows an example of a commercially available external monitoring device that measures weight, blood pressure, oxygen saturation and also transmits the patient’s responses to a series of questions about changes in their symptoms.

Clinical benefits

Much of the early support for telemonitoring comes from observational studies, without appropriate comparator groups. Such studies are likely to overestimate the clinical effect of the technology, but do at least provide firm evidence that the commercially-available platforms are physically robust, relatively easy to install and operate, and largely acceptable to both patients and health care professionals. Most studies report more than 80% compliance of patients with telemonitoring, regardless of duration of monitoring or age. In our own experience in an elderly, multiethnic, metropolitan area, poor compliance with monitoring is rarely an issue, particularly with good family support.5

More recently more rigorously designed randomised studies have been undertaken. These are likely to be much more influential on the clinical community than the earlier observational studies. Paré and colleagues undertook a review of all high quality randomised trials of home telemonitoring in chronic illness undertaken before 2006.6 Identifying a total of sixty-five studies in a variety of chronic conditions (diabetes, hypertension, heart and lung disease) they were able to conclude that telemonitoring consistently provided the health professional with accurate data on which to plan care, but there were inconsistencies in its effect upon health care utilisation and overall patient outcome.

Turning to the literature specifically related to heart failure management, Clark and colleagues undertook a review where they combined the results of five randomised trials of telemonitoring using equipment external to the patient.7 The combined results suggested an impressive reduction in the risk of death of around 40% with telemonitoring compared with usual care, with the absolute risk of death being of the order of 20% in patients in the control arms of the studies, which followed up patients for three to fifteen months. In addition, they reported a trend towards a reduction in hospitalisation (for any cause) in patients who were telemonitored, although this result could have arisen by chance (P value >0.05). An important caveat to this overview is that the studies included tended to recruit relatively young and highly motivated patients with...
advanced disease and, importantly, with fewer coexisting illnesses (comorbidities). This makes it difficult to extrapolate the findings to the general population.

More recently, we reported on the Home-HF (Heart Failure) study in a general heart failure population of elderly patients (with a mean age of 71, 45% >75 years) where we compared six months of daily telemonitoring with specialist heart failure care.\(^5\) Whilst demonstrating no difference in hospitalisation (for any cause) we found strong evidence that emergency room visits, clinic reviews and unplanned hospitalisations for heart failure were reduced. This confirms the feasibility of detecting decompensation of chronic heart failure syndrome early and making health care interventions in a planned manner as a result of daily physiological data transmission to a specialist heart failure nurse. The outcome was similar to that provided by traditional specialist heart failure care, but the specialist nurse was able to monitor considerably more patients than was usual.

**The patient perspective**

Qualitative research provides interesting insights into patients’ perceptions of health care. Patients with chronic medical conditions (and their families) often feel overburdened with the responsibility of care and frustrated by the difficulty of navigating the health care system. Whilst they know the signs and symptoms to observe, they find it difficult to identify relatively subtle changes which may warn of an impending acute exacerbation. Consequently they delay seeking professional help.\(^8,9\) Telemonitoring may have an important role in supporting people to gain confidence in living with and managing chronic disease.

Our experience with patients using telemonitoring suggests the direct link between them and the health professional provides reassurance that any important change will be rapidly identified and management commenced promptly. Telemonitoring also increases patients’ understanding of how to manage their symptoms and results in many feeling more in control of their heart failure management. Patient satisfaction with this approach to care is high.

**The changing geography of health care**

Telemonitoring challenges traditional health care practice. Whilst it can be integrated into established primary or secondary care services, it may also develop out of relationships with new service providers such as “call centres”. Working across a plurality of providers is new within many health care systems, including those in the UK. To be effective, an integrated and coordinated strategy is required that works across these different agencies and has clearly identified lines of communication and responsibility.

These changes bring perceived threats to traditional professional roles. The potential for a non-professional, protocol driven approach to the initial patient assessment and triage may restrict the identification of relevant nuances in the patient history. Telemonitoring also has the potential to increase patient contact with the specialist, possibly at the expense of contact with the primary care physician. In health care services such as those in the UK, where primary care acts as the first point of contact and is responsible for deciding when and whom to refer for specialist advice, this raises reimbursement issues that have yet to be resolved. Where telemonitoring centres operate outside of traditional professional health care services then commissioners need robust arrangements to ensure patient safety and the continued delivery of high quality care.

**Conclusion**

Telemonitoring offers much promise. It has been shown to be technically feasible and user friendly and is acceptable to patients with chronic disease. It significantly reduces the number of patients that can be cared for and facilitates timely intervention to resolve health issues. When problems cannot be resolved remotely, it enables good use of health care resources through appropriate scheduling of outpatient clinic review, a home visit or even a hospital admission. However, it changes traditional working practices and requires the flexible organisation of health care. These challenges must be overcome if telemonitoring is to fit seamlessly into the landscape of health care.

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The European Commission published proposals on patients’ rights to cross-border health care in July 20081 with a view to “help patients in getting the health care they need, and help Member States ensure the accessibility, quality and financial sustainability of their health systems and the well-being of their citizens.”2

However, a mechanism for patients to obtain planned treatment in another EU country at the expense of their home health care system already exists under longstanding EU regulations on the coordination of social security schemes3 (the ‘E112 referral’). Department of Health figures show that very few patients from England, Scotland and Wales have been treated under these arrangements.4 Data on patient flows between Northern Ireland and the Republic of Ireland also indicates low levels of cross-border activity.5 So why is a new directive on cross-border health care needed, and will it really make any difference to the NHS?

Why is it needed?
The draft directive follows a succession of cases in the European Courts of Justice (ECJ), where individuals have sought reimbursement for health care received in another EU country at the expense of their home health care system already exists under longstanding EU regulations on the coordination of social security schemes3 (the ‘E112 referral’). Department of Health figures show that very few patients from England, Scotland and Wales have been treated under these arrangements.4 Data on patient flows between Northern Ireland and the Republic of Ireland also indicates low levels of cross-border activity.5 So why is a new directive on cross-border health care needed, and will it really make any difference to the NHS?

Will it make any difference to the NHS?
The NHS European Office undertook a major consultation process with the aim of assessing the potential implications for the UK National Health Service (NHS) of the proposals set out in the draft directive.6 Whilst it is impossible to predict how patterns of cross-border health care will change in the future, overall, most NHS organisations did not anticipate a large expansion in the volume of cross-border health care, either to or from the UK, within the framework of the draft directive.

In general, the NHS view was that cross-border patient flows arising from a future directive would not have a significant impact on the NHS’ ability to manage and deliver health services for the UK population, particularly in comparison to the impacts of wider phenomena such as demographic change and migration patterns. The absence of large cross-border patient flows does not, however, mean that these proposals would have no impact on the NHS. The draft directive is intended to fully respect national governments’ responsibilities for the organisation, management and funding of health care. However, the consultation identified a number of areas where there is the potential for confusion and/or conflict between the current proposals and present NHS policy. This article discusses two areas where the draft directive’s proposed approach does not reconcile easily with existing NHS arrangements.

Entitlements
The draft directive aims to ensure that patients can access the same health care entitlements in other EU countries as at home. The principle is simple but the reality is more complex, in particular in systems like the NHS that do not have defined lists of care to which patients are automatically entitled.

Access to specialist care in the NHS is by referral from primary care and decisions about an individual’s care are usually taken by their NHS clinician, where relevant taking into account, or with reference to, local commissioners’ (the NHS equivalent to an ‘insurer’ in the context of cross-border health care) guidance on low priority treatments.

In light of this, NHS organisations noted that if a patient sought treatment abroad without a needs assessment from their local NHS, it may be extremely difficult to determine retrospectively whether treatment would have been available under

**Summary:** In July 2008, the European Commission brought forward proposals for an EU Directive on patients’ rights in cross-border health care. The NHS European Office carried out a consultation exercise to assess potential implications of the proposed legislation for the UK National Health Service (NHS). This article discusses the outcomes from the consultation and considers how proposed provisions on cross-border health care could have consequences in two areas of domestic health policy.

**Key words:** Cross-Border Health Care, NHS, Patient Mobility, Entitlements, UK
the NHS, and therefore, whether the patient is eligible for a reimbursement.

A further complexity arises because of the difficulty in determining what constitutes the same treatment in another health care system, for example because differences in clinical practice may exist. The draft directive attempts to overcome this by defining the right to reimbursement with reference to the costs which would have been paid had the “same or similar” health care been provided within the patient’s home system.

The NHS view was that such an approach could be interpreted as contradicting the principle that entitlement is limited to that which patients can receive at home. A patient might seek a treatment in another country that their home system does not fund and argue that they should be reimbursed because it is ‘similar’ to a treatment they were receiving at home. Such a system could lead to numerous disputes between ‘cross-border’ patients and their home health care systems. It could also result in patients who cannot, or do not wish to, access cross-border health care, being unfairly disadvantaged.

These problems could be avoided by clarifying the draft proposals, with regard to the limit on entitlements and also by recognising different mechanisms for determining eligibility in the text. Even with such clarifications, NHS organisations will need to ensure that patients can easily access information about processes used to determine eligibility, and that decisions about entitlements are reached and communicated to them clearly and promptly. This is likely to pose a particular challenge in relation to cases where patients apply for a treatment not usually funded or challenge a decision not to fund a treatment, when a longer timescale may be needed for a decision to be made.

There is currently significant variation in the way local NHS organisations reach and review decisions about entitlements. In the context of work to define an NHS Constitution,7 a statement of the NHS’ core values and patients’ rights and responsibilities, there are moves towards improved standards and greater transparency in local decision-making, which will be important in the context of cross-border health care.

**Patient choice**

Under the policy known as ‘patient choice’, NHS patients in England referred for specialist care are able to choose to be seen by any NHS provider that provides appropriate treatment. Many English NHS organisations viewed the proposals on cross-border health care to some degree as an extension of ‘patient choice’. The NHS view was, therefore, that where it has been established that a patient is eligible to receive a particular treatment, the fact that health care could be provided locally should not, alone, be a reason to prevent the patient from seeking treatment abroad.

However, one key difference between patient choice in England and cross-border health care is that patient choice is limited to providers contracted to the NHS. This includes a range of independent and third sector providers (for example, charitable or voluntary sector organisations), but crucially, all are required to provide health care according to NHS standards and conditions, including, for example, taking into account relevant clinical guidelines.

By contrast, in a cross-border situation, a patient can access treatment from any health care provider, private or state/public sector and without reference to issues such as compliance with quality and safety standards and clinical guidelines. NHS organisations were concerned that this implied a greater degree of risk in cross-border health care, of which patients may not even be aware.

NHS organisations considered that, in order to reduce such risks, it would be essential to ensure that patients considering cross-border health care obtain clear information on the conditions that apply before they seek treatment abroad. As this will need to include personalised information on a patient’s individual needs and entitlements, the NHS view was that there should be a process for patients to consult their local NHS before obtaining cross-border health care.

NHS organisations felt the logical way of achieving this was to put in place prior authorisation systems. Such systems were not viewed as a barrier to cross-border health care, as it was expected that authorisation would generally be granted, with refusals only in exceptional circumstances (for example, if there was a risk to wider public health associated with the patient travelling for treatment). These systems were also seen as an important way of protecting patients’ interests. By providing clarity on matters, such as what specific treatment their clinician recommends for them, what reimbursements they will be eligible for and what costs they will have to meet themselves, arrangements for any after-care needed and what will happen if anything goes wrong, such systems would enable patients to make an informed choice about the best health care option for them.

The NHS view was that the draft directive was short-sighted as it did not recognise the potential benefits to patients of prior authorisation systems, and in proposing that prior authorisation systems could only be used in exceptional circumstances. NHS organisations felt that the simplest and clearest approach to prior authorisation systems would be for each country to develop its own list of health care for which prior authorisation is required, whilst ensuring that prior authorisation systems are clear, user-friendly and responsive.

As levels of cross-border health care to and from the UK have, to date, generally been relatively low, few local NHS organisations currently have the knowledge and expertise to be able to advise patients interested in cross-border health care. The development of systems to support and facilitate cross-border health care will therefore have resource implications.

The NHS view was that prior authorisation and information systems would be a necessary investment. However, it is essential that information and data collection requirements remain proportionate, and the NHS view has been that the focus should be on enabling patients to make informed choices, for example by highlighting what questions they might ask of a potential health care provider. It is important to avoid a situation where potential cross-border patients are entitled to more information and support than domestic patients seeking care at home.

**Conclusions**

The NHS European Office’s consultation on the European Commission’s proposals on patients’ rights in cross-border health care found that NHS organisations did not fear a large amount of cross-border health care as a result of potential new legislation in this area. However, there were concerns about potential clashes between the proposals and domestic policies, and these issues should receive full consideration.

Ultimately, the extent to which the cross-border proposals will impact on the NHS and its patients will depend on the final shape of the directive if and when it is
Promoting a sustainable workforce for health in Europe

Elizabeth Kidd

Summary: The European Union’s health care workforce is both ageing and increasingly mobile, so Member States need to plan human resources for health with this in mind. On 10 December 2008, the European Commission published a Green Paper on this topic and launched a public consultation. This has sought stakeholders’ views on a wide range of issues connected with the health care workforce and preparing for the care of an ageing population. The results of the consultation will advise what the EU can do to support Member States.

Keywords: workforce, sustainable, consultation, mobility, strategies

On 10 December 2008, the European Commission published a Green Paper on the EU Workforce for Health. This publication launched a consultation period, running until the end of March 2009, which aims to identify common responses to the many challenges facing health and social care systems in Europe, as well as the workforce solutions required to tackle them.

Why a Green Paper?
The health systems of the European Union are the building blocks of Europe’s high levels of social protection. Health systems are an intrinsic component of social welfare and they contribute to social cohesion and social justice, as well as to sustainable development. The European Commission’s health strategy adopted in October 2007 and published in the White Paper Together for Health put forward a new approach to ensure the EU could do as much as possible to tackle challenges such as health threats, pandemics, the burden of lifestyle-related diseases, inequalities, EU enlargement and climate change. It aimed to foster good health in an ageing Europe by promoting good health throughout the lifespan, by protecting citizens from health threats, by improving patient safety and by supporting dynamic health systems and new technologies.

However, making progress on these objectives cannot be made without a workforce of sufficiently well-trained and highly motivated health professionals and care workers, equipped with the right skills and located in the right places. While each EU Member State is in charge of its medical infrastructure there have been growing concerns throughout the EU about health workforce numbers and the sustainability of dynamic health systems.

Responding to the challenges
EU health systems have to perform a difficult balancing act, firstly between the increasing demands on their health services and constraints on supply and secondly between the need to respond to population health needs locally alongside the need to be ready for major public health crises. There are a number of challenges facing...
health systems in Europe. Policy makers and health authorities first of all have to adapt their health care systems to cater for an ageing population. Between 2008 and 2060 the population of the EU-27 aged sixty-five and over is projected to increase by sixty-seven million, while those over eighty will be the fastest growing segment of the population. The introduction of new technology is also making it possible to increase the range and quality of health care in terms of diagnosis, prevention and treatment, but this has to be paid for and staff need to be trained to use it. Furthermore, there are also new and re-emerging threats to health, for example from communicable diseases. Finally, citizens have ever-rising expectations on access to the best possible health care. All of these factors inevitably lead to continually rising spending on health and indeed pose major long-term challenges to the sustainability of health systems in some countries.

Health services are extremely labour intensive and health workers in the widest sense constitute one of the most significant sectors of the EU economy, providing employment for one in ten of the EU workforce. However, there are serious issues facing the health workforce in the EU. Many of these problems are common to all Member States. The ageing population means that the health workforce is itself an ageing one and there are insufficient recruits coming through to replace those people leaving. This and the growing pressures on health systems mean that there are already shortages in many health professions. Migration of health professionals in and out of the EU, as well as mobility within and outside the EU, also has the effect of increasing shortages in some regions.

So, how can high standards be ensured when health professionals move between countries with very different health systems? How can the growing demands for health care be met in the light of shortages resulting from the ageing and increased mobility of the health workforce? How do countries with less economic resource in the EU retain the health professionals they train when their health systems cannot compete with higher salaries in other parts of the EU? What ethical issues arise when the EU seeks to solve these problems by attracting health workers from low and middle-income countries? How do we ensure sufficient capacity in all specialties and cope with training for new treatments and technologies?

By describing as precisely as possible the common challenges faced by the EU health workforce: demographic change, diversity in the health workforce, the limited appeal of many diverse health care and public health related jobs to new generations, the migration of health professionals in and out of the EU, unequal mobility within the EU, as well as the health brain drain from other countries, the Green Paper aims to increase the political visibility of these issues.

It signified the launch of a debate and, by engaging stakeholders, the consultation process has aimed to identify where the Commission believes further action can be undertaken to stimulate coordinated approaches. In light of the fact that Member States are facing a number of common problems with their health workforces, there is much to be gained by promoting cooperation and common approaches between Member States.

Next steps – building the workforce

The Green Paper intends to highlight the need for forward thinking, collaboration and imaginative use of robust human resource strategies to build capacity in the health workforce.

Good human resource planning and management have a vital role to play in the recruitment and retention of staff. Staff are not motivated to stay in employment solely by their rates of pay, although clearly it is an important factor. Staff need to feel valued and will feel valued if they work in a culture which promotes participation in decision making, team working and opportunities for career development. Employees are increasingly aware of potential benefits, educational opportunities and employment options.

All staff need to be supported in the work/life balance; attention to these factors plays an important part in both recruiting and retaining staff. It can even help in attracting them back to work if they have left the profession. Strategies can include job-sharing, holiday play schemes for children of working parents, maternity, paternity and special leave arrangements, as well as potential alternatives to early/late shift patterns.

Here is an example, by no means isolated, of how the quality of working life plays an important role in influencing decisions to leave jobs in nursing. In Ireland a study in 2003 indicated that an estimated 15,000 qualified nurses and midwives were living in Ireland but opting not to work in the profession. When asked why they left the nursing profession, almost 40% said that their decision to leave was affected by conditions in their working environment, such as understaffing, working hours, management problems and poor resources. When asked if they would consider returning to nursing if more attention was paid to working flexibly, 53% said they would.

The key to maintaining a sufficient workforce, in the face of the impending retirement of the ‘baby boom’ generation, is not only to retain and recruit both young and mature workers but also to embrace flexible working arrangements. Recruitment campaigns can take advantage of the growth in the proportion of those over fifty-five. ‘Return to work’ campaigns can be aimed at those who may have withdrawn from the health care sector for some time due, perhaps, to family commitments. Special training courses will be needed to help these applicants back into the workplace.

Attracting students to health-related studies, coupled with attracting workers to participate in this sector will be a major challenge, especially as there is competition in the labour market from jobs often offering better wages and working conditions. Strategies need to be geared towards the diversity of the modern European population, both in terms of the flexibility of conditions of service, but also culturally sensitive to the needs of ethnicity and religious customs.

The challenge of increased mobility

Many of the countries which have joined the EU since 2004, have witnessed an exodus in their health professionals. They have voiced concerns about the implications of the internal market and EU Directive 2005/36, which provides for the free movement of professionals and the mutual recognition of professional qualifications.

However, freedom of movement of people between Member States is a key part of the construction of the EU. Mobility of health professionals is useful. It means that health workers can go where they are most needed and can move to obtain more professional experience. There is also, of course, migration outside the EU.

As is widely acknowledged, a serious
impediment in analysing the workforce situation across the EU is the lack of up-to-date data and information. We do not have comparable qualitative or quantitative EU-wide data on the number of health workers in training or employment, their specialisations, geographical spread, age, gender and country of provenance. Instead, we work with proxy data collected from applications to register with competent authorities in the Member States. These requests are indicators only of intention and cannot provide details on whether the health professional actually left for the new country or if, having left, they returned. It is also virtually impossible to track out-flow and in-flow when the health worker does not take up a similar position as a regulated professional in the destination country. While there are some exciting and promising research projects now underway, funded in part by the EU, it will be some time before we have access to robust data and information.

The response to tackling the effects of increased mobility must surely be to address these issues through appropriate policies, such as measures to increase general labour market participation, in particular in respect of women, older workers and young people; improved workforce retention; further improvements to education and vocational training; adequate conditions of employment for public sector workers; incentives for return mobility; and measures to facilitate internal labour mobility. This response also will include managed immigration from outside the EU.

Member States will gain from collaborating with other Member States rather than being in competition with each other. Cross-border agreements on training and staff exchanges may help to manage the outward flow of health workers. Incentives to promote the ‘circular’ movement of staff could be introduced, by which the benefits of working in another health system would be recognised, while encouraging eventual return to the home country. Incentives could take the form of an agreed career pathway, so that the individual returning may come back to a post and receive a salary which recognises the experience gained.

The increased mobility of the workforce may require workforce managers at local and/or national level to review the adequacy of their recruitment and professional development measures, as well as their pay and working conditions. The creation of an EU-wide forum or platform where managers could exchange experiences might merit value in this context.

Training
Graduates and school leavers need to be aware of the rich diversity of career opportunities available in the health and caring professions. More mature workers, those returning to work after home responsibilities or those who want to change career, can be encouraged to join if specially adapted training courses are available. In some parts of Europe training programmes may need to be designed to attract people from ethnic minority backgrounds into the workforce for health so that it more accurately reflects the makeup of the population served. This will help to ensure that services can be designed to be culturally sensitive and help to increase equity of access to health service for migrant and ethnic communities.

As well as initial training, the issue of health professionals’ continuing professional development (CPD) is also important. It is through the record of CPD that a prospective employer can tell how up-to-date a professional’s skills and knowledge are. CPD helps to demonstrate the value of a health worker to the organisation being served. It is also useful to the employing organisation as part of its performance management system because the updating of professional skills has a part to play in both improving the quality of health outcomes and ensuring patient safety. One dividend is improved morale and staff retention.

Finally, it may be useful to reflect on the implications of the current economic crisis, which, while bringing pain, may also present opportunities. With many jobs being lost in all sectors of the wider economy and unemployment levels rising across the EU, health and care sector employers will have a rare opportunity to offer retraining to some being made redundant from commerce and manufacturing and so draw on a new pool of potential talent. The question is, will this opportunity be seized?

References

Further related information on EU health workforce issues can be found at http://ec.europa.eu/health/ph_systems/workforce_en.htm
The pharmaceutical sector in the Republic of Srpska, Bosnia and Herzegovina

Vanda Markovic Pekovic, Ranko Skrbić and Nataša Grubiša

Summary: Medicines are one key component in the maintenance and restoration of the health of communities and individuals, which is why they are placed amongst the top priorities in the health system of the Republic of Srpska, one of the two entities that make up Bosnia and Herzegovina. This is being achieved through the development of a national medicines policy. A central objective in the area of pharmaceutical activity to ensure that citizens have access to safe, good quality and effective medications that are made available at reasonable price and used in a rational manner.

Keywords: pharmaceutical policy, drug regulatory agency, Republika Srpska, Bosnia and Herzegovina

Republika Srpska, or the Republic of Srpska (RS), is one of two entities in Bosnia and Herzegovina, (the other being the Federation of Bosnia and Herzegovina – FBH) accounting for 49% of the land mass of the country and home to about 34% (1.5 million) of the population. It has its own executive and legislative functions and responsibilities, including those covering health care policy.1,2 As indicated in Table 1, the declining birth rate coupled with the increase in life expectancy and proportion of the population aged sixty-five and older indicates a need, common to that seen in many other parts of Europe, for the health care system to shift towards better prevention and management of chronic disease, as well as increased provision of geriatric and long-term care services.

Spending approximately 6% of its GDP on health care in 2006, RS is coming into line with countries in the region in terms of the consumption of resources for health care.3,4 While the use of medications has increased across all of Bosnia and Herzegovina, it is noticeable that the share of total consumption in RS compared to FBH has increased considerably (Table 2). Per capita pharmaceutical expenditure in RS increased from €28 in 2005 to €50 in 2007.

Authority over the health system in RS is centralised, with planning, regulation and management functions held by the Ministry of Health and Social Welfare. The Health Insurance Fund (HIF) provides universal health insurance coverage for the population and operates on the basis of solidarity and mutuality. It is the only body legally responsible for the collection and allocation of financial contributions to health care providers. Two independent professional pharmacy organisations exist: The Pharmaceutical Chamber and the Pharmaceutical Association.

Developments in the pharmaceutical sector

Pharmaceutical supply during the war and postwar period was mostly channelled through humanitarian aid programmes, which thus heavily influenced pharmacotherapy, with medicines delivery based upon humanitarian donors own estimation and stocks.7 Since the 1990s the pharmaceutical sector has undergone much reform, both through EU CARDS programme (Community Assistance for Reconstruction, Development and Stabilisation) and various World Health Organization (WHO) projects which have supported health care reforms in Bosnia and Herzegovina.

Marketing authorisation, quality control and inspection improved considerably in 1997 when the List of Essential Medicines was introduced, based on the WHO’s Essential List Model. Further improvements came with the creation of a pharmaceutical department within the Ministry of Health and Social Welfare and the appointment of a junior minister with responsibility for pharmaceutical issues. There has been a strong orientation

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towards the EU, aligning pharmaceutical legislation with EU directives. Legislation harmonised according to European standards provides the basis for maintaining standards for the quality assurance of medicines. The current applicable Law on Medicines, approved by the Parliament in 2001, was developed by local experts through the EU CARDS Programme, and was fully compliant at that time with European pharmaceutical legislation. This law was subsequently revised and updated in March 2008. Other specific aspects of pharmaceutical policy are covered through a number of bylaws.

An official national medicines policy document, linked to overall health policy, was adopted by the government in 2006. Its overall objective is to ensure access to effective, safe and quality medicines, made available in a rational and cost-effective manner to the whole population. This objective will be fulfilled through strategic action plans.

The Drugs Regulatory Agency

One of the main outcomes of the WHO and EU CARDS projects was the adoption of the Law on Medicines and the establishment of the Drug Regulatory Agency (DRA) of the Republic of Srpska. The role of the DRA is clearly reflected in the Law on Medicines, by which it was established in 2002 as an independent professional body responsible to the minister of health. All core pharmaceutical quality assurance functions fall under the auspices of the DRA, i.e. marketing authorisation, classification of medicines, licensing, quality control, medicines information, pharmacovigilance and clinical trials. It has a staff of forty employees, the majority of whom are pharmacists. Since the DRA was established, an upward trend in the number of medicines that receive marketing authorisation, in accordance with the system of international non-proprietary names (INN), has been observed. This increased from 104 INNs in 2005 to 260 in 2007. The increased number of medicines on the market can be directly linked with improved access to medicines by the population. A department of pharmacovigilance is responsible for collecting data on adverse drug reactions (ADR) and for promotion of the importance of monitoring and reporting of ADR. Through organised workshops the DRA provides pharmacists and physicians with the most relevant data on ADR, as well as demonstrating practical skills on how to report them (both spontaneous reporting and within clinical trials). A brochure entitled Guidelines for Detecting and Reporting the Adverse Effects of Medicines has also been published and reports can be submitted online or by post. The DRA is also responsible for monitoring clinical trials according to related bylaws and guidelines on good clinical practice. The case for each proposed clinical trial, including harmonisation with clinical practice guidelines, is evaluated by the RS Ethical Committee.

Pharmaceutical inspection is regulated by the Law on Inspection, with an Inspectorate established as the competent authority. Inspectors have the authority and obligation to take appropriate measures where non-compliance with legislation is identified. One problem however is a shortage of pharmaceutical inspectors, but only two currently in operation. Moreover, neither has a Good Manufacturing Practice (GMP) qualification.

Distribution, supply and quality control

The majority of medicines are imported, with the majority coming from manufacturers elsewhere in the former Yugoslavia, as well as from multinational pharmaceutical companies. There is only one local pharmaceutical manufacturer, Hemofarm, now a subsidiary of the German pharmaceutical company Stada. Pharmaceuticals are supplied by wholesalers to pharmacies. There are twenty-five licensed wholesalers, all privately owned. Four wholesalers dominate, having around 80% of the market. Prescription and over the counter medicines can only be obtained through the 274 pharmacies in RS, the majority of which are privately owned. Pharmacies may be owned by non-pharmacists, but can only be operated by one or more of the 523 licensed pharmacists in RS, usually working in partnership with a team of pharmaceutical technicians. One recent change has been...
the creation of specialist stores operated by pharmaceutical technicians in which herbal medicines, foodstuffs, other complimentary medical products, cosmetics, hygiene products and specified medical devices may be sold.

There are 35 pharmacists per 100,000 inhabitants compared with 72 per 100,000 in the EU. There is one pharmacy per 5,430 inhabitants. Density in urban areas is much higher than in rural areas; these largely remain underserved, with pharmacists having little incentive to work in such areas. Hospital pharmacies serve only inpatients, again being run by licensed pharmacists. There remains a persistent shortage of hospital pharmacists while self-dispensing by doctors is not allowed.

As noted earlier the Essential Medicines List (EML) is based upon the WHO EML model. The EML provides a base from which other outpatient and inpatient medicine lists reimbursed by the HIF have been developed. These include the Hospital List of Medicines (for inpatients), the List of Medicines used in Dom zdravlja (similar to polyclinics) by general practitioners (for ambulatory acute situations) and the Positive List of Medicines (for prescription only medicines). These lists are broader than those of the EML, reflecting therapeutic needs, but adjusted to take account of the financial considerations faced by the HIF. The WHO ATC (Anatomical Therapeutic Chemical) classification system is fully applied to all medication on these lists, while the Hospital and Dom zdravlja lists are also used for the central tender on the procurement of medicines, according to the Law on Public Procurement in Bosnia and Herzegovina.

Measures to ensure the quality control of medicines are clearly set out in the Law on Medicines and related bylaws. Pre-marketing control testing comprises evaluation of the quality element of the dossier (sample control only if necessary) and control of the first batch of medication prior to import. Post-marketing surveillance involves the regular quality control of medicines, vaccines and serums conducted normally by the pharmaceutical inspection body. There is however no government run quality control laboratory in RS, although one is in the process of being established. Quality control activities have thus been authorised in several neighbouring control laboratories.

**Reimbursement and drug price regulation**

Outpatient medicines reimbursed under the Positive List are dispensed through a network of pharmacies contracted by HIF. Criteria for reimbursement are defined by the HIF. The evidence on the therapeutic benefits and economic impacts of medicines are assessed by the Medicines Committee. Marketing authorisations are mandatory for all medicines but exceptions can be made in the case of medications of great clinical significance.

Since May 2008 the list has comprised two categories of medicine. Those on the A List are fully reimbursed up to a reference price level, while those on the B List are reimbursed at a 50% rate. A medicine can appear on either list depending on clinical indication. The A List covers medications for major chronic diseases including diabetes, epilepsy, cardiovascular disease and chronic psychiatric problems. Medications for a number of severe and/or chronic diseases including cancers, HIV/AIDS, multiple sclerosis, haemophilia and hepatitis C and B are fully reimbursed and dispensed separately through the hospital pharmacy system.

The reference price is set up to be equivalent to the cheapest generic medicine in a cluster, with medicines clustered on the fifth ATC level; thus medicines with the same active ingredient (INN), dosage form and administration route have the same price. A flat fee-for-service of €0.56 per prescription is paid by HIF to contracted pharmacies to supply and deliver reimbursable medicines to patients.

Pharmacists are allowed to substitute any prescribed medicine with another that has the same INN, but pharmacists are obliged to provide the lowest priced equivalent without any requirement for an out of pocket payment. If there remains a demand for a specific brand, either by the patient or physician then the patient must pay out-of-pocket any difference in price.

Free pricing applies to non-reimbursable and OTC medicines with patients having to pay the full retail price. A wholesale mark-up of 8% is applied to the ex-factory medicine price plus a further CIF (Cost, Insurance and Freight) levy of approximately 2%. Since 2006, Bosnia and Herzegovina has levied value added tax at a flat rate of 17% on all imported goods, including medicines. The retail mark-up is 20% of the wholesale price. According to Bosnia and Herzegovina legislation the customs tariff for pharmaceuticals ranges between 0% and 10%.

**Better use of medications and strengthening human resources**

A number of efforts have been undertaken to encourage the more efficient and rational use of medications. Detailed information on medicines are available on the DRA website. Information tailored to health care professionals can also be found in the annual Medicines Formulary. Since 2006, the DRA has also begun to collect data on medicine consumption, using the ATC/DDD (Defined Daily Dosage) methodology. Eighteen standard therapeutic guidelines relating to the most common health problems seen in primary health care have been published; others are in preparation. Hospital Medicine Committees can also play an important role in encouraging more rational use of medicines. All hospitals have now established such bodies.

One key challenge is the limited capacity in pharmacy. The Department of Pharmacy within the medical faculty at the University of Banja Luka, is the only teaching centre for pharmacy students. This is funded by the government. With undergraduate training lasting five years, 120 qualified pharmacists have been trained in the past decade. However the lack of teaching staff for both undergraduate and postgraduate pharmacy education has meant that there has been a reliance on attracting teaching staff from outside RS. In future, much effort needs to be invested in expanding and training indigenous university staff in order to help address the challenges created by the insufficient number of pharmacists having professional specialisation and academic titles, as well as the lack of hospital-based pharmacists.

**Conclusions**

Health systems should be designed so as to provide equitable access. The main challenge is to continue to make progress towards achieving key health system objectives, namely improving the health of the population and providing protection against the financial costs of illness, while ensuring financial sustainability in the health sector. The pharmaceutical sector, despite all its complexity, is well aware of the role and the impact that it can have in meeting these objectives.

Considerable efforts have already made in RS to both improve access to medicines...
and make them more affordable. We have noted that access to medications has recently been significantly improved through the development of extended hospital and outpatient positive medication reimbursement lists. In the field of legislation considerable progress has been achieved in moving towards a regulatory framework compliant with EU standards. Effective and transparent functions within the DRA have made a notable contribution to the implementation of this legislation. Much more, however, remains to be done to strengthen capacity within the pharmaceutical sector.

REFERENCES

Improving child and adolescent mental health services in Norway: Policy and results 1999–2008

Marian Ådnanes and Vidar Halsteinli

In Norway, a ten year period of governmental escalation in mental health services for children and adolescents is coming to an end. This snapshot gives a brief overview of national policy and achievements in this period, before reflecting on future challenges.

The ten-year national mental health escalation plan
A Norwegian white paper issued in 1997 expressed great concern about mental health problems among children and adolescents and concluded that access to mental health services of good quality was far too low. The paper gave rise to a national mental health escalation plan enacted over the period 1999–2008. This set out a number of strategies and targets at national, regional and local levels. The overall goal was to create adequate, coherent, well-functioning and user-friendly services at all levels for children with mental health problems.

Specialist services provide diagnostic assessment and treatment. Specific aims of reform directed at these services included an additional four hundred therapists for outpatient clinics and a 50% increase in outpatient clinic productivity, specified as consultations per therapist. Treatment capacity was to be sufficient to cater for 5% of the population below eighteen years of age, while there was also to be a minor increase in the provision of beds. Overall however, the emphasis of the reforms was very much on new treatment modalities: more outpatient care, ambulatory services, local low-threshold services and closer collaboration between primary and specialist care.

The municipalities are considered the most important arena for promotion and prevention. At the end of the 1990s, municipal services were found wanting in several respects: a lack of funding, a lack of skilled personnel and a lack of competence regarding the planning, organisation and integration of services. The government’s goal for the municipalities has thus been to expand and improve the quality of services. This has focused on the development of psycho-social services, cultural and leisure activities including ‘support contacts’ in relation to leisure-activities, more psychologists – a profession previously almost non-existent in the municipalities, and an increase of approximately eight hundred professionals for maternal and child health centres – first and foremost public health nurses, ideally having undertaken postgraduate studies in mental health.

What has been achieved?
In specialist services a substantial increase in treatment capacity has successfully been implemented. In respect of outpatient clinics the number of therapists has more than doubled in nine years. There are now 429 more therapists than originally planned. This illustrates, of course, a huge increase in public spending in this sector. The number of consultations per therapist has also increased by 80%. However, one
should take into account that the patient case-mix has changed and that the policy of introducing performance indicators might have had some unwanted effects, for example, in terms of inflated coding. Analysis indicates a 20–30% productivity increase as being more realistic; this corresponds to the increase in the number of patients per therapist.5

The increase in inpatient treatment has been modest (forty-one more beds), however, the development of ambulatory services in outpatient clinics has taken place and, in many cases, such services now represent an alternative to hospitalisation. Capacity and productivity increases imply a significant increase in access to services. In 2007, 4.5% of children and adolescents below eighteen years made use of specialist services. Nonetheless, substantial regional differences remain part of the picture.4 In other words, one year before the end of the plan period, access to mental health services is close to, but still below, the original target.

Within the municipalities as well, there has been a substantial increase in personnel. There are still, however, too few psychologists, although measures to boost recruitment are now in place. Moreover, the targeted increase in the number of public health nurses has not yet been attained, although it is now within reach.6

Increased spending as a result of the escalation plan has been used, both for preventative measures and for treatment/follow-up, within the municipalities.7 The objective has been to uncover non-optimal child development as early as possible, in order to implement curative and preventative measures at an early stage.

Pilot programmes initiated at family assistance centres have been evaluated, providing examples of suitable tools for the coordination of municipal services directed at children, adolescents and their families. Child health clinics, as well as school health services, provide low threshold services for pregnant women, children, and adolescents as a core element of their services. An evaluation of these low threshold services indicates that they represent an important supplement to specialist mental health care. They do not however, and are not intended to, replace assessment and treatment performed by specialists.

**Governmental strategic plan**

In parallel with the escalation plan, a further strategic plan for the period 2003–20088 sets out how the government plans to strengthen and develop actions for improved mental health among children and adolescents through one hundred different measures. These have been implemented within the different levels of service, at school, in volunteer organisations and through initiatives directed at parents. This strategic plan is an expression of intent to create a holistic approach to enhancing child and adolescent mental health.

It has a clear health promotion and prevention profile, and emphasises the strengthening of children and adolescents’ own resources and abilities to cope with challenges in life. It flags up the central role of the local community. The plan also points to particular challenges facing services for children and adolescents who already have mental health problems. A new strategic plan in now in development.

**Challenges and future policy**

There is no doubt that both services and attitudes related to child and adolescent mental health problems have improved over the last ten years in Norway. The national escalation plan has successfully increased capacity across the different levels of mental health care, but barriers and issues still exist.

While improving the accessibility, quality and the organisation of mental health services and treatment at all levels has been the focus of reform, it remains a major challenge, not only to develop smoother collaboration and cooperation between primary health, social care (at the municipal level) and specialised health services, but also to improve coordination within existing primary health services.

The government’s policy9 continues to place a strong emphasis on preventative psycho-social work for children and adolescents, in order to strengthen mental health and identify needs as early as possible. Access to specialist services should improve further through reduced waiting times for treatment. The government also sees the necessity of increasing competence in the field of mental health to address its broad multi-sectoral impacts. An emphasis is thus put on the provision of information and other measures, to both those of school and working age, in order to help improve attitudes towards people making use of mental health services.
The introduction of long-term care insurance in South Korea

Soonman Kwon

Background
In July 2008, Korea introduced a new social insurance scheme for long-term care (LTC). Several important demographic and social changes have contributed to the introduction of LTC insurance, including the rapid ageing of the population as a result of the increase in life expectancy and the sharp decline in fertility which fell below 1.1 in 2005. The proportion of older people (those over sixty-five) in Korea was 9% in 2005, but is forecast to increase at an unprecedented rate. Older people are expected to account for 16% of the population by 2020 and 38% by 2050, resulting in an old-age dependency ratio of 70%.

With population ageing the demand for LTC has increased. Family structures have also contributed; the proportion of older people living with adult children had decreased to 38% by 2004. The availability of informal or family caregivers is diminishing, given that female labour participation is increasing and thus they are less willing to provide care. Only 36% of those who receive LTC also receive care from their spouse. However there are difficulties in obtaining residential care because the supply of LTC facilities is limited and, unlike health care which is covered by the public to pay contributions which are also easier for the government to persuade the public to pay contributions which are exclusively for LTC. However, the separation of LTC financing from health insurance may be a barrier to coordination between health and LTC if the two different financing schemes try to offload their financial burdens on each other.

Social Insurance for long-term care
Tax-based financing was never given serious consideration from the beginning of discussions on a possible LTC financing system. Contribution-based social insurance financing was adopted because the Korean welfare state is based on various social insurance schemes such as health insurance, pensions, unemployment insurance, and workplace injury compensation. By making use of the existing administrative structure of the health insurer, the National Health Insurance Corporation (NHIC), LTC insurance can minimise administrative costs.

Path dependency also affects the financing mix: LTC insurance in Korea is not a pure social insurance, but financing from contributions has a greater role than tax subsidies. As in the case of health insurance, the Ministry of Health Welfare and the Family (MHWF) will play a key role in the policy for LTC insurance and tightly monitor the insurer. The NHIC, the single payer of health insurance, also strongly supports LTC insurance as an opportunity to extend its own operation and mitigate against the pressure of down-sizing/employment adjustment within its own organisation.

LTC insurance, separate from health insurance, also has the potential benefit of being able to the ‘de-medicalise’ LTC. It is also easier for the government to persuade the public to pay contributions which are exclusively for LTC. However, the separation of LTC financing from health insurance may be a barrier to coordination between health and LTC if the two different financing schemes try to offload their financial burdens on each other.

Population coverage
The new LTC insurance scheme provides coverage for all those over the age of sixty-five, as well as age-related LTC needs for younger people. As a result, the Korean LTC insurance scheme does not provide coverage for disability-related care needs. The government has prioritised population ageing and related problems, rather than aiming to solve problems related to LTC. Thus the new LTC insurance, targeted to cover only aged-related care needs, will have a limited effect on social solidarity.

In contrast to health insurance, individuals need to obtain prior approval for services through an assessment of functional limitations. In order to determine eligibility, a visit team from the local branch office of the NHIC assesses the functional status of individuals using a fifty-six item evaluation. There are three levels of functional status/limitations, each with different benefit levels. Local assessment committees comprise no more than fifteen members, including a social worker and medical doctor (or traditional medical doctor). All decisions of the committee are based on the assessment of ability to perform activities of daily living (ADL) undertaken by the visit team, alongside a doctor’s report.

The difference in entitlements compared to health care may not immediately be understood by older people. Initially there may be many appeals for reassessment of eligibility (functional status) as the LTC scheme is rolled out. The current
assessments are likely to reach about 3-4% of the older population. This, however, appears to fall short of the demand for long-term care, leading to criticisms that the limited coverage threatens the universalism of LTC insurance. The government does not have plans to increase population coverage incrementally, but progress in achieving this will depend on the financial sustainability of the LTC insurance system.

**Level and type of benefits**

Contributions to the LTC insurance are determined as a fixed percentage (currently 4.05%) of the health insurance contribution, with the two contributions collected together. Overall, financing consists of a government subsidy of 20%, co-payment of 20% (institutional care) or 15% (home-based care), and an insurance contribution of 60–65%. The poor are exempted from co-payments. Meals and private rooms are not covered by LTC insurance. As LTC delivery in Korea is predominantly private, one potential challenge is that private providers might have perverse financial incentives to induce demand for these additional areas of service, resulting in an increased financial burden on older people.

LTC insurance provides largely service benefits. Cash benefits are provided only in exceptional cases (for example, when no providers are available in the region). Benefits depend on the level of functional limitation determined in the assessment process. There are ceilings on the benefits for non-institutional care, ranging from 1,097,000 Korean Won (about US$1,000) per month for level one to just 760,000 Korean Won (about US$1,000) per month for level three. The type of payment to providers varies from pay per hour for home care, pay per visit for home nursing and baths, and pay per day for institutional care and day/evening care.

The limited role of cash benefits needs to be reconsidered in Korea. A cash benefit system was not adopted because of the potential for abuse and the low quality of care provided by informal care givers. The feminist movement, worried about the potential pressure on women to provide care in the case of cash benefits, did not influence the development of the system. Nonetheless, cash benefits can have positive effects on consumer choice and competition among formal and informal caregivers. Cost savings may also be possible when the level of cash benefits is lower than that for services. Cash benefits can also mitigate some of the problems associated with the insufficient supply of LTC service providers in Korea.

**Delivery of long-term care**

While the number of (private) providers in the LTC sector has increased rapidly, lack of access to care providers still remains a concern, with variation across localities a persistent problem. As of 2008, there were 1,530 LTC institutions with 64,671 beds, covering 1.28% of those aged 65 and over. There are 8,011 home care providers, which are estimated to cover 2.2% of the older population. Entry of new providers will depend on the generosity of compensation and fees set by the government.

Quality of care is a critical issue. There is a broad spectrum in quality of care across LTC institutions. The government needs to monitor and disseminate information on the quality of these providers.

**Concluding remarks**

The introduction of LTC insurance represents a major change for social care in Korea. It will also have a significant impact on the healthcare system because older people account for a large share of health expenditure and admissions for social care needs have been increasing. Coordination between health insurance and LTC insurance will be a key to the continuum of care and the prevention of unmet need. Benefits provided through LTC insurance should be coordinated with those of health insurance, where out-of-pocket payment amounts to more than 30% of total health expenditure. The relative generosity between payments to long-term care hospitals (paid by health insurance) and those to long-term care institutions (paid by LTC insurance) will also affect provider incentives.

LTC should also be closely coordinated with welfare services. At present however, the role of local government is very limited in the provision of LTC. It is only active in the area of financing for the long-term needs of the poor (through the public assistance programme) and the regulation and certification of LTC institutions. Going forward LTC policy needs to empower local governments, so as to help facilitate effective coordination between LTC and welfare services.

**References**


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**International Conference on ‘Markets in European Health Systems: Opportunities, Challenges, and Limitations’**

The European Observatory on Health Systems and Policies and the Ljubljana based Centre of Excellence in Finance (CEF) are organizing an International Conference on ‘Markets in European Health Systems: Opportunities, Challenges, and Limitations’.

This conference, which will take place in Kranjska Gora, Slovenia from 16 to 17 June 2009, will focus on how health systems’ financing can be reformed to ensure the most efficient resource allocation. It will address a number of questions concerning the extent to which the use of market mechanisms and competition are effective for better containing cost and improving health systems performance and how it relates to the reality of health systems in the Central and Eastern European region.

More information on the event at [http://www.cef-see.org/health/](http://www.cef-see.org/health/)
These days it’s all about cost. That’s what many people think about modern medicine. Others, and most health economists and purchasers would say, au contraire, it’s all about value. The most expensive medicine, they would say, is the one that doesn’t work. Yet others, perhaps those giving this a little bit more deep thought, would point out that no medicine works in every patient, and perhaps if we could discover which patients would benefit from which medicine we might do rather better for all of them.

While the argument rages, or mumbles on, we are stuck with a definition of good value that works out, for a quality-adjusted year of life (QALY) of about £30,000 or $50,000 or less. These are not easily calculated, and lead into some very convoluted paths, as the example of age-related macular degeneration (ARMD) demonstrates.¹

**Visual value**

We measure vision most commonly by visual acuity, a quantitative measure of the ability to identify black symbols on a white background at a standardized distance as the size of the symbols changes. Visual acuity is the smallest size that can be reliably identified. The well-known phrase ‘20-20 vision’ refers to the distance in feet that objects separated by an angle of 1 arc minute (one sixtieth of one degree) can be distinguished as separate objects. The metric equivalent is 6–6 vision.

20/20 means one can see small letters, 20/40 moderate letters only but not small ones, while 20/100 means that only the very largest letters can be distinguished at 20 feet (6.096 metres), but that someone with normal vision would be able to distinguish these letters at a distance of 100 feet (30.48 metres). As the second number increases, then, visual acuity gets worse.

A review¹ brings together some aspects of the way we value vision. For instance, Figure 1 shows the time trade-off utility values for different levels of visual acuity, where a value of one is normal health and zero death. Here people are asked how many years of remaining life they would trade for permanent normal health. People with a moderate reduction in acuity to 20/40 say they would be willing to trade four of 20 remaining years of life for a return to normal visual acuity (1.0 minus {4/20}).

Clearly, impaired vision impacts significantly on health utility, but the degree by which vision is valued is under appreciated by the public, clinicians in general, and ophthalmologists in particular (Table 1). Ophthalmologists, for instance, considered that patients would be prepared to lose 2% of available life years to return to 20/40 vision from 20/40, which is what a utility value of 0.98 says in Table 1. By contrast, patients were prepared to lose 17% of their remaining time of life (utility = 0.83).
**Comparison with other conditions**

Visual acuity of <20/200 in the better eye (severe ARMD) has utility values similar to severe stroke, or advanced prostate cancer with uncontrollable pain. Moderate ARMD (20/50 to 20/100) has similar utility values to moderate stroke or a hip fracture. Mild ARMD has similar utility values to vertebral fractures or symptomatic HIV.

When value gains are compared between some interventions for macular degeneration and interventions for other conditions (Table 2), it is clear that they compare well in terms of quality or length of life.

**Comment**

This particular paper is not one that Bandolier would normally consider for its pages. It is not a systematic review, and though it does look at quality of evidence, there are some deficiencies in the amount of evidence available. But it does make one think, and for that reason alone is worth a quick read. For those engaged in the difficult decisions around value and cost for different interventions, it is probably worth a more detailed read, especially with some effective but perhaps costly therapies coming our way.

**Table 2: Value gain in quality or length of life for interventions in age-related macular degeneration and other conditions**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Value gain (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions for macular degeneration</td>
<td></td>
</tr>
<tr>
<td>Laser photocoagulation; subfoveal classic</td>
<td>4.4</td>
</tr>
<tr>
<td>Laser photocoagulation; extrafoveal classic</td>
<td>8.1</td>
</tr>
<tr>
<td>Photodynamic therapy</td>
<td>8.1</td>
</tr>
<tr>
<td>Intravitreal pegaptanib</td>
<td>5.9</td>
</tr>
<tr>
<td>Intravitreal ranibizumab</td>
<td>&gt; 15</td>
</tr>
<tr>
<td>Interventions for other conditions</td>
<td></td>
</tr>
<tr>
<td>Bisphosphonates for osteoporosis</td>
<td>1.1</td>
</tr>
<tr>
<td>Alpha-blockers for BPH</td>
<td>1–2</td>
</tr>
<tr>
<td>Statins for hyperlipidaemia</td>
<td>3.9</td>
</tr>
<tr>
<td>Beta-blockers for hypertension</td>
<td>6–9</td>
</tr>
<tr>
<td>PPI for reflux</td>
<td>11</td>
</tr>
</tbody>
</table>

**Reference**


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**Investing in hospitals of the future**

*Edited by: Bernd Rechel, Stephen Wright, Nigel Edwards, Barrie Dowdeswell and Martin McKee*

Despite considerable investments in health facilities worldwide, little systematic evidence is available on how to plan, design and build new facilities that maximise health gain and ensure that services are responsive to the legitimate expectations of users. This book brings together current knowledge about key dimensions of capital investment in the health sector.

A number of issues are examined, including new models of long-term care, capacity planning, the impact of capital investment on the health care workforce, markets and competition, systems used for procurement and financing, the whole lifecycle of health facilities, facility management, the wider impact of capital investment on the local community and economy, how care models can be translated into capital asset solutions, and issues of therapeutic and sustainable design.

This book is of value to those interested in the planning, financing, construction, and management of new health facilities. It identifies critical lessons that increase the chances that capital projects will be successful.

AN OVERVIEW OF “SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT”

Jonathan Levy

“Risk assessment should be viewed as a method for evaluating the relative merits of various options for managing risk, not as an end in itself”

Introduction
While risk assessment has existed in various forms for many years, the process used by the United States Environmental Protection Agency (EPA) and others was formalised in the pivotal 1983 National Research Council (NRC) report known as the Red Book. The Red Book codified the well-known four steps of risk assessment (hazard identification, exposure assessment, dose-response assessment, and risk characterisation) and emphasised the necessity of a conceptual distinction between risk assessment and risk management. Over the intervening quarter-century, risk assessment has evolved substantially, driven in part by additional NRC reports, EPA and other agency guidelines, and publications in the peer-reviewed literature.

However, concerns about the value and relevance of risk assessment for making policy decisions have grown over time, especially as risk-management issues that appear difficult to address with standard risk assessment methods (such as global climate change, endocrine disruption, nanotechnology, and environmental justice) have come to the fore. Risk assessments for some chemicals have taken decades to complete, in part because the presence of uncertainty has contributed to decision-making gridlock. At the same time, the underlying science has changed substantially in recent years, with advancements in genomics, analytical methods to measure biomarkers, and computational capacity for exposure models. In addition, there have been major changes in the expectations of the public and interest groups with respect to consultation and public participation, and risk assessments are increasingly integrated with other decision-making inputs such as regulatory cost assessments.

Against this backdrop, the EPA asked the NRC to form a committee to develop scientific and technical recommendations for improving the risk analysis approaches used by the EPA. The “Committee on Improving Risk Analysis Approaches Used by the US EPA,” on which I served, was charged to focus on human health risk analysis and to consider all environmental media (water, air, food, and soil) and all routes of exposure (ingestion, inhalation, and dermal absorption). The committee was asked to consider practical improvements that could be made in the near term (the next two to five years) and over a longer term (ten to twenty years). The committee released its final report in December 2008. This issue of Risk in Perspective provides a brief overview of the key conclusions of the report. The text and figures below are largely based on the report.

Framework of the Committee’s evaluation
The committee determined that risk assessment could be improved either by improving the technical analyses (by incorporating improvements in scientific knowledge and techniques) or by improving the utility of risk assessment for decision-making. The latter can be achieved in several ways, including improving the ways in which risks are characterised and uncertainties expressed and ensuring that risk assessments are constructed in a manner that is maximally informative for decision-makers.

As a general principle, the committee recommended that risk assessment should be viewed as a method for evaluating the relative merits of various options for managing risk, not as an end in itself. This has a number of implications for the practice of risk assessment. It implies a greater need for upfront planning of the risk assessment, in which considerable discussion among risk managers, risk assessors, and other stakeholders helps to determine the risk-management questions that risk assessment should address. It also implies that the technical analyses within the risk assessment should be more closely
aligned with the questions to be answered. For example, the level of detail of uncertainty and variability analyses should align with what is needed to inform risk-management decisions, rather than being defined as a task limited only by computational capacity. The committee’s conclusions were therefore organised around measures to improve either the utility or the technical content of risk assessment, within a decision-oriented framework.

Design of risk assessment
The committee encouraged EPA to focus greater attention on design in the formative stages of risk assessment, including planning, scoping and problem formulation, similar to the approaches articulated in EPA guidance for ecological risk assessment and cumulative risk assessment. With risk assessment considered as a decision-support product, it should be designed as the best solution to achieving multiple simultaneous and competing objectives while satisfying constraints on the process or the end product. For example, while use of the best scientific evidence and methods is a clear design objective, this may compete with objectives to be more expansive in scope, to provide timely outputs, and to have transparency in process.

One dimension of interest to the committee and EPA was the application of value-of-information (VOI) principles, which can be key components of the iterative design of risk assessments. When risk assessments are used within a decision-making environment, there is a need to determine whether information is adequate to make a decision or if more research is required. VOI analysis can help determine when investments in further information gathering are worthwhile. However, the committee concluded that formal quantitative VOI analysis may only be possible or desirable for a small number of decisions, in which decision rules are clear, estimates of uncertainty are comprehensive, and the stakes of the decision are high enough to warrant the effort. The committee offered two alternatives to formal quantitative VOI methods. The first alternative is to maintain the logic of the formal method by describing and evaluating, though in a qualitative manner, the impact of specific potential reductions in uncertainty on the choices facing the decision-maker. The second alternative is to apply an analogous ‘value-of-methods’ approach to characterise the potential benefits of the many choices among risk assessment design options (for example, consultative processes, peer engagement and review processes, means to improve transparency, methods for analysing uncertainty) considered from the perspective of their ultimate impact on the overall quality of the agency’s decision-making processes.

Uncertainty and variability
Characterisation of uncertainty and variability cuts across all elements of a risk assessment and many of the topics in the committee’s statement of task. As a general principle, the committee concluded that EPA needs to characterise and communicate uncertainty and variability in all key computational steps of a risk assessment and noted that many risk assessments implicitly or explicitly omit multiple areas of uncertainty or variability. For example, emissions estimates are often treated as known and variability in cancer susceptibility is often ignored or isolated to defined subpopulations. That being said, the committee also emphasised that the level of detail with which uncertainty and variability are characterised should depend on the extent to which detail is needed to inform specific risk-management decisions and recommended that EPA adopt a “tiered” strategy for selecting the level of detail within the planning stage of the risk assessment.

Selection and use of defaults
One of the more vexing challenges involves the use of defaults within assessments and the decision to apply substance-specific data or default values. In the Red Book, it was recognised that there was a need for uniform inference guidelines (or defaults) that would specify the assumptions to be used generally within risk assessments in order to ensure consistency and avoid manipulation of assessment outcomes. While such guidelines are necessary for decision-making, the appropriateness of the use of a default in the face of data and theory that may support an alternative plausible assumption has been debated extensively, often leading to protracted delays. The committee concluded that established defaults need to be maintained for the steps in risk assessments that require such inferences, and that clear criteria should be made available for judging whether, in specific cases, data are adequate to support an inference in place of a default. The committee proposed that EPA should adopt an alternative assumption in place of a default when it determines that the alternative is ‘clearly superior’ (that its plausibility clearly exceeds the plausibility of the default), while EPA should report additional risk estimates corresponding to alternative assumptions within the risk characterisation whenever the alternative assumptions are of ‘comparable plausibility’. Applying these criteria allows EPA to balance the need for comprehensive uncertainty characterisation with the need for timely and consistent decision-making.

The committee also emphasised that there are many implicit or missing defaults within current risk assessment practice, such as the assumption that an untested chemical has no risk and the assumption that all humans (at the same life-stage) are equally susceptible to carcinogens. The committee concluded that EPA should develop explicitly-stated defaults to take the place of the implicit defaults.

A unified approach to dose-response assessment
Historically, dose-response assessments have been conducted differently for cancer and non-cancer effects. For cancer, it has generally been assumed that there is no dose threshold of effect and dose-response assessments have focused on quantifying risk at low doses (although consideration of mode of action has led to some recent exceptions). For most non-cancer effects a dose threshold has been assumed, below which effects are not expected to occur or are extremely unlikely. This dose is referred to as a reference dose (RfD), with an analogous definition for a reference concentration (RfC).

There are both scientific and operational limitations with these current approaches. Non-cancer effects do not necessarily have a threshold or low-dose nonlinearity. Background exposures and underlying disease processes contribute to population background risk and can lead to a non-threshold response when considered at the population level. In addition, because the RfD does not quantify risk at different levels of exposure but rather provides a bright line between possible harm and possible safety, its use in risk-management decision-making is both limited and prone to misinterpretation. For cancer risk, the mode of action of carcinogens varies and assessments usually do not account for differences among humans in cancer susceptibility other than possible differences in early-life susceptibility.

The committee concluded that both scien-
tific and risk-management considerations support unification of cancer and non-cancer dose-response approaches. This unification can occur within a framework that includes formal systematic assessment of background disease patterns and exposures, possible vulnerable populations, and modes of action (MOA) that may affect a chemical’s dose-response relationship in humans (Figure 1). This approach redefines the RfD as a risk-specific dose that provides information on the percentage of the population that can be expected to be above or below a defined acceptable risk with a specific degree of confidence. The redefined RfD can still be used as the conventional RfD has been to aid risk-management decisions, but it provides additional information that allows for the inclusion of non-cancer endpoints in risk-risk and risk-benefit comparisons. The new definition also decreases the potential for misinterpretation when the value is understood as an absolute indicator of a level of safety.

Other characteristics of the committee’s recommended unified dose-response approach include use of a spectrum of data from human, animal, mechanistic, and other relevant studies; a probabilistic characterisation of risk; explicit consideration of human heterogeneity (including age, sex, and health status) for both cancer and non-cancer endpoints; characterisation (through distributions to the extent possible) of the most important uncertainties for both cancer and non-cancer endpoints; use of probabilistic distributions instead of uncertainty factors when possible; and characterisation of sensitive populations.

**Cumulative risk assessment**

EPA is increasingly asked to address broader public health questions that extend beyond individual chemicals to consider multiple exposures, complex mixtures, and vulnerable populations in a community setting. In response, EPA has developed cumulative risk assessment, defined as an evaluation of the combined risks posed by all routes, pathways, and sources of exposure to multiple agents or stressors. The committee applauded EPA’s move toward this broader definition to make risk assessment more informative and relevant to decisions and stakeholders, but felt that EPA cumulative risk assessments fall short of what is possible and supported by agency guidelines. In particular, there has been little consideration of non-chemical stressors, vulnera-

![Figure 1. New unified process for selecting approach and methods for dose-response assessment for cancer and non-cancer endpoints involves evaluation of background exposure and population vulnerability to ascertain potential for linearity in dose-response relationship at low doses and to ascertain vulnerable populations for possible assessment](image-url)
The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.

**Stage 1: Planning**
For the given decision-context, what are the attributes of assessments necessary to characterise risks of existing conditions and the effects on risk of proposed options? What level of uncertainty and variability analysis is appropriate?

**Stage 2: Risk assessment**
- **Hazard identification**
  What adverse health or environmental effects are associated with the agents of concern?
- **Dose-response assessment**
  For each determining adverse effect, what is the relationship between dose and the probability of the occurrence of the adverse effects in the range of doses identified in the exposure assessment?
- **Risk characterisation**
  What is the nature and magnitude of risk associated with existing conditions?
  What risk decreases (benefits) are associated with each of the options?
  Are any risks increased? What are the significant uncertainties?
- **Exposure assessment**
  What exposures/doses are incurred by each population of interest under existing conditions?
  How does each option affect existing conditions and resulting exposures/doses?

**Stage 3: Confirmation of utility**
Does the assessment have the attributes called for in planning?
Does the assessment provide sufficient information to discriminate among risk management options?
Has the assessment been satisfactorily peer reviewed?

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**FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES**
The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.

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The framework has at its core the risk assessment paradigm established in the Red Book, but differs from the Red Book paradigm primarily in its initial and final steps. The framework begins with a ‘signal’ of potential harm (for example, a positive bioassay or epidemiologic study, a suspicious disease cluster, findings of industrial contamination). It focuses upfront on the options that are available to reduce the hazards or exposures that have been identified and on the structure of the risk assessments needed to evaluate the merits of the options being considered (that will generally include ‘no intervention’ as an option). The framework also calls for formal stakeholder involvement throughout the process, with time limits to ensure that decision-making schedules are met and with incentives to allow for balanced participation of stakeholders, including impacted communities and less advantaged stakeholders.

Additional dimensions and conclusions

The committee's recommendations call for considerable modification of EPA's risk assessment efforts. Improving risk assessment practice and implementing the framework for risk-based decision-making will require a long-term plan and commitment to build the requisite capacity within EPA. EPA's current institutional structure and resources may pose a challenge to implementation of the recommendations and moving forward with them will require a commitment to leadership, cross-program coordination and communication, and training. That will be possible only if leaders are determined to reverse the downward trends in budgeting, staffing, and training and to making high-quality risk-based decision-making an agency-wide goal. The committee therefore recommended that EPA should initiate a senior-level strategic re-examination of its risk-related structures and processes to ensure that it has the institutional capacity to implement the committee’s recommendations. The committee further recommended that EPA should develop a capacity-building plan that includes budget estimates required for implementing the committee’s recommendations.

EPA is already taking steps to implement some of the key recommendations from this report, with staff preparing to meet and consider recommendations such as ways to harmonise cancer and non-cancer risk approaches and to increase the utility of assessments. Now that the Obama Administration and new Congress are in place, early senior-level leadership attention to several issues will be critical, including developing explicit policies that commit EPA to the revised framework, addressing funding levels, and adopting a set of evaluation factors for assessing the outcomes of policy decisions and the efficacy of the framework.

Because of the high financial and political stakes of risk-management decisions, there is unprecedented pressure on risk assessors and decision-makers at EPA. However, the committee felt that risk assessment remains essential to the agency’s mission. The goal of the committee’s recommendations was to provide a template for the future of risk assessment at EPA, strengthening the scientific basis, credibility, and effectiveness of future risk-management decisions.

Although the committee’s statement of task and report focused on practices at EPA, many aspects of the committee’s recommendations should be relevant to other agencies and applications. While NRC committees have previously cautioned that risk assessment differs greatly across federal agencies and should not be approached identically, the general concept of designing a risk assessment to be aligned with risk-management needs should be broadly applicable. The framework for risk-based decision-making would also apply in many settings, especially given its emphasis on conducting assessments with appropriate scope and level of complexity for the decision context. This framework may be particularly helpful in settings where analytical and computational resources are limited, as it emphasises that the most computationally complex model is not always the most appropriate. Turning to the technical content, the proposed unification of cancer and non-cancer dose-response approaches would be expected to have far reaching impacts, potentially elevating the importance of non-cancer endpoints in risk-management decisions in many settings. Coupled with the revised approach toward defaults and cumulative risk assessment, the committee’s technical recommendations should also stimulate new primary research that will enhance the scientific basis for risk assessment.

REFERENCES


HEPL invites high quality contributions in health economics, political science and/or law, within its general aims and scope. Articles on social care issues are also considered. The recommended text length of articles is 6,000 words for original research articles, 2,000 words for guest editorials, 5,000 words for review articles, and 3,000 words for debate essays. Instructions for contributors can be found at http://assets.cambridge.org/HEP/HEP_ifc.pdf

All contributions and correspondence should be sent to: Azusa Sato, Assistant Editor, LSE Health, London School of Economics and Political Science, Houghton Street, London WC2A 2AE, UK. Email hepl@lse.ac.uk

Eurohealth Vol 15 No 1 36

Health Economics, Policy and Law

International trends highlight the confluence of economics, politics and legal considerations in the health policy process. HEPL serves as a forum for scholarship on health policy issues from these perspectives, and is of use to academics, policy makers and health care managers and professionals.

HEPL is international in scope, and publishes both theoretical and applied work. Considerable emphasis is placed on rigorous conceptual development and analysis, and on the presentation of empirical evidence that is relevant to the policy process. The most important output of HEPL are original research articles, although readers are also encouraged to propose subjects for editorials, review articles and debate essays.
Across the Pond – Lessons from the US on Integrated Healthcare

Richard Gleave

London: Nuffield Trust, 2009
39 pages
Freely available online at: http://www.nuffieldtrust.org.uk/publications/detail.aspx?id=0&PRid=554

This report investigates integrated care in the United States and suggests lessons for the English health system. It is argued that although the English National Health Service’s (NHS) single-payer system seems to be the ultimate integrated health care system, at a local level, NHS organisations have often struggled to deliver integrated care. Three cross-cutting themes are identified: integrated governance; risk management and use of incentives; and integrated health information technology.

On integrated governance, Gleave argues that American systems are founded upon strong leadership and management which deliver locally sensitive and practical governance structures. Additionally, structures must be juxtaposed with a culture that prompts integrated care delivery as well as accountability. With regards to risk management, integrated payer systems should harness sophisticated risk adjustment methodologies in order to align incentives within a single organisation or between health plans and providers. Again, this approach calls for stronger management. Finally, integration between services, care and structures will support more fluid information flows between key actors.

Gleave's takes a holistic approach, using evidence from medium-sized and smaller integrated models. Four integrated system case studies are used: Kaiser Permanente Colorado; Geisinger System Pennsylvania; Kaiser Permanente North West; and Health Partners Minnesota. The report concludes that the spirit of innovation is lacking in the English NHS, compared to the US where integrated care systems are built upon dedicated and well managed physician and administrative leaders.

Contents: Foreword; Executive Summary; Introduction; Divided by a Common Language – integration in the UK and US; Integrated Governance; Risks and Incentives; IT and Integration; Policy Implications for the NHS; Conclusion; Glossary; Appendix and References

The Swiss and Dutch Health Insurance Systems: Universal Coverage and Regulated Competitive Insurance Markets

Robert Leu, Frans Rutten, Werner Brouwer, Pius Matter and Christian Rütschi

40 pages

This report from the Commonwealth Fund evaluates systems that combine universal coverage with private insurance and regulated market competition. The authors contrast the systems of Switzerland and the Netherlands in light of the health reforms undertaken by the State of Massachusetts and considered by other federal states.

It is found that the two systems have many features in common: an individual mandate, standardised basic benefits, a tightly regulated insurance market, and funding schemes that make coverage affordable for low- and middle-income families. For example, in both countries uninsured rates are under 1.5% with a wide range of benefits offered. Furthermore, insurers are regulated to guarantee acceptance of all applicants, a scheme encouraged through the use of risk equalisation which redistributes funds on the basis of measures of population need.

Differences between the Netherlands and Switzerland include the degree of centralisation, basis of competition among insurers, availability of managed care and reliance on patient cost-sharing to influence care-seeking behaviour. For example, Dutch health insurance companies are allowed to make a profit whilst Swiss insurers must be non-profit; similarly, collective insurance contracts are outlawed in Switzerland whilst up to 57% of enrolees are insured through this mechanism in the Netherlands.

The Swiss and Dutch health models provide blueprints for feasible co-existing private-public systems in the US, and the working paper urges policymakers to take this into account especially in light of increasing demand for universal coverage for American citizens.

Contents: Foreword; Introduction; System Overview; Enforcement of Mandatory Health Insurance; Basic Benefit Package; Cost-sharing by Patients; Market for Basic Health Insurance; Premium Differences; Mobility of Consumers; Risk Equalisation; Managed Care Plans, Gatekeeping and Selective Contracting; Conclusion; Appendix; References
Please contact Azusa Sato at a.sato@lse.ac.uk to suggest web sites for potential inclusion in future issues.

**DG Information Society and Media, ICT for Health**

This European Commission website looks at the role of Information and Communication Technologies (ICT) in the field of health. It provides information on current and previous research projects, research opportunities, news, events and links to conferences related to eHealth. A library provides further resources with newsletters and videos available for free download under the ‘information centre’ tab. The web site is hosted in German, English, Spanish, French, Italian and Polish.

**European Health Telematics Association**
http://www.ehtel.org/

EHTEL was founded in 1999 to provide a pan European multi-stakeholder forum for European institutions, policymakers and corporations for the betterment of health care delivery through eHealth. The homepage hosts a variety of resources for upcoming events and conferences, links to other sites, policy papers freely available for download and press releases. A forum provides users with further information to stakeholder groups and announcements.

**European Patients’ Smart Open Services (EPSOS)**
http://www.epsos.eu/

EPSOS is a thirty-six month European eHealth project which aims to enable secure access to patient health information between European health care systems. The web site provides details of the initiative, including a work plan and information examples include patient summaries for cross-border communication and ePrescriptions. Past and future events are advertised and a press area provides major news articles and progress reports on the project. In a download area, users are able to browse and print a variety of policy papers.

**The International Council on Medical and Care Compunetics**
http://www.icmcc.org/

The ICMCC is an international foundation, making information on medicine and care available to patients and professionals using compunetics. Compunetics is shorthand for COMPUTing and Networking, ETHICs and Social/societal implications. The main homepage lists events, conferences and news headlines. A patient record access link deals with aspects of accessibility and portability of electronic health records for patients, carers and service providers. It outlines the rationale, benefits, current research and overviews on six countries using the system (UK, USA, The Netherlands, Estonia, Canada, Australia). An online poll and contact form encourages user feedback, and the community section, including a blog, welcomes interaction and further exchange.

**Telecare LIN**
http://networks.csip.org.uk/IndependentLivingChoices/Telecare/

Telecare LIN is an English national network supporting local service redesign through the application of telecare and telehealth to aid the delivery of housing, health, social care and support services for older and vulnerable people. Advice on telecare use, services and outcomes are contained in free monthly newsletters, reports and factsheets.

**Telecare Services Association (TSA)**
http://www.telecare.org.uk/

The TSA is a representative body for the telecare industry within the UK, its mission being ‘to unlock the potential of telecare and telehealth’. The homepage distinguishes between professional users/suppliers and service users/carers, providing a separate portal for each. For both users, the web site explains what telecare is, how it works and who can benefit from it, with examples of available products and case studies presented. For professional users, a section on current affairs and policy gives further links to articles which have appeared in the news, government guidance on telecare, publications and speeches, all of which are available for download. Additional links detail past and forthcoming events related to telecare, as well as a ‘find a service’ facility whereby consumers and service providers alike can search for services around Great Britain.
Press releases and other suggested information for future inclusion can be emailed to the editor.
David McDaid
d.mcdaid@lse.ac.uk
cially training and employing more health workers.

The Taskforce also discussed a companion report containing initial proposals for new ways of financing health care to meet the gap. The report reviews a number of innovative options to raise and use additional money more effectively. It highlights the case for frontloading expenditure, solidarity levies on airline tickets, using market mechanisms to stimulate health investments, and encouraging greater contributions from the public and the private sector. Further, it sets out that international external and domestic financing must increase simultaneously and be managed cohesively. The Working Group will report its findings to the Taskforce in May and the Taskforce will publish its recommendations before the G8 Summit in Italy.

More information including speeches in London and reports from the two independent working groups are available at http://www.internationalhealthpartner.org/taskforce_working_groups.html

European Conference of Health Ministers and Prague Declaration

A ministerial conference entitled “eHealth for Individuals, Society and Economy” organised by the Ministry of Health as one of its priority events during the Czech Presidency of the Council of the EU, took place in Prague on the 19-20th of February. This is already the seventh conference in a series of eHealth conferences and, traditionally, is attended not only by representatives of the EU member states, but also the candidate countries, the European Free Trade Association states and countries of the Western Balkans.

The conference officially opened with a ministerial panel discussion, the aim of which was to address two overarching questions: what are the benefits of eHealth to patients and health care workers, society and the economy, and what are the main obstacles to the development of eHealth services among the member states? The conference ran in parallel sessions and during the two-day programme, more than fifty experts from across Europe presented their views and opinions.

“Primarily, eHealth brings benefits to patients and health care workers. It gives doctors easier access to information on patient health, the possibility to control expenditure and greater mobility. Patients will be able to obtain information about their health or drug dosage while their personal data will be fully protected”, said Czech Minister of Health Daniela Filipová.

At the end of the conference the Prague Declaration was adopted. Its main objective was to sum up the current state of the Europe-wide effort to use information and communication technologies in health care for the benefit of patients, as well as for improved economic efficiency in the health sector. It also aims to determine further steps to be taken at member state level, as well as by European institutions. At the same time, a common European eHealth area should be built, where individual national systems will be able to communicate with one another. Integrating eHealth solutions into the national health strategies of the EU member states will also be of great importance.

Delegates also agreed that actions of member states directed towards eHealth implementation and their mutual high-level coordination should become a regular part of the agenda of each Presidency. Chair of the meeting, Marek Snajdr, Czech First Deputy Minister of Health said that he was very pleased that the Czech Presidency had brought together high level ministers to discuss this issue for the first time. He noted that their agreement on the importance of the issue “is a breakthrough as it aims at establishing a high-level coordination structure which should deal with issues such as data compatibility of the individual systems and the protection of patient data. This is a key step towards accelerating eHealth implementation in the EU”.

More information at www.mzcr.sk

Commission warns Spain on EU pensioners access to health care

On 19 February the European Commission sent a reasoned opinion to Spain for failing to comply with EU legislation on social security rights for people travelling in Europe. The Commission takes the view that Spain discriminates against EU pensioners by refusing them access to free medication when they stay temporarily in Spain.

EU Social Affairs Commissioner Vladimír Špidla said, “European legislation guarantees everyone in the EU the same access as residents to necessary health care when visiting another EU country. Spain is the one of the top tourist destinations in Europe, but the current Spanish rules impose additional red tape on EU pensioners who might need access to medication during a temporary stay. We’re taking action today to make sure holidaymakers from other EU countries enjoy the same rights as residents.”

Under Article 31 of Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community, pensioners are entitled to receive necessary health care during a temporary stay in another member state.

The European Health Insurance Card (EHIC) facilitates access to necessary care when the holder falls ill or has an accident in one of the participating countries. It can be used on any temporary stay abroad, be it for holidays, work or studies. Over 170 million Europeans now hold an EHIC, which is valid in 31 European countries (EU + Switzerland, Norway, Iceland and Liechtenstein).

Spanish legislation allows pensioners insured in Spain to get medication for free. But EU pensioners are required to show an additional document issued by their national social security services, in Spanish, to certify that they are in receipt of a state pension. The Commission believes this is contrary to European provisions and discriminates against EU pensioners on holiday in Spain. Moreover, the requirement to present a supplementary document is not consistent with the principles of the EHIC, which aims to simplify procedures and reduce red tape for people when travelling in Europe.

The ‘reasoned opinion’ is the second stage in the infringement procedure, following the first ‘letter of formal notice’. If there is no satisfactory reply within two months, the Commission can refer the matter to the European Court of Justice in Luxembourg.

Report on cross border health care adopted by Parliamentary committee

Proposals for a directive for cross border health care were adopted by the European Parliament’s environment, public health and food safety committee (ENVI) on 31 March. It aims to ensure that there are no obstacles to patients seeking care in a member state other than their home one.
It also clarifies the right to be reimbursed after a treatment in another member state. These rights have been confirmed by the European Court of Justice, but are not yet included in EU legislation. At the same time, the directive aims to ensure high-quality, safe and efficient health care and to establish health care cooperation mechanisms among member states.

The ENVI’s report, drafted by MEP John Bowis (EPP-ED, UK), was adopted with thirty-one votes for, three against and twenty abstentions. Members of the Socialist (PES) group abstained during the final vote, since the Committee did not follow their request to add Article 152 concerning action in the field of public health as a second legal basis for the proposal, which is based on Article 95 (internal market) and since they wanted clearer the rules regarding the prior authorisation. Further amendments have been tabled ahead of the debate and first reading vote of the whole Parliament on 23 April.

Directives for patients – national competences and existing rights are respected

In the committee vote, MEPs underlined that the proposal is about patients and their mobility within the EU, not about the free movement of service providers. They also stressed that the directive fully respects the national competences in organising and delivering health care and that it does not oblige health care providers in a member state to provide health care to a person from another member state. The Committee pointed out that the new directive will not affect current patient rights, which are already codified under another EU regulation, or the regulations on the coordination of social security systems.

Prior authorisation for hospital treatments

The committee agreed with the possibility of introducing a system of prior authorisation for the reimbursement of the costs of hospital care, but wanted member states to define what hospital care is and not the Commission, as originally proposed. It also underlined that the prior authorisation requirement must not create an obstacle to the freedom of movement of patients.

Reimbursement of costs to be made easier

On the reimbursement of medical costs incurred, MEPs agreed with the general rule that patients are to be reimbursed up to the level they would have received in their home country. They added that member states may decide to cover other related costs, such as therapeutic treatment and accommodation and travel costs.

Since the proposed rules would in practice mean that patients need to pay beforehand and get reimbursed only later, MEPs added a provision that member states may offer their patients a system of voluntary prior notification. In return, reimbursement would be made directly by the member state to the hospital of treatment. MEPs said member states must ensure that patients having received prior authorisation, will only be required to make direct payments, to the extent that this would be required at home. The Committee is to examine whether a clearing house should be established to facilitate the reimbursement of costs.

Exceptions for patients with rare diseases or disabilities

The committee added special rules for patients with rare diseases and disabilities that might need special treatment. Patients affected by rare diseases should have the right to reimbursement even if the treatment in question is not provided for by the legislation of their member state. Special costs for people with disabilities must also be reimbursed under certain conditions. Furthermore, all information must be published in formats accessible to people with disabilities.

Information to patients and establishment of a European Patients Ombudsman

MEPs agreed with the proposal that national contact points shall be established, to increase access to information for patients. They also proposed establishing a European Patients Ombudsman, to deal with patients’ complaints with regard to prior authorisation, reimbursement of costs or harm once all complaint options within the relevant member state have been explored.

Long term care and organ transplantation excluded from the directive

According to the committee, the directive should not apply to long-term care and to organ transplantation.

Speaking after the vote on the report, John Bowis commented that “patients have a right to seek treatment across the European Union if their national health provider has let them down with a poor or delayed service. The current system has too often caused people unnecessary confusion at a particularly vulnerable time in their lives and it is essential that we provide greater clarity and legal certainty.” He added that the “directive will enable patients to seek treatment across the EU with a greater sense of confidence and certainty. It is particularly important that this system is not exclusive and bases a patient’s right to treatment on their needs and not their means.”


112: Commission says EU single emergency number must get multilingual

The European emergency number 112 was introduced in 1991 to provide, in addition to national emergency numbers, a single emergency call number in all EU member states to make emergency services more accessible, especially for travellers. Since 1998, EU rules have required member states to ensure that all fixed and mobile phone users can call 112 free of charge. Since 2003, telecoms operators must provide caller location information to emergency services so that they can find accident victims quickly. EU member states must also raise citizens’ awareness of 112.

While 112 complements existing national emergency numbers, Denmark, Finland, the Netherlands, Portugal, Sweden and most recently Romania have decided to make 112 their main national emergency number. In other countries, 112 is the only emergency number for certain emergency services (such as Estonia and Luxembourg for ambulances or fire brigades). Moreover, since December 2008, EU citizens have been able to contact emergency services from anywhere in the European Union by dialling 112, the EU-wide emergency number, free of charge from both fixed and mobile phones.

Despite this, only one in four Europeans knows that this life-saving number exists in other member states and almost three in ten 112 callers in other countries have encountered language problems. The Commission, along with the European Parliament and the Council, declared 11 February ‘European 112 Day’ to spread the word about 112 and push national authorities to make the EU’s single emer-
ergency number more multilingual. The Commission and member states are then expected to step up their efforts to publicise 112, especially before the summer holiday period.

“The European emergency number should no longer be Europe’s best kept secret. We have a single emergency number, 112, that works for every emergency and every member state and every citizen that needs it. But it is unacceptable that less than a quarter of citizens are aware of 112, or that language barriers prevent travellers calling 112 from communicating with the emergency operator,” said EU Telecoms Commissioner Viviane Reding. “The EU must work to guarantee the safety of our 500 million citizens with the same intensity as we have worked to guarantee their ability to travel freely across the borders of twenty-seven countries. Europe’s first 112 day should act as a wake up call to national authorities who need to improve the number of languages available in their 112 emergency centres and boost awareness about this life-saving number.”

An EU-wide survey conducted for the European Commission shows that 94% of EU citizens think it is useful to have a single emergency number available in the EU. The Eurobarometer survey also highlighted areas where there is still room for improvement.

Language problems

28% of callers have language problems when they call 112 while abroad, despite the fact that information provided by 21 member states indicates that their 112 emergency centres should be able to handle calls in English (12 member states in German, 11 member states in French, 4 member states in Italian). A number of member states have also indicated the ability of their emergency call centres to answer calls in the languages of their neighbouring EU countries, while in some others, such as the UK and Sweden emergency call centres can use an interpretation service covering all major languages (170 languages in the case of the UK).

Awareness of 112

Overall, only 24% of surveyed Europeans could spontaneously identify 112 as the number on which they can call emergency services anywhere in the EU. This is a 2% improvement since February 2008 but knowledge varies greatly between countries, from 3% in Italy to 58% in the Czech Republic. Many member states are informing their citizens and visitors about 112, for example, in Finland 112 day is celebrated annually on 11 February while visitors to Bulgaria receive a welcome text message informing them about 112. 112 is publicised on motorways and toll gates in Austria, Greece and Spain and at train stations and airports in Belgium, the Czech Republic, Estonia, Ireland, Greece and the Netherlands, among others. At least a 10% increase in awareness of 112 was seen in Bulgaria, Sweden, Romania, Lithuania, and Portugal in the past year.

The Eurobarometer survey also showed that a quarter of EU citizens have called an emergency number in the last five years. The majority of calls were made from fixed lines: while 53% of calls were made from a fixed line, there was an increase in emergency calls made from mobile phones (45% compared to 42% in 2008).

More information available at www.ee.europa.eu/112

New guidelines for pharmacists to be developed

The WHO Regional Office for Europe and EuroPharm Forum, a joint network of professional associations of pharmacists from countries in the WHO European Region, will join efforts to support organisations of European pharmacists in developing the best practice models. The models to be developed will provide practical and cost-effective examples that can be used in chronic diseases, mental disorders, obesity, palliative care and other sectors. Together with WHO, the EuroPharm Forum will develop and make these models available to all countries through its Observatory on Pharmacy Practice.

A memorandum of understanding between the two organisations was signed on 30 March in Copenhagen. The overall objective is to help them in developing services and skills to increasingly meet patients’ needs. Both WHO and the EuroPharm Forum recognise that pharmacists have been faced with increasing health demands that extend beyond selling medicine. Pharmacists have a vital role to play in efforts to provide safe and effective medicines, helping to ensure the best treatment for patients and save lives. The memorandum of understanding aims at strengthening this role.

By signing the memorandum of understanding, Dr Nata Menabde, WHO Deputy Regional Director for Europe, and Dick Tromp, EuroPharm Forum President, have agreed to continue the collaboration between their organisations. They have also agreed that further discussions will take place as a matter of course to define and develop additional areas of collaboration for the future.

“Pharmacists are an integral part of the health system. They assume varied functions ranging from procuring and supplying medicines to pharmaceutical care services, helping to ensure the best treatment for patients”, said Dr Menabde. “Sharing the best practice models will allow us to make better use of resources and have a greater impact on pharmacies’ role in public health.”

Dick Tromp expressed satisfaction that the memorandum of understanding could be established saying that “we have a long-standing tradition of working very closely with WHO Regional Office for Europe for the benefit of our members. With the signing of this memorandum, we affirm the value of this partnership and set the stage for future joint activities. The close collaboration with WHO is important, since it emphasises the pharmacist’s role in health care.”

The memorandum of understanding is available at http://www.euro.who.int/ pharmaceuticals/20090330_1

COUNTRY NEWS

Nordic council to debate increase in TB and HIV/AIDS in north-west Russia

The Nordic Council, a body established in 1952 between the parliaments of Denmark, Finland, Iceland, Norway and Sweden, is looking at ways to tackle the recent dramatic increase in multi-resistant tuberculosis and HIV/AIDS that has been observed in north-west Russia. The Council’s Welfare Committee has brought together different experts from within authorities, institutions and organisations to participate in a conference in Kaliningrad on 29 and 30 April. The objective is to find partners and projects for a more effective cooperation against these life-threatening diseases.

Meeting in Copenhagen on 16 and 17 April, the members of the Committee issued a joint communiqué stating that
“the increase of the life-threatening diseases tuberculosis and HIV/AIDS is a serious threat to the population in north west Russia. As neighbours we must give the necessary support to turn this negative trend and in this way contribute to a positive development of the quality of life in the area”

At the conference parliamentarians in the Nordic Council’s Welfare Committee will endeavour to develop best practice models. They have also proposed that this work will be carried out by the Expert Group on HIV/AIDS, TB and multi-drug resistant TB that already exists within the Northern Dimension Partnership in Public Health and Social Wellbeing. The MPs’ proposal will be discussed by the Nordic Council Presidium, following which it is expected to be forwarded as a recommendation to the Nordic Council of Ministers for consideration.

Further information at http://www.norden.org/nr/utskott/calfa_rd/uk/index.asp

Russia: Press conference marks World TB Day 2009

The keynote speaker, Professor Mikhail I. Perelman, Chief TB Specialist of Russia, Director of the Institute of Path physiology and Pulmonology of the Moscow Medical Academy and a Member of the Russian Academy of Medical Sciences, characterised the TB situation in the country as ‘tense’, but acknowledged good political support for TB control at the national level and called for more support at regional level. He stressed that Russia had achieved noticeable improvement in TB incidence and mortality in the past few years but that much more needed to be done. The risk of TB may increase due to social stress, rising unemployment, falling personal earnings, and poorer nutrition caused by the financial and economic crisis. Multi-drug resistant TB and HIV-associated TB are fast growing challenges. The Russian Ministry of Health did though give an assurance of its commitment to continued support for TB control, including the centralised procurement of key TB drugs at the national level, despite the financial hardships and new challenges. The Federal Correctional Service also highlighted improved TB control in the penitentiary sector.

The press conference included an award ceremony for the winners of the children’s poster contest “I am helping fight TB!” The contest included submissions from around twenty regions, ranging from the Khakasiya Republic to the Vladimir region. The contest, which has been part of World TB Day events for eight years, has the aim of raising awareness among school students about TB and equipping them with knowledge about early symptoms and basics of TB prevention, as well as the need to live a healthy life.


Poland: End of transitional period for pharmaceuticals
31 December 2008 marked the end of a transitional period for pharmaceutical products awarded to Poland in the Accession Treaty, which came into force on 1 May 2004. The transitional period was meant to ‘protect’ products marketed in Poland against the need to become compliant with EU pharmaceutical law (including much stricter legal requirements than Polish pre-accession pharmaceutical law) immediately upon Poland’s accession to the EU.

According to Annex XII to the Accession Treaty, all products which: (i) were included in the list provided in Appendix A to Annex XII to the Accession Treaty, and (ii) for which marketing authorisations were issued under Polish law prior to the date of accession (before 1 May 2004) could benefit from the over four and a half year-long transitional period for upgrading to the requirements of quality, safety, and efficacy laid down in Directive 2001/83. Such products could not, however, be subject to the mutual recognition procedure in other member states.

There was a great incentive for companies to obtain marketing authorisations for their products prior to Poland’s accession to the EU, because their products would then benefit from the transitional period. However, many companies did not manage to submit all the documents required for the authorisation of their products, or when they submitted such documentation, the Minister did not have enough time or resources to review the documentation. This led to the Minister of Health taking action that did not comply with EU law, and led to multiple legal problems and disputes and a number of so-called ‘ghost drugs’.

In order to allow products to ‘squeeze’ into the transitional period, the Minister of Health issued marketing authorisations without reviewing the submitted dossiers, with conditions obliging the marketing authorisation holders to submit the registration documentation after the authorisation had been approved. Those conditional marketing authorisations, granted without prior review, were challenged in Polish courts and were thereafter ruled unlawful. The conclusion as to their unlawfulness was also widely shared by academics and the highest institutions of public control, such as the Supreme Chamber of Audit.

The European Commission found that by issuing conditional authorisations on the eve of accession, Polish authorities breached the Accession Treaty and submitted a complaint against Poland to the European Court of Justice on 2 September 2008 (case C-385/08). A similar case has been taken by the Commission against Lithuania (case C-350/08).

The termination of the transitional period on 31 December 2008 brought about additional problems, particularly as regards the fate of products that were denied an upgrade. (According to the data published by the Minister of Health, 6,771 pharmaceutical products were successfully upgraded during the transitional period, while 177 products were denied an upgrade.) Typically, the denial of extension of validity of the marketing authorisation means that a product may still be manufactured and put on the market for six months following the denial. In the case of non-upgraded products, the Minister of Health adopted the interpretation issued by the Office of the Committee for European Integration, which indicated that this six month period may not go beyond 31 December 2008; thus, the non-upgraded products could only be put onto the market until 31 December 2008.
When marketed, such products may stay on the market until their expiry date. At the same time, however, the General Pharmaceutical Inspector, in cooperation with the Minister of Health, issued a very lenient interpretation of the notion of “putting on the market”, equating it with the date of batch release. The companies that are denied upgrade are also asked to provide the General Pharmaceutical Inspector with detail of the batches of products that were released before 31 December 2008 and that will be in trade circulation until their expiry date.

**Hungary: Off-label use of medicines to be allowed**

The laws in Hungary, for many years, have strictly prohibited physicians from prescribing registered medicinal products for other than their approved indications. As a general rule, off-label use was considered to be a clinical trial, which if carried out without a proper licence may have even resulted in criminal sanctions.

Act XCV of 2005 on Medicines Intended for Human Use (the “Medicines Act”) and Decree 44/2004 (IV. 28.) of the Minister of Health on the Prescription and Supply of Medicines Intended for Human Use (the ‘Decree’) have recently been amended to allow off-label prescribing and the use of medicines, provided compliance with the following detailed conditions is ensured.

A physician may prescribe a medicine for use other than its approved indication if:

(i) the treatment of the patient with other approved medicines is not possible or is shown to be unsuccessful, and based on available evidence, there is a chance to improve or stabilise the health status of the patient with the off-label application of the medicine;

(ii) the medicine is registered either in Hungary or in another country; and

(iii) an approval has been received from the National Institute of Pharmacy (NIP) in response to a request for the off-label use of the medicine for the relevant indication.

The request for approval from the NIP must contain certain information, including the medical history of the patient, detailed data on the medicinal product and indication for which it will be prescribed and the professional reasons for the off-label prescription, as well as medical literature to support the off-label use. There is no need to submit medical/scientific literature if the NIP had already approved the off-label use of the medicine for the indication concerned.

The NIP must assess the applications for off-label use within twenty days from the request being filed but in urgent cases the NIP must proceed immediately and make a decision within two days. The NIP publishes statements on its homepage regarding the assessment of individual requests for off-label use of medicines. The physician prescribing the medicine off-label must provide the patient with information about the proposed treatment and must seek the patient’s approval to the off-label use of the medicine. He or she must keep proper records on any off-label prescribing.

Despite this recent decision, it should be noted that Hungarian laws still strictly prohibit marketing, advertising or otherwise promoting of the off-label use of drugs. The new Hungarian regulation represents a delicate balance between the regulatory objective of protecting patients from, on the one hand, unsafe or ineffective drugs and, on the other hand, the prerogative of physicians to use their professional judgment in treating patients.

**Scotland: Focus on access to new medicines**

The NHS in Scotland will offer staff, patients and the public a better understanding of the processes and decisions involved concerning new medicines, it has been announced. Making a statement to the Scottish Parliament, on March 25 Health Secretary Nicola Sturgeon described the ‘substantive progress’ made over recent months to improve arrangements for introducing new medicines into the NHS in Scotland and the guidance in place to support this.

The announcement builds on Scotland’s long standing arrangement for the introduction of new medicines through the Scottish Medicines Consortium (SMC) and NHS Quality Improvement Scotland (QIS). The new measures include the introduction of patient access schemes in Scotland, a proposal that has been put forward by manufacturers to improve the cost effectiveness of a new drug. Such schemes can operate when a product has been launched on the market but is being assessed for introduction into the NHS. An arrangement can be considered between the manufacturer and the NHS to help the NHS secure access to the medicine in a cost effective way. A shortlife working group involving key stakeholders has been considering the basis on which patient access schemes could operate in Scotland through a national framework.

There are also plans for the SMC to publish the ‘modifiers’ which it uses when considering new medicines so that special circumstances can be taken into account. New guidance for NHS Boards on the end-to-end process for the introduction of new medicines and a new framework to enable a consistent approach to the principles applied for ‘exceptional prescribing’ will be developed. Health Rights Information Scotland has also been commissioned to produce new information for the public on the revised arrangements and guidance which will come into place.

Since 2008, the Scottish Parliament’s Public Petitions Committee has been undertaking an inquiry into the availability on the NHS of cancer treatment drugs. The Scottish Government responded formally to the Committee in September 2008. Exceptional prescribing arrangements are in place in each NHS Board in order to consider the circumstances of individual patients where their clinician wishes to prescribe a drug not recommended by the SMC or NHS QIS following a National Institute for Health and Clinical Excellence Multiple Technology Appraisal.

*The Health Secretary’s statement can be accessed at [http://www.scotland.gov.uk/News/This-Week/Speeches/Healthier/medsprvtecare](http://www.scotland.gov.uk/News/This-Week/Speeches/Healthier/medsprvtecare)*

**Germany: Drug use to improve workplace performance on the increase**

While Germany tries to combat doping in sports, drug abuse amongst office workers in the country is on the rise, according to a study published by German health insurer Deutsche Angestellten-Krankenkasse (DAK). As long-distance drivers on amphetamines or classical musicians on beta-blockers become less surprising in today’s society, more people in varied industries are resorting to prescription drugs to improve workplace efficiency or simply lift their mood, the study said.

DAK questioned some 3,000 employees between the ages of twenty and fifty years and researched some 2.5 million insurance records to find out more about doping in...
the workplace. Almost two million were found to have already used certain remedies to cope with increasing stress levels at work, while 800,000 people regularly and intentionally used antidepressants or prescriptions meant to treat dementia or attention deficit hyperactivity disorder. They often named colleagues, friends, family and the internet as the sources of supply, the study revealed.

The survey looked at those engaged in jobs involving greater stress, less security and the pressure to achieve results. Academics in particular were prone to use medication to enhance their ability to combat fatigue and increase performance. Four in ten people said they knew prescriptions meant to fight illness-related memory loss or mood swings can also have an effect for healthy people. Meanwhile, two in ten people questioned said they considered the benefits of taking performance-enhancing prescription drugs to outweigh the risks and side effects. The study also showed the differences in doping between men and women. While men preferred efficiency-increasing supplements, their female co-workers often resorted to sedatives.

Speaking to the Berliner Zeitung DAK head Herbert Rebscher called the study results an “alarm signal,” although workplace doping is not yet a widespread trend due to fears of side effects while the employers’ trade association the BDA said that the abuse of prescription drugs needs to be seen as a serious problem. Ministry of Health spokesman Klaus Vater also told the paper that the study is being taken seriously by the German Health Ministry. In 2008 the number of sick days employees took off from work increased by almost 8%.

**England: Restaurants and catering companies bring in calories on menus**

On 6 April it was announced that eighteen major catering companies, including many high street brands, will introduce calorie information on their menus for the first time. The list of trail-blazers, announced by Public Health Minister, Dawn Primarolo and the Food Standards Agency will start displaying calorie information from the end of April. A number of restaurant chains already provide information in their outlets or on company websites, regarding salt, fat and sugar in their products. According to British Hospitality Association, the catering sector has seen sales triple between 1981 and 2005 while the Food Standards Agency’s National Diet and Nutrition Survey shows men get 25% of total food energy intake and women get 21% of energy from eating out of the home.

The new list of companies includes workplace caterers, sit down and quick-service restaurants, theme parks and leisure attractions, pub restaurants, cafes and sandwich chains. Companies involved include a number of well-known high street names and several major contract caterers including Burger King, Kentucky Fried Chicken, Pizza Hut, Pret A Manger, Sainsbury’s Cafes, Subway, Waitrose Cales and Wimpy.

This it is hoped will benefit individuals and families who are trying to choose a healthier diet and follows experience in New York where in April 2008 the City Board of Health passed a law which obliged some restaurants to list calories on their menus. By June, more than 450 food outlets across the country will have introduced calorie information – some of these will be on a pilot basis. Each company has agreed to display calorie information for most food and drink they serve; print calorie information on menu boards, paper menus or on the edge of shelves; and ensure the information is clear and easily visible at the point where people choose their food.

Commenting on the announcement Ms Primarolo said that “we know that people want to be able to see how many calories are in the food and drink they order when they eat out. I want to see more catering companies join this ground breaking first group to help their customers make healthier choices.”

Tim Smith, chief executive of the Food Standards Agency said that “we are pleased that such a diverse range of companies has agreed to work with us by introducing calorie labelling at the crucial point where their customers make a decision about what to eat. Our aim is to ensure that consumers have better information so they can make informed choices to improve their diet when eating out, whether that is a snack on the go, a meal in a staff restaurant or at a table being served by a waiter.”

Independent research will assess how easily customers understand and use the system and gather feedback from the restaurants themselves to look at practical issues and the costs involved in providing the information. Gathering this data will inform the next steps for a wider rollout of calorie labelling on menus.

Research published by the Food Standards Agency published in 2008 indicated that consumers would welcome simple, clear and visible nutrition information when eating out. This research followed a survey carried out by the Agency in June 2008, which suggested that 85% of consumers agreed that restaurants, pubs and cafes have a responsibility to make clear what is in the food they serve. More than 80% of respondents said that nutrition information would be most useful if provided at the point they choose to order food, such as on menus or menu boards.

The names of the eighteen companies introducing calorie information on their menus are also published in the first annual report of the Government’s obesity strategy in England, ‘Healthy Weight, Healthy Lives – One Year On’. The report sets out the Government’s efforts to tackle obesity over the last year and plans going forward. The strategy included the challenge to industry as a whole to provide information on the nutritional content of food in a wide range of settings in a manner which is clear, effective and simple to understand.

For a full list of the companies involved and more information on healthy food commitments by the industry see [http://www.food.gov.uk/healthiereating/healthycatering/cateringbusiness/commitments](http://www.food.gov.uk/healthiereating/healthycatering/cateringbusiness/commitments)

**Channel Islands: End of reciprocal health care agreement with UK**

The Channel Islands, located just off the coast of Normandy, are British Crown Dependencies that are internally self-governing and have their own health services separate from the UK NHS. Since 1 April UK residents visiting the Channel Islands must ensure they have adequate travel insurance. The recommendation comes from the UK Department of Health given the end of the reciprocal agreement on health care arrangements for UK visitors on 31 March 2009. Travellers cannot rely on cover from the European Health Insurance Card scheme as the islands are not part of the EU.

The previous agreement which had been in place since 1976, allowed UK travellers to get a limited number of medical treat-
Slovakia: Government approves new quality indicators

As reported by the independent Bratislava based thinktank, the Health Policy Institute (www.hpi.sk), health insurance companies (HICs) will assess health care providers making use of a new set of quality indicators, following the approval of a new regulation by the Slovakian government. Although the government came to power in 2006 this is the first time that the quality indicators have been updated. According to the regulation the purpose of the indicators is to obtain relevant information on the effective use of common diagnostic and treatment procedures, transport services, pharmaceutical and medical device expenditures and patterns of service use. The move has been welcomed by the Health Policy Institute which believes that they can contribute to a more objective view of the Slovak health care system.

The law on health insurance mandates HICs to establish and make public their criteria for provider contracting at least once every nine months. These criteria include staff mix, access to specialist equipment, certification of quality and use of quality indicators. Each HIC ranks providers based on these criteria and should take this into consideration when entering into contractual agreements. There are however differences in the weights given to different criteria by different HICs. While many private HICs have attached a weight of 50% to quality indicators, public HICs have only allocated 10% to existing indicators.

“We adjusted some indicators, added economic indicators and, in particular, included indicators based on data collected by HICs from service providers” said Minister of Health Richard Raši. The Health Ministry in compiling the new set of indicators has thus tried to eliminate subjective influence when data is submitted. “The HICs will be able to retrospectively evaluate whether providers submitted the correct data,” the Minister further explained. The Ministry also plans to centrally evaluate HICs by also analysing data from service providers.

The indicators cover inpatient, general and specialised ambulatory care. For hospitals, indicators include measures of surgery, repeat surgery, readmission rates and overall mortality. For general practitioners, for example, indicators include rates of utilisation and use of preventive measures. According to Raši, differences in rates of mortality for the same condition between facilities may potentially lead to an investigation to determine whether this is due to differences in patient case mix or mistakes made during service provision.

Ireland: Obesity Taskforce report launched

On 17 April Mary Wallace, Minister of State at the Department of Health and Children with special responsibility for Health Promotion and Food Safety launched a report of an intersectoral group reflecting the progress and developments made in the implementation of the recommendations of the National Taskforce on Obesity since its publication in 2005. The Group, established by the Minister in December, 2008, comprises representatives of all stakeholders, including experts from government departments and agencies, the food industry and relevant non government organisations.

Speaking at the launch, the Minister pointed to the fact that the most recent Survey of Lifestyles, Attitude and Nutrition or SLAN 2007 Report, indicates that 38% of the population is overweight and a further 23% are obese. Therefore, 61% of the population are either overweight or obese. Of particular concern, was the increasing levels of obesity in children. Recent research reveals that 26% of seven-year old girls and 18% of seven-year old boys are overweight or obese.

It is estimated that obesity is responsible for around 2,000 premature deaths in Ireland each year. The indirect cost of obesity in Ireland is estimated at €0.4 billion, per annum. “The importance of halting the rise in obesity is therefore critical”, said the Minister. While the report pointed to significant progress in the implementation of the Taskforce’s recommendations, Minister Wallace said “we must re-double our efforts to row back the rising tide of overweight and obesity. It is not going to be an easy task, involving as it does, changing our own and especially our children’s attitudes and behaviour in relation to eating patterns and levels of physical activity. We must continue to work to make it easier for people to make the healthy choices required for them to take better care of themselves and to lead healthy lives, to literally invest in themselves and their futures.”

Chief executive of the all-island Institute of Public Health in Ireland (IPHI), Dr. Jane Wilde, welcomed the Minister’s statement on the need to re-double efforts in tackling obesity and her commitment to taking a cross-government approach, noting that “most of the actions needed to prevent obesity fall outside the health sector and a much wider societal response is required.”

Dr Wilde added that “it is essential that the food industry acts responsibly on issues such as the composition of food...
products, sourcing and pricing of food products, simpler, consistent food labelling across the island and controls on marketing in the media and in-store promotions – particularly those aimed at children – as well as the location and content of retail food outlets."

The IPH is establishing an Obesity Knowledge Centre to support implementation of obesity strategies, North and South. The Centre will widen access to data, evidence and good practice; help develop evidence about what works and what doesn’t, and help implement good policy and practice.

The report of the intersectoral group is available at http://www.doch.ie/publications/report_ntfo.html

Danmark pays compensation to night shift women with cancer

BBC Radio Scotland reported on 16 March that the Danish government has begun paying compensation to women who developed breast cancer after working night shifts. The Danish National Board of Industrial Injuries reports that in 2008, breast cancer after night-shift work was recognised as an industrial injury in thirty-eight of seventy-five cases that were submitted to the Occupational Disease Committee. Compensation was granted in all but one of these cases, and was paid by the employer’s industrial-injuries insurance. The cases that won compensation involved women who typically worked at least one night a week for at least twenty to thirty years, and where there were "no other significant factors that might explain the development of breast cancer,” the Board said.

The move comes after a UN health body said that working nights probably increases the risk of cancer. The International Agency for Research on Cancer (IARC) placed shift work in the same category as anabolic steroids, ultraviolet radiation and diesel engine exhaust in terms of cancer risk. In a statement released in December 2007, the IARC said that its expert working group had concluded that shift work that involves circadian disruption is "probably carcinogenic to humans,” and it was ranked in group 2A, along with ultraviolet light radiation. This is below the group 1 category, which is "carcinogenic to humans," and includes asbestos, but above group 2A, which is "possibly carcinogenic to humans,” and includes lead, the pesticide DDT (dichlorodiphenyl-trichloroethane), and engine exhaust.

The next step is for the Board to review the work of the International Agency for Research on Cancer (IARC) in this field and to decide if breast cancer after night-shift work should be included on the list of occupational diseases.

Ulla Mahnkopf, who developed bilateral breast cancer after working for thirty years as a flight attendant for SAS, told BBC Scotland she had “no idea” her work patterns could have caused a health risk. But when you think back now I can see that when I stopped flying it was like coming out of a shell,” she said. “I had been living in there because of jet lag and I can see now I had a totally different life.”

Dr Vincent Cogliano of the IARC said that it believed that alterations in sleep patterns caused by working nights could lower the body’s production of melatonin. This multitasking hormone keeps your biological clock ticking over, making sure that you are alert during the day and sleepy at night. It also seems to play an important role in cancer protection.

Melatonin lowers levels of the female hormone oestrogen in the blood - oestrogen is known to encourage the growth of certain cancers, notably breast and ovarian cancer. It could also block the growth of cancer cells and boost the body’s immune system by killing cell-damaging ‘free radicals’ (killing free radicals also happens to be why antioxidants are so prized) and block cells from dividing. Since the brain produces the most melatonin in the middle of the night when it is dark, night-shift workers – whose bodies are saturated by artificial light – have abnormally low levels.

However according to Cancer Research UK, any night-shift panic would be premature. “The breast cancer risk has not been conclusively shown,” says Dr Kat Arney, senior science information officer at Cancer Research UK. This is because there are so many complicating factors when you try to study the effects of lifestyle on cancer risk. “At the moment we just don’t know how other lifestyle factors, such as taking HRT, obesity, having fewer children or drinking alcohol, interact with shift work to increase a woman’s risk of breast cancer,” says Arney.

All these factors – rather than melatonin – could be the real reasons behind any apparent cancer links. For instance, explains Arney, “we know that breast cancer is more common in inactive women, so if shift workers get less exercise than the general population, this could explain their higher risk.” A representative from the UK’s Health and Safety Executive told the BBC that they had commissioned their own report on the link between shift work and breast cancer and were expecting it to be finished in 2011.

More information at http://news.bbc.co.uk/1/hi/scotland/7945145.stm

Czech Republic: user fees reduced but not abolished

In February the Czech coalition government narrowly forced through parliament a proposal to abolish some user fees for patients below the age of eighteen. 99 of 196 MPs voted in favour of the proposal. Fees for emergency services, as well as for hospital stays will continue to be enforced. For people over the age of sixty-five the maximum limit for user fees and co-payments will be reduced from 5000 to 2,500 Crowns. For prescriptions, a fee should only be charged if the co-payment is less than 30 crowns. This bill does not go as far as the parliamentary opposition would like; they have called for the complete abolition of all user fees, a platform which was significant in their electoral gains in regional elections in November 2008.

The system of user fees had been introduced by former Health Minister Tomáš Julínek early in 2008 and was intended to reduce excessive utilisation of services and generate additional revenue for the health care system. However administration of the system has proved problematic; and there have been conflicts between the regional and national administrations.

Although the newly elected Central Bohemian Governor David Rath abolished fees in all hospitals in his region in November 2008, insurance companies announced in February 2009 that they planned to fine five Central Bohemian hospitals that had not collected mandatory health fees from patients. Other opposition Social Democrat governed regions have also agreed to abolish the fees in regional hospitals, with the costs being met entirely by these regions.
NICE issues guidelines on promoting physical activity for children
The National Institute for Health and Clinical Excellence (NICE) in England has issued guidance on promoting physical activity and sport for all children and young people, both at school and with the family. The guidelines have been issued following studies which show that the national recommended levels of physical exercise for young people are not being met, causing concern about the rising levels of obesity in the country.

More information at http://www.nice.org.uk/media/183/33/2009002PromotingPhysicalActivityForChildren.pdf

Experts meet to discuss health implications of global economic crisis
The global economic downturn occurs as the world is confronted with the consequences of major demographic changes and global environmental/energy problems. With the economy slowing down and unemployment rising, the living conditions of millions of individuals in Europe are seriously threatened or already affected, as is the revenue base of health and social protection schemes.

Overcoming the crisis will require timely, well targeted, fully coordinated efforts. Experts met in Oslo on 1–2 April at a meeting organised by Norwegian Ministry of Health and Care Services, in partnership with the WHO Regional Office for Europe, to discuss how the health sector can help reduce negative health and social impacts and counter the economic downturn. It also considered the advice given by WHO/Europe to its Member States.

The Oslo meeting is one of a series of meetings looking at health and the ongoing global crisis. A high-level consultation on financial crisis and global health was held in Geneva in January 2009. The 62nd World Health Assembly in May and 59th session of the WHO Regional Committee for Europe in September will also allow for further comprehensive discussions.

Further information and materials from the meeting are available at http://www.euro.who.int/healthsystems/ecnocrisis/20090316_1

EU health prize for journalists
In 2009, an EU Health Prize for Journalists will be awarded. The Prize is part of the ‘Europe for patients’ campaign, launched by EU Health Commissioner Androulla Vassiliou in September 2008, highlighting ten health policy initiatives the Commission will adopt in 2008–2009. The Prize rewards journalists who have contributed in a significant way to help citizens understand health issues under the campaign, and through their work reflect patients’ and health workers’ expectations and thoughts.

Articles must have been published (press or on-line) between 2 July 2008 and 15 June 2009 in one of the official languages of the European Union. All participants must be nationals or residents of an EU Member State and registered journalists. Articles must be submitted through online entry form. The Prize will be awarded in autumn 2009.

More info at http://ec.europa.eu/healtheu/europe_for_patients/prize/index_en.htm

New OECD working paper analysing trends in obesity
A new working paper authored by Franco Sassi, Marion Devaux, Michele Cecchini and Elena Rusticelli provides an overview of past and projected future trends in adult overweight and obesity in OECD countries. Projected future trends show a tendency towards a progressive stabilisation or slight shrinkage of pre-obesity rates, with a projected continued increase in obesity rates. Aspects of physical, social and economic environments that favour obesity have been consolidating in the last thirty years. But the long term influences of changing education and socioeconomic conditions have also made successive generations increasingly aware of the health risks associated with lifestyle choices, and sometimes more able to handle environmental pressures. Variations in obesity status by education and socio-economic condition, and the influence of health-related behaviours, particularly those concerning diet and physical activity, are also highlighted.

The working paper can be downloaded at http://www.olis.oecd.org/olis/2009doc.nsf/LinkTo/NT00000EFE/$FILE/JT03261624.PDF

Joint conference on well-being in the workplace
A joint conference on well-being in the workplace took place in Berlin on 17 and 18 March, organised by the WHO Regional Office for Europe and the German Alliance for Mental Health, in cooperation with the European Commission’s Directorate General Health and Consumers and supported by the German Federal Ministry of Health. The conference focused on maintaining good mental health at the workplace through the social integration and empowerment of vulnerable people, as well as looking at how to tackle the stigma and prejudices relating to mental health problems.

More information at http://www.mental-wellbeing.net/

EU Health Policy Forum
The EU Health Policy Forum (EUHPF) aims to bring together umbrella organisations representing stakeholders in the health sector to ensure that the EU’s health strategy is open, transparent and responds to the public concerns. The intention is to provide an opportunity to organise consultations, to exchange views and experience and assist in implementation and follow-up of specific initiatives.

A meeting of the forum was held on 21 January in Brussels. The significant impact of the financial crisis on health was the most pressing issue, and the need to act quickly led to the drafting of an Open Letter calling for action. Concerning the implementation of the Health Strategy, the European Commission felt it was important for the EUHPF to contribute to the implementation of the strategy and will be collecting inputs on the specific priorities.


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