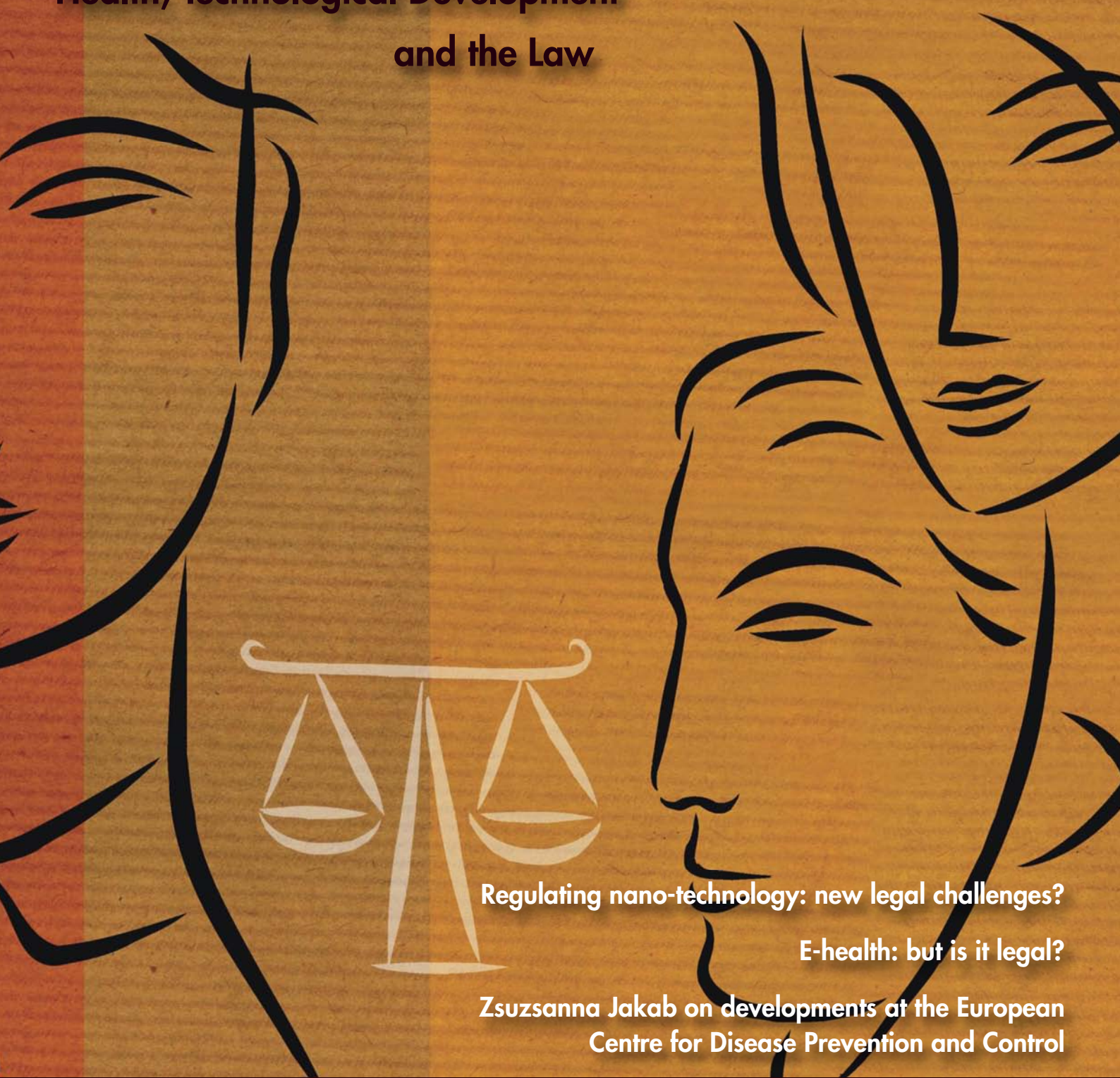


Eurohealth

RESEARCH • DEBATE • POLICY • NEWS

Volume 13 Number 2, 2007

Health, Technological Development
and the Law



Regulating nano-technology: new legal challenges?

E-health: but is it legal?

Zsuzsanna Jakab on developments at the European
Centre for Disease Prevention and Control

Dutch health insurance reform: the role of collectives • Palliative care
Health service quality in Bulgaria • Experience from public-private partnerships in Eastern Europe

COMMENT

Health, law and technological change

The speed of technological advance can be truly breathtaking; possibilities that a few years ago were confined to the realms of science fiction are rapidly becoming reality. Most obviously, the way in which we communicate has been transformed beyond all recognition. We live in a world of instant access, through mobile phones, laptops and PDAs, to the information superhighway. Moreover, social networking platforms, such as Facebook, are being used to a scale never envisaged by their creators; their potential for marketing and brand placement is the subject of millions of euros of research.

The health sector is not immune from these changes. Not only do we have access to health information on the internet, albeit sometimes spurious, but we may book hospital appointments, download personal medical records, use remote diagnostic technologies and perhaps purchase health care products. This growth of e-health in all its forms, according to Celine Van Doosselaere and colleagues, has therefore as many serious implications for health care regulators and lawyers as it does for the medical professions. They note the uncertainty about the full legal implications of using many e-health applications; further clarification, they argue, at European level is merited.

Having a more flexible legal framework to respond to technological change can also be applied to the potential use of nanotechnology. As well as ethical concerns, resultant legal issues concerning consent, privacy, and use in the context of research remain to be fully debated. In this issue Jean McHale calls for an effective and pro-active, rather than reactive, EU response to these new challenges.

Preparedness is a theme also found elsewhere in this issue of *Eurohealth*. We are delighted to include a contribution from Zsuzsanna Jakab, Director of the European Centre for Disease Prevention and Control. The ECDC provides some excellent examples of how technology may be harnessed to collate and disseminate information on rapidly emerging and unexpected health threats in Europe and beyond.

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Contents

Eurohealth
Volume 13 Number 2

Health, Technology and the Law

- 1 eHealth..... but is it legal?
Celine Van Doosselaere, Petra Wilson, Jean Herveg and Denise Silber
- 4 Regulating nanotechnology: new legal challenges?
Jean V McHale

Health Policy Developments

- 7 Public-private partnerships in Eastern Europe: Case studies from Lithuania, Republika Srpska and Albania
Katja Kerschbaumer
- 10 Dutch health insurance reform: the new role of collectives
Peter P Groenewegen and Judith D de Jong

Public Health Perspectives

- 14 Medicine, care of the dying, and care of the chronically ill
Milton Lewis
- 16 ECDC: Tackling the free movement of microbes
Zsuzsanna Jakab

European Snapshots

- 19 Promoting the quality of health services in Bulgaria
Olga Avdeeva and Lidia Georgieva

Evidence-informed Decision Making

- 21 "Mythbusters" Early detection is good for everyone
- 23 "Bandolier" The case for chocolate

Monitor

24 Publications

25 Web Watch

26 News from around Europe

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eHealth..... but is it legal?

Celine Van Doosselaere, Petra Wilson, Jean Herveg and Denise Silber

Summary: Unconstrained by familiar points of entry to health care or traditional channels for delivering information or care, the eHealth revolution has as many serious implications for health care regulators and lawyers as for medical professionals. In the context of the Commission's eEurope Action Plan, the "Legally eHealth" study established a baseline report on existing EU level legislation, its impact on the delivery of eHealth and an analysis of the legal and regulatory barriers and gaps that may exist. This article gives an overview of some of the issues studied and key recommendations made.

Keywords: eHealth, Security and Privacy, Liability; Data Protection and Ownership

eHealth is a broad term with many definitions, including health informatics, health telematics, ICT (information and communication technology) for health, connected health, medical computing, or medical informatics, all of which are used to describe the use of a wide range of information technology applications and services in the healthcare setting. For the 'Legally eHealth'* study described in this article we use the term eHealth as defined by the Action Plan for a European eHealth Area: "the application of information and communication technologies across the whole range of functions that affect the health sector".¹

eHealth is premised on a fundamentally new patient experience unconstrained by familiar points of entry and structures or traditional channels for delivering information or care. Not surprisingly therefore, the eHealth revolution has as many serious implications for health care regulators and lawyers as for medical professionals, including questions about patient and professional identification, maintenance of patient confidentiality in an environment of electronically shared care, as well as questions of liability for care provided in this new environment.

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In response to the lack of legal certainty about the use of eHealth tools, the European Commission, through its eHealth Action Plan, called for a study to establish a base-line report on existing EU level legislation, its impact on the delivery of eHealth and an analysis of the legal gaps which may exist. The 'Legally eHealth' study, which we present in this article, was completed in response to that call.

The 'Legally eHealth' Framework

The one year study, completed in May 2007, looked in detail at three particular legal aspects of using information society technologies (IST) in health care: privacy, liability and competition. Although other legal issues arise in the context of providing health care services using eHealth tools, we focussed on these three as the main legal issues with European level implications.

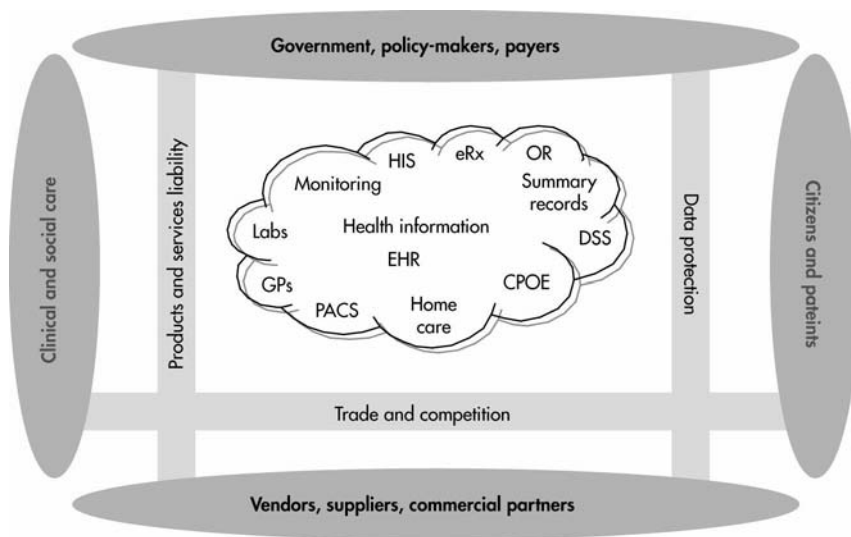
We first looked at the key tools and applications and then the main stakeholders and existing regulations that have an impact on the use of eHealth. These covered a wide range of information technologies found in hospitals and primary care settings, including administrative tools such as hospital information systems (HIS), summary records and discharge letters; clinical applications of a technical nature

such as picture archiving and communications systems (PACS), as well as clinical support systems such as operating theatre systems (OR), decision support systems (DSS); and systems linking key health care actors such as General Practitioners Systems, and electronic prescribing systems linking general practitioners (GPs) with pharmacies (eRx).

Having established what concepts and tools were included in eHealth, we next classified the stakeholders in eHealth into four groups of actors: citizens and patients; clinicians and care providers; payers, policy-makers and governments; and, vendors, suppliers and commercial partners. All four groups of actors have highly significant but not always equal roles to play in health care. We looked in particular at the tensions that can arise between clinicians and patients with respect to privacy and confidentiality, or between governments and vendors with respect to competition in the health care market.

The study considered the impact of European data protection legislation, European consumer protection and liability legislation, and European competition law. We analysed this legislation in detail, and followed the analysis by a series

* European Commission contract #30-CE-0041734/00-55. Study on Legal and Regulatory Aspects of eHealth, 'Legally eHealth'. Partners in the study include the European Health Management Association, the Centre de Recherche Informatique & Droit (CRID) at the Facultés Universitaires Notre-Dame de la Paix (Namur, Belgium), and Basil Strategies. Special thanks are due also to Cisco Systems Internet Business Solutions Group who gave technical input and writing support. Further details on the Study can be obtained from EHMA (www.ehma.org) or European Commission (http://ec.europa.eu/information_society/activities/health/studies/index_en.htm)



of small case study ‘vignettes’ which demonstrated the practical implications of the key legal concepts. Key legal aspects studied in the ‘vignettes’ included:

Electronic Medical Records

- responsibility of the service provider to the physician
- responsibility of the physician to his/her patients

Sale of medical products on line

- responsibility of the manufacturer's website
- responsibility of the consumer

Distance monitoring products

- responsibility of the manufacturer,
- responsibility of the service provider

Using digital records pedagogically

- protecting patient anonymity

eHealth industry

- role of the state versus private sector
- monopoly and competition

We concluded with recommendations to the European Commission on further regulatory activities to support the implementation of eHealth.

In this article we outline the three legal aspects we studied and the key recommendations made.

On data protection

The study looked in detail at the requirements of EU privacy and data protection legislation, providing a thorough examination of the Data Protection Directive (95/46/EC) and the Directive on Privacy in Electronic Communications (2002/58/EC).

We looked carefully at the existing regulations and concluded that while the Direc-

tives are probably sufficient to meet the needs of IST in health, further clarification of specific legal duties would be helpful. Data protection legislation is now well established in Europe: while health data is always sensitive and requires special protection, such data may be processed on the basis of patient consent; or in the vital interests of the patient; or for the purpose of medical diagnosis and care provision; or, in certain cases, if there is a substantial public interest in such data processing.

We believe that generally the existing data protection legislation at EU level and its transposition at Member State level are sufficient to allow eHealth tools and applications to be used efficiently in health care. However, we recommended that the European Commission and Member States cooperate, in particular through the Data Protection Working Party set up under Article 29 of the Data Protection Directive, to address uncertainties in the role of consent to the processing of medical data; the necessity to state a finality of purpose for data collection; and technical aspects of data processing and storage security.

There are particular difficulties connected with the concept of ‘consent’ in health related data processing. A particular problem with consent lies in the fact that, in order to be valid, consent must be freely given. Thus, if the creation of electronic medical records is a necessary and unavoidable aspect of providing good quality health care, then withholding consent may be to the patient's detriment. We argue therefore that it would seem appropriate for the European Commission to coordinate the adoption of specific rules for the processing of health information

that allows for proper balancing of patients’ and public health interests, without recourse to the concept of consent.

On eHealth and product liability

Traditionally, medical liability is restricted to the relationship between the patient and the health practitioner (usually a doctor). When a patient is a victim of medical negligence or of a medical error, he or she will usually seek to introduce a civil or criminal lawsuit against the doctor. However, the use of eHealth tools, as well as the multiplication of intermediaries in the field of health services, is changing the legal relationships between the various actors, and often makes it more difficult for a patient to know where liability lies if something goes wrong.

Although general legal rules have been agreed to provide consumers with a legal guarantee of high quality products and services, the legal texts do not specifically address health or eHealth. The current EU level law is applied within the general context of service provision and product delivery, whether by traditional or electronic means. As a result it is often difficult to ascertain which EU level legislation applies to an eHealth product: is it considered a medical device, a software package, and does other legislation (for example, on hazardous substances) also apply? In terms of health goods, whether eHealth or traditional, standard contracts for sale of goods will apply. In general therefore in the eHealth arena, the purchaser of an eHealth good will need to make reference to the relevant national legislation based on Directive 1999/44/EC on the Sale of Consumer Goods.

The study concluded that while specific eHealth sale of goods legislation is probably not needed, it might be appropriate to consider the adoption of specific EU level guidelines on the sale of eHealth goods in order to encourage the adoption of EU wide markets in eHealth tools rather than the fragmented national level markets one sees currently.

Beyond the sale of the product, Directive 2001/95/EC on General Product Safety requires that any product put on the market for consumers, or likely to be used by them, is safe. Further it requires that producers provide consumers with the relevant information enabling them to assess the risks inherent in the product, and take appropriate actions to avoid these risks (withdrawal from the market, warning to the market consumers, recall

products already supplied etc).

National authorities have been established to monitor product safety and to take appropriate measures to protect consumers and an information system has been put in place which imposes collaboration not only between distributors, producers and the national authorities but also between Member States and the European Commission (RAPEX).² This system has thus far not been used well (if at all) for eHealth products, which are still rather new and for which little legal guidance currently exists. Accordingly, the study recommended that the European Commission should adopt policy tools to encourage the use of the RAPEX system for eHealth products.

We also noted also that some eHealth products are considered medical devices, in the terms of Directive 93/42/EC on Medical Devices. The Directive includes in its definition of medical devices electronic equipment and software manufactured or promoted for medical purpose. Thus, monitoring devices, for example, could be considered as medical devices under the European Medical Device legislation, while eHealth tools used for the administration of general patient data will generally not be considered medical devices unless such a product (for example, a laptop, printer, screen, etc.) has had a specific medical purpose assigned to it.

It is clear that more clarity is needed on the extent to which eHealth products are covered by Medical Devices Legislation. Many of the currently available monitoring devices are covered only by general product liability, not by a specific liability provision. It is suggested that further consultation on the application of medical devices legislation to eHealth tools takes place to establish if special guidelines should be issued.

On competition law

Health services, in most European countries, are provided at least to some extent though direct taxation and compulsory health insurance. However, most eHealth services are offered through private enterprises and businesses and thus eHealth

poses difficult questions concerning competition within public and private markets in situations where the distinction between the two is often very hard to establish.

The principles of free trade and free competition are among the most important economic principles supported by the European Community. It is therefore not surprising that the European Community has adopted a wide range of legislation to support free competition through a legal system that prohibits any disloyal practices that restrict competition.

The core of European competition law is found in the rules applying to private firms or 'undertakings' in Articles 81 and 82. Article 81 prohibits agreements and concerted practices with an anticompetitive objective or effect on the market, while Article 82 prohibits abuse of a dominant position. Article 86(2) states that the rules on competition also apply to public undertakings, as long as the "application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them."

The rules of competition law on abuse of dominant position and concerted practices are defined by the Treaty to apply only to those organisations classified as 'undertakings'. The key question for purposes of health care providers is therefore whether any of the parties to an eHealth service are deemed to be undertakings and therefore subject to competition law.

Recent case law at national and EU level³ has established that publicly funded health bodies may, in certain circumstances, be subject to competition law. However, the case law is unclear and would seem to provide that the same institution may, in some aspects of its conduct, be regarded as an undertaking (if it offers goods or services on the market) but in other aspects (such as contracting out certain care services) will not be considered an undertaking.

This ambiguity in law will be unsettling for both public and private sector health care providers. The study recommended, therefore, that the appropriate committees

of the European Commission should be encouraged to examine the recent decisions of the European Court of Justice (ECJ) on the application of Articles 81 and 82 to health care providers, in order to draw up clear guidelines establishing when a health care provider will be regarded as an undertaking and when not. Such guidelines should address the widest possible range of health care providers and suppliers, covering traditional and eHealth care.

Further to Article 86(2), the Treaty provides that an undertaking normally subject to the rules of competition law may be exempted from their application if it has been entrusted by a public body to provide a Service of General Economic Interest (SGEI)⁴ and if the application of the rules on competition would obstruct the performance of the particular tasks assigned to them. While it is left up to Member States to define the services they consider as SGEI, considerable lack of clarity still exists at EU level on the designation of health services.

Recognising that many European health systems are provided through public funds, the European Commission has, in a number of communications, suggested that health services are not generally to be regarded as SGEI nor are they to be included in the wider definitions of Services of General Interest (SGI) or Social Services of General Interest (SSGI)*. The Commission has instead proposed that, because health services have such a unique character, special targeted rules on health services of general interest should be established. However, despite first raising this issue in 2001, the European Commission has yet to clarify the position of health services and their possible exemption from competition law.

The study recommended that the Commission adopt a communication or guidelines setting out clearly the circumstances under which a health service provider may make use of the provisions on SGEI in the Treaty and thus be exempted from competition law. Such guidelines should address the changing nature of health services, recognising that a wide range of actors from both public and

* For the evolution of the definition on Services of General Interest, see Green and White Papers at http://europa.eu/eur-lex/en/com/gpr/2003/com2003_0270en01.pdf (COM(2003) 270 final, May 2003) and http://europa.eu/eur-lex/en/com/wpr/2004/com2004_0374en01.pdf (COM(2004) 374 final, May 2004), announcing a more systematic approach in the field of social and health services of general interest. This systematic approach is proposed by a Communication from the Commission 'Implementing the Community Lisbon programme: Social services of general interest in the European Union' (COM(2006)177, April 2006), available at http://ec.europa.eu/employment_social/social_protection/docs/com_2006_177_en.pdf. For more information, see http://ec.europa.eu/employment_social/social_protection/questionnaire_en.htm.

private enterprises will be involved in the provision of both traditional and eHealth services. In order to encourage adequate investment in eHealth services, both public and private enterprises must have legal certainty on their position with respect to competition law.

Conclusion

eHealth is important for Europe, it can drive up service quality, improve patient safety, contain costs and facilitate access to health care. The 'Legally eHealth' study has examined aspects of European law related to data protection, liability and consumer protection, and competition law. It has identified that a significant body of European law already addresses a number of the key legal issues in eHealth. However, there is still great uncertainty in the eHealth actors, ranging across public bodies, big industry and small enterprises about the full legal implication of using and offering eHealth services.

It is notable that despite the large numbers of communications on Services of General

Interest, the Lisbon agenda and long-term care, as well as heated debates on health services with the Services Directive, little emphasis has been given to an impact assessment of the proposed legislative responses to health services in general. Moreover, none have considered in depth their impact on eHealth services. Given however, that the development of eHealth markets is considered to have major economic potential for Europe,⁵ further legal clarifications are necessary both to encourage the development of these markets in optimal conditions, all the while respecting the unique nature of health services. Therefore, in addition to the specific recommendations made on each of the three clusters of legal issues, the study calls for a mainstreaming of eHealth impact assessment across all European policy initiatives.

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Regulating nanotechnology: new legal challenges?

Jean V McHale

Summary: The development of nanotechnology has huge potential for medical science. However at the same time it gives rise to a range of legal and ethical regulatory challenges for the EU and Member States. This paper explores first what is meant by nanotechnology and its use in medicine. Secondly, it considers some of the ethical and regulatory challenges discussed by the European Group on Ethics in Science and New Technologies in their recent Opinion on the ethical aspects of nanomedicine. It suggests that there are many legal and ethical issues which will need to be further explored at both EU and Member State level, including the diversity of current regulatory structures applicable in this area, issues of consent, privacy and the regulation of risk.

Key words: Nanotechnology, Medicine, Health, Law, European Union

The rise of nanotechnology in general and nanomedicine in particular has led to considerable debate and controversy.¹ 'Nanotechnology' can enable us to better

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understand how the body functions at molecular level. 'Nano' itself refers to 'one billionth' and originates from the Greek word meaning 'dwarf'. As the European Technology Platform Report comments:

"It is an extremely large field ranging from in vivo and in vitro diagnostics to therapy including targeted delivery and regener-

ative medicine. It has to interface nanomaterials (surfaces, particles or analytical instruments) with 'living' human material (cells, tissues and body fluids). It creates new tools and methods that impact significantly on existing conservative practices".²

The development of this technology may

result in more efficient interventions in relation to illness.³ Nanotechniques can involve the use of technologies which are more cost-effective and accurate, such as the ability to enhance resolution to a single-molecule analysis of any sample. Nanowire arrays enable testing of a single pinprick of blood. This reduces the prospect of invasive procedures but still enables efficient testing results and can enable such tests to be undertaken at home easily and with little pain.²

Use of nanotechnology in imaging, such as ultrasound, may result in a much more precise diagnosis. The use of miniaturised imaging systems makes it possible for image-based diagnosis to be undertaken, not simply in research centres, but much more widely. This has the advantage of potentially enabling the earlier detection of disease, with a consequent need for less invasive and lower cost treatments.²

Nanotechnology also enables the development of miniature devices which may be used in treatment itself. This can reduce the invasiveness of procedures and lead to the development of new forms of treatment.

Nanopharmaceuticals may deliver particular molecules through biological barriers such as blood-brain barriers. Carriers on the shell of these molecules can be targeted at molecules which are typical for cancer. Nanotechnology may also facilitate regenerative medicine. It may enable the improvement of the activation of genes which stimulate regeneration, through stem cell therapy with nanotechnology based upon magnetic cell sorting identifying/activating and guiding stem cells to the particular part of the body which needs regenerating. There is also the prospect of continuous medication through implants with controlled administration of drugs over a period of time. In addition, access to nanotechnology may also facilitate tissue engineering.²

But is nanotechnology really 'something new'? As has been commented:

"In many cases nanotechnology includes technology which has been in use for a long time and most of the concepts used are not strictly speaking new. For instance, the mode of action of all pharmaceutical products occurs at nano scale. Nanomedicine essentially provides tools that may be useful for well identified medical problems."³

Nonetheless, although not totally new, it

is the scale of nanotechnological development and the wide range of issues with which nanotechnology is concerned, which may give rise to notable regulatory challenges. Developing technologies give rise to issues of legitimacy and the need to ensure public trust and confidence, as we have seen in the context of the debates over embryo research and stem cell technology.

Nanotechnology and the EU

The immense potential of nanotechnology in general, and that in relation to health in particular, has already been identified by the European Union. The EU has been responding to the challenges of nanotechnology. In 2004 the Commission issued the Communication *Towards a European strategy for nanotechnology*.⁴ This identified the potential of nanotechnology but also recognised its risks and the need for the early identification and resolution of safety concerns.

It noted the need for effective research and development support. It stressed the need for effective coordination of national measures through mechanisms such as the 'Open Method of Co-ordination'. It was recognised that there was a need for a "world class infra structure" with "poles of excellence". This document also highlighted the need for recognition of ethical principles in accordance with the EU Charter of Fundamental Rights and Freedoms and other European and international documents.⁴

It also identified the need for effective communication of such information within the scientific community. In addition, the Communication noted the importance of international cooperation. It suggested that there should be an international debate on those matters of global concern, including public health, safety, the environment, consumer protection, risk assessment, regulatory approaches, methodology, nomenclature and norms".⁴

Ethical review

The European Technology Platform on Nanomedicine, an industry-led consortium, brought together the key stakeholders in the area to examine the impact of nanotechnology.² As part of the Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee, entitled *Nanosciences and nanotechnologies: an action plan for Europe 2005–2009*, the European Group on Ethics in Science and New Technologies were asked

to undertake an ethical review of nanomedicine which would enable the future appropriate ethical review of proposed projects concerning nanoscience and nanotechnology.⁵

This Expert Group highlighted one uncertainty in this area, namely that there was no clear legal definition of nanomedicine.³ They also identified a major practical problem in attempting to take a holistic approach to the regulation of nanotechnology, namely that there is a diverse range of forms of legal regulation of such technologies. So, for example, at EU level regulation of nanotechnology may arise in the context of the regulation of pharmaceuticals⁶ or medical devices⁷ where other health care law principles are applicable, such as consent, confidentiality and data protection.⁸ It was not necessarily always obvious which precise regulatory regime would apply.

One notable concern regarding the development of nanotechnology is that of safety. A United Nations Education Scientific and Cultural Organization report on the ethics and politics of nanotechnology commented that the question of safety of nanotechnology and nanomedicine raised:

"two concerns: the hazards of nanoparticles and the exposure risk. The first concerns the biological and chemical effects of nanoparticles on human bodies or natural ecosystems; the second concerns the issue of leakage, spillage, circulation, and concentration of nanoparticles that would cause a hazard to bodies or ecosystems".⁹

There are concerns that there may be a risk of toxic effects to patients. There is also the possibility of side-effects to patients where nanomedicines cross blood-brain barriers. It has also been suggested that there are health-related risks from the effects of nano-pollution on the environment. The European Ethics Group recommended that there should be more research into the safety of nanomedical products/devices.³ The Group was of the view that without strategic risk research public confidence in nanotechnologies could be reduced through real or perceived dangers. It was important for the relevant authorities to assess the risks of nanomedicine and that both national and EU bodies concerned with safety of patients and citizens should review the safety of nanotech devices.

While the European Ethics Group recognised a range of regulatory issues, they rejected the introduction of a new broad

regulatory structure for nanomedicine. Instead it was thought that changes should come from within existing structures.³ However, they were concerned with ensuring that the differences within the range of regulations already in existence would be addressed by regulatory bodies. It was noted that while many of the problems associated with new materials are addressed through product liability legislation, at the same time there are difficulties in ascertaining the risks and related liability from negligence. Further concerns relate to the use of patenting in hindering the therapeutic availability of such technology.

The Group also expressed their concern at the prospect of internet tests using nanotechnology becoming available. They suggested that in the interest of consumer protection, policies should be developed to monitor the introduction of tests directly marketed to customers.³ As with any new technology, there are also challenges in relation to nanotechnology in terms of the provision of information as part of an 'informed consent' process.

The Expert Group emphasised the need for transparency and public trust. Recognising the on-going nature of the challenges faced by nanotechnology, the Group suggested that there was a need for inter-disciplinary research on the ethical, legal and social implications of the technology. They proposed that there should be a dedicated European network on nanotechnology ethics, established and financed by the Commission under the Seventh Research and Development Framework Programme.

They also suggested that initiatives should be developed to enhance information exchange between research ethics committees in different Member States. Interestingly, the report also suggests that measures should be taken at a European level to create databases not only for scientific aspects of nanomedicine but also for their ethical, legal and social implications.

One other concern raised by the Expert Group was the prospect of any overlap between medical and non-medical uses.³ They noted that there was a possibility that

“the distinction between therapeutic goals and enhancement goals may become less clear, if for example, predisposition tests are available more easily and cheaply. Especially in the reproductive context of pre-implantation

genetic diagnosis the line between 'negative' and 'positive' selection may be blurred.”

The Group noted that, in future, it may be the case that neurological stimulation of brain activity goes beyond therapeutic and diagnostic use. The Group suggested that appropriate monitoring and guidelines as to the use of nanotechnology in this particular area should be introduced. They were also of the view that priority should not be given to “enhancement technologies”, rather health care concerns should first be addressed.

Conclusions

Where do we go from here? Nanotechnology does have great potential, but is it truly 'special' and different? The answer to this question is surely both yes and no.¹⁰ Yes because it is a new technology with potential new risks, but at the same time in other ways it can be seen as not being that new at all. It is derivative upon regulation across a wide range of different areas and this will, clearly in itself, give rise to particular regulatory challenges.

The report of the European Group on Ethics in Science and New Technologies raises a series of important issues which need to be addressed. Nanotechnology is included in the Seventh Research and Development Framework programme under the theme 'Nanosciences, Nanotechnologies, Materials and New Production Technologies'.¹¹

Both at EU and Member State level, there is a need for prioritisation between different types of nanotechnology. The lines between therapeutic and non-therapeutic uses will pose challenges. Ethical concerns over the implications of nano-scale implants, such as brain implants in relation, for example, to issues of impact on autonomy, integrity, self-identity and freedom will need further exploration.

Equally, the resultant legal issues concerning consent, privacy, and use in the context of research remain to be fully debated. The challenge, as with other new technologies such as embryo research and stem cell therapy, is to balance public demand for the development of new medical therapies with public concerns regarding the risks that these new technologies entail. An effective pro-active, as opposed to reactive EU response, is to be welcomed in dealing with these challenges across the Member States of the EU.

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Public-private partnerships in Eastern Europe:

Case studies from Lithuania, Republika Srpska and Albania

Katja Kerschbaumer

Summary: Public-private partnerships (PPP) in the health sector have become a viable tool for governments seeking to reduce financial pressure without lowering quality standards and unreasonably burdening patients. Lithuania, Bosnia and Herzegovina, and Albania have successfully established several partnerships with the private sector. Key factors for a PPP's success include: the active involvement of patients and medical staff, an enabling legislative framework, the conduct of feasibility studies and the introduction of performance control mechanisms.

Keywords: Public-Private Partnership, Health Care, Concession Contracts, Outsourcing, Lithuania, Republika Srpska, Bosnia and Herzegovina, Albania

Many countries are looking at various forms of public-private collaboration (PPC) in order to support reforms and improve efficiency and fiscal sustainability in the publicly financed health sector. To date, there is limited information available on the different options for PPC, in particular on reasons for success, the necessary institutional and financial requirements and ways to manage the related financial risk.

PPC in the health sector can take a variety of forms, with differing degrees of public and private sector responsibility and risk. They are characterised by the sharing of common objectives, as well as risks and rewards, as might be defined in a contract or manifested through different arrangements, so as to effectively deliver a service or a facility to the public.

Health care public-private partnerships (PPP) typically involve the Ministry of Health or the national health insurer signing a contract with the private sector for a specific service. PPPs can be applied

to a wide range of clinical and ancillary services, such as design and construction, catering, laundry, clinical support services (for example, laboratory analysis) and specialised clinical services (for example, haemodialysis). It may even be used to outsource the management of an entire hospital.

Contracts may stipulate that the private sector be responsible for all or some project operations; financing might be undertaken jointly or by either the public or private sector alone. In practice, the main types of PPP frequently encountered in the health sector include: concession contracts (in which asset ownership remains in public hands, but where the private partner is responsible for new investments, as well as operating and maintaining assets), management and service contracts, leases, the creation of brand new joint venture projects or privatisation.

The following three case studies report initial experiences with public-private arrangements in South-Eastern and Eastern Europe.

Clinic concession contracts in Vilnius, Lithuania

A major problem in hospitals in the municipality of Vilnius had been the shortage of funds for essential maintenance and renovation, as well as for the purchase of modern information technology and medical equipment. Waiting times for appointments and surgery were also disproportionately long. Medical personnel were not very motivated, due to a lack of direct responsibility or incentives.

There were however public concerns over any suggestion of reforming the system, because of the discovery of a corruption scandal in 2004 related to the proposed establishment of a PPP clinic in Kaunas. Doctors were also key opponents of reform; they feared losing their privileges, including informal payments from their patients. These negative attitudes were overcome through ongoing meetings between representatives of the municipality, doctors and patients, as well as through a major information campaign in the press and television. Most importantly,

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* On 4–5 December 2006, The World Bank, together with the International Finance Corporation advisory and investment team and the Slovenian Center of Excellence in Finance, organised a two-day workshop on public-private collaboration in health. This article is based on three case studies that were presented by country representatives at the workshop. Background material as well as all presentations given at the workshop can be found on the Bank's website: www.worldbank.org.

meetings between private investors and medical personnel allowed trust between the two groups to develop. Given the fact that Lithuania is facing a major lack of health care professionals because of migration to other European Union countries where salaries are higher, it was crucial to reach consensus with these professionals.

Through a selection process, the municipality of Vilnius chose two of eight potential clinics for the introduction of PPP. There were no firm criteria for this selection; the municipality simply wanted the clinics to be 'representative' with regards to their size and economic performance. Thus, one large and one small clinic, both of average performance, were chosen. In addition, in order to ensure that the population would not avoid using those hospitals where reforms would be introduced, politicians chose clinics located in areas without easy access to alternative health care providers.

The municipality of Vilnius also hired consultants to carry out a feasibility study, including a patient survey in 2005/06. The study evaluated ten different options for collaboration with the private sector: these involved various combinations of contracting out maintenance and/or medical services, privatisation and outsourcing of management. According to the study, only private sector participation that included several different activities was financially viable.

The contract put out to tender thus included the renovation and maintenance of clinic buildings as well as administrative and health care services. A two year timetable was put in place to issue the concession. This would run for 25 years, with each clinic needing to reach 30,000 patients to break even. The investment into one clinic from the successful concessionaire, a Lithuanian firm registered in Cyprus, is €4 million. The firm is projected to start making a profit in eight years.

It is expected that the new arrangements will lead to an increase in the number of patients per doctor and the installation of a patient registration system by the private investor. This registration system will be slowly extended by the Ministry of Health to all clinics in Lithuania. It is also anticipated that a decrease in waiting times from their current level of 40 minutes to (eventually) 15 minutes will also lead to an increase in patient satisfaction.

These PPP contracts are expressly labelled

as 'concession contracts', with the whole procedure largely governed by the Lithuanian Law on Concessions. In the case of the above clinic, the contract was 50 pages long and signed by four parties: the director of the municipality's administration, the concessionaire, the firm established by the concessionaire and the clinic director. An administrative committee was created by Vilnius municipality to supervise the process of drawing up the contract.

A key challenge in this project was that some (very limited) property rights in the clinic building and equipment were held by the Ministry of Health rather than the municipality. This made it impossible for the municipality to lease these assets directly to the 'Special Purpose Vehicle' (SPV – a limited company set up to fulfil a narrow objective and legally isolate a high risk project from a parent company set up for the contract). However, the Ministry of Health instead was able to enact legislation transferring these limited property rights to the municipality who in turn could lease this to the SPV.

Some would have liked to have gone even further than these arrangements to lease facilities to the private sector. The advisor to the mayor of Vilnius called the concession contract a 'second-best solution', suggesting that the clear desirable option would have been privatisation. Such a view however was not reconcilable with the views held by the general public, and in particular by health service users, that health care provision should be a core responsibility of the state alone.

Specialist dialysis services in Banja Luka and Bijeljina, Republika Srpska, Bosnia and Herzegovina

The dialysis centres of Banja Luka and Bijeljina provide another example of how individual clinic services can be outsourced. The PPP process benefited from no opposition from either the public or government. Indeed, patients were very supportive and even went to the construction sites to witness progress and enquire as to when the new centres would be ready.

Thus a contract was signed by the Prime Minister, the Minister of Health, the

Minister of Foreign Economic Affairs, the Health Insurance Fund Director, the hospital director and successful bid winner – the Dutch firm International Dialysis Center (IDC).^{*} The contract itself was very simple and only eight pages long. From a legal standpoint, the outsourcing of dialysis services could be undertaken without the need to pass new laws or use other legal instruments. This could be achieved simply through a contract with the services provider, supported by laws governing companies with limited liability and foreign companies.

Republika Srpska (RS) first began using the PPP contractual model in 2000. As the National Health Insurance Fund did not have a specific estimate of costs of treatment provided in the state haemodialysis centre an economic analysis was conducted. This found that treatment could in fact be obtained at a lower price in the private sector. Based on this finding, the Government of RS decided to collaborate with private health care institutions, being mindful of three objectives: improvements in the quality of the national health care system; increased access to high quality medical services; and cost reduction within a self-sustaining health system.

The direct investment now made by IDC includes the renovation of the existing haemodialysis centre in Banja Luka and the construction of a brand new building for the Bijeljina Centre. The total investment made by IDC for construction, reconstruction and all medical and non-medical equipment equated to €4 million.

The price for one treatment by IDC is fixed in the contract (in fact the only figure written in the contract) and includes a whole set of services. The contract also bound IDC to a number of obligations including the core functions of establishing and managing the dialysis centres for the period of the contract duration; purchasing and installing new equipment; providing patients with one meal during every treatment; having complete responsibility for training local medical personnel; and guaranteeing to increase their salaries. Fulfilment of the terms of the contract is overseen by the Ministry of Health, the Insurance Fund and the two host hospitals.

^{*} When the tender was issued, RS had not yet passed legislation on public procurement. The tenders were simply held on the basis of 'general practice': advertisements were published in daily newspapers and a minimum of three acceptable bids were required for opening the evaluation procedure.

IDC Banja Luka and IDC Bijeljina became operational in April 2001 and May 2002 providing services to 84 and 100 chronic patients respectively. Both have expanded their operations; currently, IDC Banja Luka provides services to more than 180 patients and performs more than 2,500 haemodialysis treatments per month; comparable figures for IDC Bijeljina are 200 patients and 2,700 treatments per month. The two centres now account for more than 50% of all RS's dialysis patients. The increase in the number of patients treated is primarily due to the decreased mortality rate of dialysis patients. Quality assurance is carried out by annual patient surveys conducted according to ISO standard 9001:2000.

One unforeseen challenge that the centres must face was the introduction of value added tax (VAT) from 2006. While health care service delivery is exempt from this tax, the dialysis centres must pay 17% VAT on all equipment purchased. This is problematic as the centres now have to deal with an inevitable increase in expenditure, without any possibility of being able to pass this increase on to patients, since the activity price is already fixed in the contract. A regulation that would waive health care service providers from VAT on all equipment is being discussed.

Initially, IDC Banja Luka and Bijeljina contracts were awarded for seven and nine years respectively. The Ministries of Health and Social Welfare and Foreign Economic Affairs will now sign new contracts with both centres for an additional fifteen years. Based on these positive experiences, the National Health Insurance Fund has issued PPP guidelines* as a foundation for future privatisations, with the ultimate goal of privatising 80% of all state dialysis centres.

The success of the pilot has also triggered interest in using this model in other areas such as radiotherapy and radiology. The government is now looking at ways to attract other international investors and to promote more competition in the private delivery of health care services. Neighbouring countries have also requested more 'how-to' information, expressing their interest in learning from this type of PPP, in an attempt to make their post-

conflict health care systems more cost effective and of higher quality.

Hospital catering in Tirana, Albania

In 1996, a survey of the 1,450-bed Mother Theresa University hospital in Tirana indicated that patients were very dissatisfied with the food served, such that 80% was refused. All food was being prepared in one central kitchen and then distributed to the six different hospital buildings. The kitchen and its equipment were in a poor state; moreover electricity and running water were not always available. Frequently food intended for patients actually ended up in the hands of hospital employees and their families.

Considering these challenges, the hospital administration decided to outsource catering services to a specialist company. An assessment of needs was conducted, the cost of the service calculated and the documents for the tender prepared.

The contract was subsequently awarded to an Italian firm for approximately US\$66,000. This value is adjusted twice a year to take account of official inflation rates reported by the National Statistical Institute. Approved by the Minister of Health, the ten-page contract requires the delivery of 1,125 meals a day, stipulates different diets for different illnesses and is not a concession contract. The successful bidder is also responsible for the construction of a new fully equipped central kitchen, as well as training for the much reduced work force of 25 employees (compared with 69 under the old system). Under the terms of the contract, the private contractor directly employs the catering staff. It is also responsible for purchasing foodstuffs, general expenses and maintenance costs. The menu must also be approved by a doctor.

The Italian company has invested US\$700,000 in building and furnishing the new kitchen, upgrading the electrical and heating systems, improving delivery services and staff training. In turn, the hospital provides space within its premises and makes a fixed monthly payment. The service is controlled by a support service unit within the University Hospital Centre.

Both the quality of the food and patient

satisfaction levels have increased. One problem that still remains however lies with the distribution system. Although the food is prepared by the Italian company's staff, it has continued to be distributed by hospital employees and unfortunately food often still does not reach the patient. This situation will be taken into consideration when drafting new contracts, so as to guarantee that all companies have an obligation to directly deliver meals to patients.

Conclusion – the future of PPP

These case studies from three countries in the World Bank's Eastern Europe region indicate that factors for successful public-private collaboration include support from key stakeholders including government, patients and health care professionals; this support can be built through information and communication campaigns.

It is also important to have appropriate enabling institutional, legal and regulatory frameworks in place; sufficient measures were already in place in the three countries highlighted here. Almost every model of PPP or PPC can be created through a contract, provided the country has a sound legal framework (civil code that includes sophisticated contract law) in place and a constitution that does not forbid the privatisation of health care services.

It is also important before embarking on any PPP venture to undertake feasibility studies to ensure risk management and risk-sharing mechanisms between the private and public partners are put in place. Control mechanisms to evaluate the performance of these newly created entities are also required.

Given that all these preconditions are put in place, a PPP can be a success for all stakeholders and help ease the financial pressures on any state's health budget, provide high quality services for patients, and increase employee satisfaction through training and higher salaries which may also dissuade staff from seeking employment elsewhere.

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* The definition of PPP in RS according to the Health Insurance Fund guidelines for PPP in the health sector is: a cooperation between public/state institutions and private operators whose aim is to finance, construct/reconstruct, provide management, maintain infrastructure or provide services.

Dutch health insurance reform: the new role of collectives

Peter P Groenewegen and Judith D de Jong

Summary: In the new Dutch health insurance system individuals have the option of joining a collective insurance contract. Insurers are allowed to offer premium reductions of up to 10% to members of collectives, based on the number of insureds. Collectives might exert more influence on insurers than individuals because of the threat of moving large numbers of the insured from one insurer to another. Collectives have become an important feature in the new health insurance system as two-thirds of the Dutch population aged eighteen and over are now insured as part of a collective. Most collectives are employment based and specifically put more emphasis on premium levels than on service or quality of care compared to other collectives, such as patient organisations.

Key words: Health insurance, Reform, Premiums, Collective contracts, the Netherlands

In January 2006, after years of gradual preparatory steps, a new health insurance law was introduced in the Netherlands.¹ One of the new elements is the possibility of collective insurance. In the old system, collective contracts only existed in private insurance where employers could negotiate collective contracts for their privately insured employees. In the new system, collective insurance is open to everyone who is, or becomes a member of, a collective (whatever the basis of the collective) that has a contract with an insurance company. Any group of individuals, whether united through employment, sports, patient interests or even any other organisation formed solely for the purpose of obtaining collective insurance, can enter into a contract with an insurance company.

One of the reasons to include this possibility in the new insurance law was to give the insured more of a voice in their

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dealings with insurance companies. By uniting in collectives, individuals, it was thought, might be able to exert more influence on the policies of insurance companies compared to those individually insured. Insurance companies have an incentive to keep collectives satisfied because of the threat of losing a collective contract and thus a large number of insured individuals.

The Netherlands is quite unique with respect to the possibility of collective insurance. Social health insurance systems are employment based, or at least started as employment-based systems.² In Germany, company funds (Betriebskrankenkassen) can still be limited to employees (and their dependents) of one specific company. In contrast to Dutch employer-based collectives, these company funds are separate risk pools. Private health insurance in the United States is also predominantly employment based. Over 60% of non-elderly Americans had employment-based health plans in 2002. Most employment-based health plans are self-insured, i.e. the employer is financially responsible for paying the health care claims of its employees.³ However, these examples are different from the Dutch collectives, whether employer based or not. The Dutch system has national prospective risk adjustment and the risk

pool is formed by all the insured of one insurance company, irrespective of the type of contract.

A brief outline of the insurance reform is given in Box 1. One of its aims is to improve quality of care and secure affordability and long-term access to care by means of a system of regulated competition. In the insurance market, insurers compete to attract as many insureds as possible, presumably by offering a good balance between premium level and service quality. In the purchasing market, insurers will presumably contract health care providers with the best balance of price and quality. However, purchasing activities are supposed to be steered by the preferences of those being insured.

Since the implementation of the new law in 2006, the number of individuals that have taken out collective insurance has been much larger than expected. This new emphasis on collective contracts sat well with the strategies of insurance companies as it was consistent with their objective of securing as large a share of the insurance market as possible. Although collectives have now become a major phenomenon on the Dutch health insurance landscape, it remains to be seen whether they will be able to exert much influence on the insurers.

Box 1: The Dutch health insurance law

Abolition of distinction between private and public insurance.

Insurance under private law with public limiting conditions.

Obligation for every citizen to take out health insurance.

Obligation for insurance companies to accept every citizen without premium differentiation, risk selection or risk adjustment.

Free choice for citizens between insurance organisations (switching is possible once a year).

Premium level: nominal (typically around €1,100 per year) plus income related contribution initially paid by employees and then subsequently reimbursed by employers; overall half of the total costs of premiums will be from nominal premiums and the remainder from income related contributions.

Compensation for low income individuals.

Basic package is identical for everybody, with a choice between schemes where health care providers are directly paid by insurance companies and schemes where individuals initially pay the bills and then are reimbursed by their insurance companies.

Complementary insurance (not obligatory and not necessarily with same insurer as basic package).

Choice of deductible (minimum €100, maximum €500).

No-claim premium reimbursement if annual health care costs less than €255.

Sources: Bartholomé Y, Maarse H, 2006,¹ Ministry of Health, Welfare and Sports, 2006.⁴

This article therefore focuses on the new position of collectives in the Dutch health insurance system and focuses on highlighting who is taking out collective insurance and their characteristics and motivations. It also highlights the origins of collectives, i.e. whether they are linked to employment or some other basis; and to discuss whether collective contracts actually increase the power of the insured and in what direction. The information used here is derived from regular surveys of participants of two large panels: the Health Care Consumer Panel and the National Panel of People with Chronic Health Problems and Disabilities (both run by the Netherlands Institute for Health Services Research, NIVEL), as well as through a survey among collectives.^{5,6}

Collective or individual insurance

Collective insurance is attractive to potential insurees because the law allows insurance companies to offer a reduction of up to 10% on the nominal premium (around €1,100 annually) for members of a collective. The insurance law states that

the percentage of premium reduction may only be based on the size of the collective and not on other characteristics of the collective or its members. Thus, collectives of similar size should receive a similar premium reduction. For complementary insurance, the size of premium reduction is not limited by law. Premium reductions to date are on average 7%.⁷ However, the cheapest insurance premiums without any reduction are still cheaper than the most expensive, even with a maximum reduction of 10%, as monthly premiums for the basic package for 2007 before any discount are at their cheapest €85, compared with €100 for the most expensive insurance schemes.⁸

It is also important to note that individuals cannot be forced to join a collective insurance contract. Thus, if an employer negotiates a collective contract, its employees have the choice of joining this collective contract, joining some other collective contract (for example, through a voluntary organisation they are a member of) or having an individual contract.

To insurance companies, collective contracts are attractive, at least in the initial years of the new system, as they can help attract as big a share of the insurance market as possible, even at the risk of losing money on collective contracts. Collective contracts may have economic advantages as a result of lower administrative costs, when the collective guarantees payment of the nominal premium.

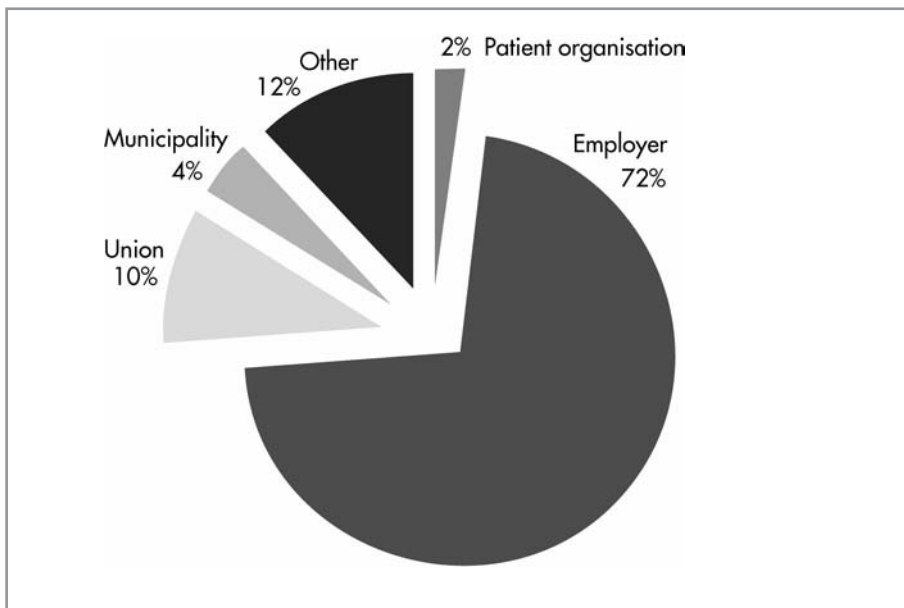
Certainly they appear to have been popular. An unexpectedly high number of individuals are now insured via collective contracts; 55% of all those insured during 2006, increasing to 63% in 2007.⁵ The likelihood of being collectively insured is higher for those of working age, men, those with a higher educational attainment level, as well as those who perceive their health as good.⁹ These differences are, to some extent, related to the fact that the biggest category of collectives are those organised via employment.

Organisational basis of collectives

A wide range of organisations provide collective insurance; however, almost three-quarters of those with collective insurance are insured through their employer (Figure 1). The principal reasons for employers to offer their employees the option of collective health insurance are to maintain their reputations as good employers, as well as the incentives that collective insurance has in attracting and retaining employees. The dependents of employees can also be collectively insured via their employer.

Municipal social service departments usually have a collective contract for those dependent on social welfare benefits. Collective contracts for these groups are also attractive to insurance companies as the nominal premiums are directly paid by social service departments. A small number of individuals are also collectively insured via patient organisations.⁶ A notable example is the Diabetes Patients' Organisation (DVN), which has formulated its own terms of reference and subsequently invited insurance companies to make offers to the organisation.

The DVN is however one of the biggest patient organisations in the Netherlands and the risk adjustment system is such that insurance companies receive higher compensation from the central fund for diabetics. For many of the smaller patient organisations it is much more difficult to have a collective contract, both as a result of their size and because the risk

Figure 1: Collective insurance by organisational basis, 2007⁵**Table 1: Percentage of collectives that judged an aspect as (very) important in their choice of insurance company (19 employers' collectives and 23 other collectives)**

Aspect		Employers	Other collectives
Premium	Premium reduction for additional insurance	95%	83%
	Premium reduction for basic insurance	89%	87%
	Premium for additional insurance	89%	78%
	Premium for basic insurance	84%	70%
	Deductible and related premium reduction	21%	35%
Content of the insurance	Coverage of additional insurance	89%	100%
	Quality of contracted providers	79%	96%
	Coverage for specific aids or drugs	63%	78%
	Special care programmes	37%	65%
Quality of the insurance company	Service	84%	100%
	Reputation	79%	78%

adjustment may be less preferential. A NIVEL survey showed that patient organisations have to put more effort into negotiating collective contracts than employers.⁶ It is therefore possible that smaller patient organisations, which are less professionally organised, do not always have the means to negotiate a collective contract.

A new phenomenon is the special purpose

collective. Examples might include a collective of individuals who buy their insurance through a specific internet site and thus automatically become part of a collective, or those who buy their insurance through a chain of retail chemists. In the case of insurance companies with the legal status of cooperatives, by which members are not individually liable for any deficits of the fund, the insured are nonetheless formally members

and therefore could be defined as a collective. Even insurance companies with other legal status can establish an association of their insurees, so as to be able to give them a discount on the grounds of being part of a collective. However, if all those insured are receiving such a discount, one could ask whether this in fact really is a discount? Nevertheless, insurance companies might still be able to attract additional insurees as a result of such discounts.

Possible influence on insurance companies

One of the aims of the new insurance system is that the insured exert influence on insurance companies through the threat of switching insurers. This influence should lead to an optimal balance between the nominal premium, services of the insurance company, and the quality of care purchased by the insurer.

The main reasons why individuals switch insurer are the premium level and their wish to join a collective contract with another insurer. Collectives could also be in a better position to influence insurers because of their size. The question then is to what extent collectives choose an insurance company on the basis of the premium or of service and purchasing quality?

In general, younger and healthier people choose more on the basis of the insurance premium, while older and less healthy people tend also to take into account quality aspects of the insurer and the care that they purchase.⁹ The NIVEL survey of collectives indicates that this is the same for employment-based collectives, compared with other collectives (Table 1).

Patients' collectives, in particular, emphasise service and quality aspects of collective contracts. In this way they could, in theory, contribute to the goals of insurance reform. However, as Figure 1 illustrated, they are quantitatively of minor importance compared to employers' collectives.

The NIVEL survey also shows that patient organisations are in a different position from employment-based collectives, in that they more often drive the initial process of contacting an insurer. Negotiations also take longer and premium reductions tend to be smaller. One reason for the smaller premium reductions might be that the percentage of members of patient organisations that join the collective

contract is lower than the percentage of employees that join the collective contracts obtained by their employers. However, if the premium reduction is related to the type of collective and its members, differences might develop in the costs of health insurance between different population sub-groups. One implication might be that population sub-groups that generate higher health care costs have less access to collective contracts. Another question is whether or not individuals would use the collective if they were dissatisfied with their insurer? In one survey of the Health Care Consumer Panel, 16% of the collectively insured indicated that they would turn to their collective in the event of complaints.

Conclusions

Approximately two-thirds of the Dutch population is now collectively insured; however, it is unclear whether or not the percentage covered by collective contracts will continue to increase. Individuals might be lured into collective contracts by the headline reduction in premiums without looking too closely at absolute differences in premium cost. Furthermore, if the number of collectively insured continues to grow, it may be questioned as to the basis of any premium reduction. If everybody receives a premium reduction then the premium without reduction is solely a virtual option.

For the overall aims of the insurance

reform to be achieved, the willingness of individuals to switch between insurers is important, if they are dissatisfied with either price or quality. In practice however, it is only the young and healthy who are likely to switch on grounds of price alone. Switching for other population groups may be more difficult. The newly established Dutch Health Care Authority (NZa) which monitors the health insurance market does however have the authority to intervene if it believes that the interests of consumers are under threat.¹⁰

Nonetheless, for the time being, collectives are not likely to have much impact on the purchasing activities of insurance companies. They may however have more impact on their service orientation, particularly if and when the collectively insured collectively voice their dissatisfaction over the services of any insurance company.

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Medicine, care of the dying, and care of the chronically ill

Milton Lewis

Summary: The palliative care movement began in Great Britain and spread quickly, not only to the United States, Australia, Canada, and New Zealand, but also to continental Europe. This article provides an overview of material covered in a new book entitled 'Medicine and Care of the Dying. A Modern History'. Historically, concern about palliative care has developed separately from that about better care for the chronically ill. But the same demographic and other forces are now shaping the context in which more patient-centred services are needed. Palliative care and care for the chronically ill should be better integrated, as should health services generally.

Keywords: History, Care of Chronically Ill, Palliative Care, Dying

Medicine, Death, and Dying

A historian of medicine and public health, I recently published *Medicine and Care of the Dying. A Modern History*.¹ The main aim of this study was to explore the relationship between modern medicine's approach to the care of the dying and the changing social, cultural, demographic, economic and political context over the last two centuries or so in five 'Anglo-Saxon' countries: the United Kingdom, the United States, Australia, Canada and New Zealand.

Although the study takes this specific geographical focus, I believe it is of interest to those involved in palliative care, as well as health services generally, across Europe. Given ongoing media concern in Europe (as in other parts of the western world) about access to means of euthanasia, the chapter on the history of the euthanasia debate, as well as that on the development of palliative care services and policy, will perhaps be of greatest interest to readers of *Eurohealth*.

The rise of modern scientific medicine has been marked by a growing conflict between a medical-reductionist view of human functioning and a deep and widespread cultural need in late-modern,

western society to find meaning in dying and death. Furthermore, American philosopher of medicine, Daniel Callahan sees a struggle within medicine between a research imperative, with its ultimate goal of overcoming death itself, and a long-standing clinical imperative to treat death as part of life and to make the process of dying as humane and comfortable as possible.

Structure

The first two chapters of the book provide a broad background, ranging over the relationships between medicine and religion and the internal development of scientific medicine in the west since the sixteenth century. Medicine was deeply influenced by a Cartesian body-mind dualism that in practice favoured the material and depersonalised the patient, while at the same time the Christian view of death as a transition to a superior, supernatural reality was losing its meaning for an increasing number of people. Material success, earthly happiness, and collective mastery of the natural world were attracting more and more adherents as the goals of the good life.

In the course of the nineteenth century, experimental physiology, cell biology and bacteriology also provided medicine with a hitherto unprecedented reliable knowledge base. Thus the modern hospital and the laboratory became critically linked in the process of producing and applying this new scientific knowledge.

The subsequent chapter is more narrowly concerned with the history of medicine's approach to cancer and is something of a case study of the tensions between advancing scientific knowledge for the long-term attainment of cures compared with caring compassionately here and now for the terminal patient. Promoting the humane care of patients dying, mainly of cancer was, of course, the prime concern of the pioneers of modern hospice and palliative care like United Kingdom's Cicely Saunders.

The book also includes a detailed account of the ways in which this movement spread from the United Kingdom to other 'Anglo-Saxon' countries, showing how the original hospice idea was adapted to local organisational and financial conditions. Recently, selected letters of Dr Saunders, covering the first forty years of the movement in the United Kingdom, have been published.² The correspondence provides a fascinating, blow-by-blow account of the pioneering phase of the hospice and palliative care project.

It also shows that from an early date that it had international dimensions. Cicely Saunders frequently exchanged information on palliative care and related subjects like euthanasia and care of AIDS patients with health professionals and hospice enthusiasts in countries across the world; from North America to Europe (for example, Poland, West Germany, France and Italy) to Africa, Asia and Australasia.

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Of the remaining three chapters in the book, one relates the history of pain control. Clearly, effective pain management has been and remains the *sine qua non* of successful palliative care. Another chapter discusses the history of euthanasia from classical to contemporary times, although the emphasis is on the period from the late nineteenth century when this discussion ceased to be confined to philosophical circles and later became the subject of serious public policy debate.

The final chapter brings together observations and conclusions, especially about medicine's heritage of materialism, reductionism and the cultural roots of caring in late-modern, 'secular' societies. From the late 1980s, the spread of palliative care across Europe was rapid. When the European Association for Palliative Care was set up at the close of 1988, there were 42 members from nine European countries. In less than a decade this had grown to 8,481 members from 29 European countries (plus 141 individual members from 27 countries outside Europe).³

Resonance in Europe

While this book is concerned to a large extent with developments in North America and Australasia, most if not all, the leading issues raised will have strong resonance in Europe. Certainly, this is the case with philosophical issues concerning the nature of modern medicine, the core values of palliative care, or debates about the legalisation of euthanasia. Even, for example, when considering the important issue of the organisation of palliative care services, the history of adaptation of the British hospice archetype is similar to that in other European countries. So the material in the book, in this respect, will provide European readers with more in-depth information about experiments in organisational forms in different but relevant health systems in comparable economically advanced countries.

Diversity of service form was, of course, the case in Europe itself virtually from the outset. The United Kingdom pioneered the process with inpatient hospice care from 1967. Sweden introduced hospital-based home care in 1977, Italy a home care programme in 1980, Germany hospital inpatient care in 1983, Spain a palliative care unit within a hospital medical oncology department in 1984, Belgium a palliative care unit and a home care service in 1985 and the Netherlands inpatient hospice care in 1991. Interest in hospices

Table 1 The 'Bridges to Health' model

Population characteristics	Priority concerns	Major health care components	Health care goals
Healthy	Longevity by preventing accidents, illness and early stage illness progression	Doctors' offices, health clinics and publicly available health information	Staying healthy
Maternal and infant health	Healthy babies, low maternal risk, fertility control	Perinatal services, delivery and perinatal care; fertility control/ enhancement	Staying healthy
Acutely ill, with likely return to health	Return to healthy state with minimal suffering	Emergency services, hospitals, doctors' offices, medications or short term rehabilitation	Getting well
Chronic conditions, with generally 'normal function'	Longevity, limiting disease progression, accommodating environment	Self-management, doctors' offices, hospitalisations, accident and emergency visits	Living with illness or disability
Significant but stable disability (including mental disability)	Autonomy, rehabilitation, limiting progression, accommodating environment, caregiver support	Home-based services, environmental adaptation, rehabilitation and institutional services	Living with illness or disability
"Dying" with short decline	Comfort, dignity, life closure, caregiver support, planning ahead	At-home services, hospice and personal care services	Coping with illness at the end of life
Limited reserve and serious exacerbations	Avoiding exacerbations, maintaining function and specific guidance planning	Self-care support, at-home services, 24/7 on-call access to medical guidance and home-based care	Coping with illness at the end of life
Long course of decline from dementia and/or frailty	Support for caregivers, maintaining function, skin integrity, mobility and specific advance planning	Home-based services, mobility and care devices, family caregiver training and support and nursing facilities	Coping with illness at the end of life

emerged as early as the 1970s in Poland, but only after the fall of communism were services systematically developed in central and eastern Europe in the 1990s.^{4,5}

Towards integration of palliative care and care of the chronically ill

Historically, concern about palliative care developed separately from that about serious, chronic illness management, but they are both in fact quintessentially patient-centred responses to the same contemporary epidemiological, demographic, social and economic forces, requiring basic changes in health system organisation and medical practice. Across the economically advanced world, health services managers, researchers, clinicians and policymakers are now focussed on the need for better quality, integrated care for chronic disease sufferers and on the more

general issue of restructuring health care systems. This restructuring has the objective of moving systems away from their historical orientation to hospitals devoted to medical specialities and acute care, towards more community and home-based care for people, especially older people, with serious, chronic conditions.

The next logical step is to better coordinate palliative care and chronic illness care. The 'Bridges to Health' model recently developed for application in the United States health system in response to the Institute of Medicine's six goals for care in general (safety, effectiveness, efficiency, patient-centeredness, timeliness, and equity), is one interesting conceptual approach to this task, as well as the larger task of health care system restructuring.^{6*}

Focussed on the interests of patients,

rather than those of individual or institutional providers, the proponents of the model divide the whole population into eight groups: those in good health; in 'maternal/infant situations'; those with acute illness; living with stable chronic conditions; with serious but stable disability; with failing health near death; with advanced organ system failure; and with long-term frailty. Each group has its own service priorities, as well as definitions of optimal health, and the model encourages us to think how programmes for groups that meet the universal need for integrated care might be promoted, as specified in Table 1.⁶

Many health professionals, and indeed

citizens in general, have become used to conceiving of the health care system in the old fragmented way.⁷ The 'bridges to health' model offers new conceptual clarity and helps launch us on the journey to a more integrated system of health care. This promises to improve quality of care for the chronically ill and the dying as well as other population groups.

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ECDC: Tackling the free movement of microbes

Zsuzsanna Jakab

Summary: Now entering its third year, the European Centre for Disease Prevention and Control (ECDC) is showing the value of having an expert agency to support EU Institutions and Member States in meeting the challenge of managing communicable diseases in an interconnected world: strengthening EU preparedness and response to disease outbreaks and consolidating EU level disease surveillance. The Centre produces scientific advice and risk assessments on a wide range of issues; communicating the results of its activities via Eurosurveillance (an independent scientific journal), as well as using new technologies such as webcasting. ECDC's first ever Annual Epidemiological Report, published in June 2007, analyses ten years of surveillance data from across the EU and identifies a number of key public health challenges posed by communicable diseases. ECDC's Multi-Annual Strategy for 2007–2013 focuses on how the Centre can help address these challenges.

Key words: EU Health Policy, ECDC, Communicable Diseases, Surveillance, Epidemiology

A generation ago, when a WHO-led global programme had just succeeded in eradicating smallpox, many public health experts believed we were at the dawn of a

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new era. All the major scourges would soon be eliminated, and epidemics would be consigned to the history books. Unfortunately, the emergence of HIV/AIDS in the 1980s and SARS (Severe Acute Respiratory Syndrome) in 2003 shattered this illusion. We are now painfully aware that new communicable diseases can appear

without warning, and that 'old' diseases can re-emerge, sometimes in new drug resistant strains. Furthermore, SARS highlighted the speed with which a communicable disease can spread internationally in the age of globalisation. This interconnectedness of public health in Europe and internationally, was one of the main

reasons why the European Union established a European Centre for Disease Prevention and Control (ECDC).

Why ECDC was created

Increasing the interconnectedness of its Member States' economies and societies is a central objective of the European Union. The Union is built on four freedoms: the free movement of goods, persons, services and capital. However, as people, farm animals and food cross borders they will inevitably, on occasion, take unwanted microbes with them. This 'free movement of microbes' means that public health developments in one EU country can be of immediate concern to its European partners. For example, big hotels in major EU cities typically have guests from across the EU, so a disease outbreak centred on such a hotel can have implications for numerous Member States. Food producers in the EU typically sell to clients across the EU, so investigating food borne outbreaks can also require cross border investigation.

EU cooperation on the surveillance of communicable disease started in the 1980s with the EuroHIV network and expanded during the 1990s. By 2004 there were some sixteen EU funded networks carrying out disease surveillance and linking disease experts. Since the late 1990s Member States have also been exchanging information on disease outbreaks with the potential to spread across borders, via the EU's Early Warning and Response System (EWRS) on public health threats.

ECDC was created to consolidate and further develop this cooperation. Surveillance networks had been funded on a project by project basis, often focusing on just one or a small group of diseases. ECDC's mission was to develop a long term surveillance strategy and consolidate existing activities. ECDC was to assist the European Commission in running the EWRS and offer a pool of expertise and resources to help respond to incidents. The Centre was also given the role of expert advisor to the EU Institutions and Member States on communicable disease issues.

What has been achieved

Enabling legislation to create ECDC was passed by the European Parliament and Council¹ in the spring of 2004. The Centre's first Director, Zsuzsanna Jakab, who was formerly the State Secretary at the Ministry of Health in Hungary, was appointed at the end of 2004 and took up

her post on 1 March 2005. By May 2005 a core staff was in place and ECDC became operational.

Although still a young organisation, ECDC has become a key partner for EU and EEA/EFTA countries in the fight against infectious diseases. The Centre played a significant role in the EU's response to the arrival of H5N1 avian influenza in the EU neighbourhood in the autumn of 2005, providing an overall assessment of the public health risk associated with this development, scientific guidance on the protection of people exposed to infected birds and participating in international missions to affected countries. Working closely with the European Commission and WHO Europe, ECDC developed a methodology to help countries assess their preparedness against a possible influenza pandemic. By the end of this year ECDC officials will have conducted preparedness assessment visits to all of the EU and EEA/EFTA Member States.

ECDC is also developing input to the European Commission on actions to address the continuing challenge of tuberculosis in the EU and held a scientific seminar on tuberculosis in March 2007.² It has also led an expert group to investigate the emergence of drug resistant strains of *Clostridium difficile* in EU countries and established a network of national focal points on antimicrobial resistance issues.

ECDC's disease-specific activities are carried out within seven horizontal projects which cover the range of 49 communicable diseases that are notifiable at EU level.* The Centre has expanded from 40 staff at the end of 2005 to nearly 200 staff by the end of 2007. Though much smaller than its US namesake, and considerably smaller than the public health institutes of France, Germany and the UK, it can still make a sizeable scientific contribution.

Improving EU level disease surveillance

As already mentioned, a core task for ECDC is the consolidation and development of a Europe wide surveillance system that provides high quality, comparable and easy to access information on all infectious diseases of interest at EU level. By 2005, when the Centre became operational, each of the sixteen Designated

Surveillance Networks had their own databases and systems of reporting. With a growing number of networks, the need for coordination and a standardised approach to data collection became urgent. To address this need, ECDC has been conducting an external evaluation and assessment of the existing EU wide surveillance networks.

Already in 2007, Member States will report their data to a single EU level surveillance database hosted by ECDC (TESSy – The European Surveillance System). This task includes managing the delicate transfer of their various existing surveillance databases to ECDC. A number of benefits arise from this approach, in particular the standardisation of procedures, databases and outputs. This in turn allows for the tackling of infectious disease surveillance in a synergistic way, in order to better understand and control the threat posed by infectious diseases. In addition, ECDC will also be responsible for the maintenance of networks of reference laboratories.

Vigilant to the emergence of health threats

ECDC is tasked with reinforcing and developing Europe's rapid alert systems against disease outbreaks. The Centre is constantly monitoring health threats across the EU and, as intended, is taking over the responsibility of hosting the information technology system that supports the Early Warning and Response System.

ECDC's early warning and response activities are based on three main sets of functions: a 'round the clock' availability of specialists in communicable diseases, a daily briefing where all active threats are discussed and decisions are made about epidemic intelligence processes and ECDC actions to be taken, as well as a database to store, process and report potential health threats (the Threat Tracking Tool – TTT).

Furthermore, a state of the art Emergency Operations Centre (EOC) has been set up at ECDC's premises, in order to ensure optimal communication and coordination mechanisms for risk assessment with all Member States. It is used on a daily basis for standard epidemic intelligence activities, but allows for rapid and efficient response and communication should a

* 46 diseases are specified in Commission Decision 2003/542/EC, plus West Nile Virus, SARS and human cases of H5N1 avian influenza which are also notifiable.

major international public health event occur. In addition, ECDC can assist countries by mobilising Outbreak Assistance Teams and contributing experts to international teams if needed.

Technical and scientific advice

Another core task of ECDC is to provide sound and independent technical and scientific advice. For this the Centre brings together technical expertise in specific fields through its various EU wide networks and ad hoc scientific panels. These panels have been set up in order to answer specific questions forwarded to the Centre by the European Commission and Member States. Two scientific panels have already produced scientific advice, one on avian influenza and the other on seasonal influenza vaccine and pneumococcal vaccine. Their work has been published as technical reports. Currently, scientific panels are addressing questions regarding the human papilloma virus (HPV) vaccine and influenza H5N1 human vaccine.

As already mentioned, ECDC has been working with the European Commission and the WHO Regional Office in Europe to assess national pandemic preparedness plans through country visits and by organising regional workshops. It has already produced a report with a first preparedness review of 27 countries (25 EU member states plus Iceland and Norway),³ with a second status report to be released after completing the assessment of all EU countries. This report is the first formal documentation of the EU's pandemic preparedness status; it describes progress made and highlights areas where further improvements are needed.

Communicating on ECDC's activities

The Centre has a mandate to communicate both to stakeholders and the general public about its activities. Reports and guidelines are made available on ECDC's website and the media is kept updated on the Centre's major activities through press releases, press conferences and webcasts.⁴ Currently the Centre has an interim website which is being continuously improved until a fully fledged webportal is in place in 2009. Information addressed to the general public will be offered in all EU official languages, while information targeted at experts and public health officials will be published in English only.

The leading open access European scientific journal devoted to communicable diseases, *Eurosurveillance*, became the

independent scientific in-house journal of ECDC. Following ten years successful collaboration between the Institut de Veille Sanitaire in Paris, France and the Health Protection Agency in London, United Kingdom and under the auspices of the European Commission, the ECDC took over the funding and publication of this journal in March 2007. *Eurosurveillance* is available in three separate formats: weekly and monthly online releases and a quarterly print compilation.⁵

The EU's main challenges in infectious diseases

The Centre launched, in June 2007, its first ever Annual Epidemiological Report, a key publication that for the first time offers an overview of the situation in respect of communicable diseases in 25 EU countries and Iceland and Norway. It also examines the social and demographic contexts over the last decade, in order to make action proposals for decision makers to strengthen prevention, control and surveillance in Europe.

The report shows that the incidence of most of the 49 diseases analysed by ECDC has either declined or remained stable over the past ten years, which confirms that public health systems in the EU are generally good at fighting infectious diseases. But this should not lead to complacency, as some negative trends were identified. The fact that new infectious diseases can emerge without warning, and existing viruses and bacteria can adapt or mutate, should also not be underestimated.

This report also gives a clear picture of the major health threats faced by Europe in the area of infectious diseases, which also represent the areas identified by ECDC as priorities in its work plan. These include the growing problem of antimicrobial resistance and healthcare associated infections, as well as the rising rates of HIV/AIDS; with an estimated 30% of HIV positive individuals in the EU being unaware of their infection. Another threat is tuberculosis, which is rising among vulnerable groups such as migrants, and also where cases of drug resistant tuberculosis are being seen across the EU, particularly in the Baltic States.

Not to be dismissed is the ongoing threat posed by seasonal influenza, which each winter causes hundreds of thousands of people in the EU to become seriously ill. ECDC's epidemiological report shows two further diseases with very high incidence numbers, namely Chlamydia

infection and campylobacteriosis. Even though they do not cause such serious disease as the priority diseases mentioned above, the high number of cases already represents a huge challenge.

The future of ECDC

In June 2007 ECDC's Management Board endorsed the key principles of a long term strategy to develop the Centre's activities and help address the key challenges identified in its Annual Epidemiological Report. There is a long term and ambitious agenda for ECDC to work on in the area of communicable diseases. Equally though, it is possible that the Centre's mandate could be expanded to include some other public health issues.

This autumn, following a public tender, ECDC will appoint an independent consultant to conduct an evaluation of the Centre's activities. The results of this evaluation will be given to the Centre's Management Board, who in turn will make recommendations to the European Commission. Based on the results of the evaluation and the recommendations of the Management Board, the European Commission will decide, probably towards the end of 2008, whether the ECDC's Founding Regulation needs to be amended.

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Promoting the quality of health services in Bulgaria

Olga Avdeeva and Lidia Georgieva

From the mid-1990s, Bulgaria has been undergoing significant economic, political and social change arising from the challenges of transition and the structural measures needed to achieve EU accession in January 2007. Health system reforms, as an integral part of economic and social reforms, have aimed to make the Bulgarian health system more efficient and responsive to patients' needs by improving both the delivery and quality of services.

Specific mechanisms were expected to promote better quality health services and provide solutions to a range of challenges, including: competition between providers for contracts with the National Health Insurance Fund (NHIF); inclusion of quality control mechanisms in these contracts; and increased choice for Bulgarians, in terms of both service providers and voluntary health insurance plans.

Legal and structural improvements to facilitate better quality

The quality of medical services in Bulgaria is now monitored by the Ministry of Health, NHIF, the Bulgarian Medical Association and the Union of Dentists. Standards for different medical specialities were laid out in the 2004 Health Act.¹ This also outlined the responsibilities of the 28 regional health centres and the Ministry of Health in controlling the competencies of medical specialists and monitoring the quality of care.

In 2003, hospital accreditation, undertaken by an Accreditation Council at the Ministry of Health, was introduced; now

some hospitals have the International Organisation for Standardisation (ISO) certificate. However, these initiatives have neither been very successful, nor well received, due to a lack of incentives to reward such high quality care, as well as the poor links between the accreditation process and any difference in payments received from the NHIF.

Amendments to the Act on Professional Organisations of Physicians and Dentists in 1998² imposed an obligation on these professional associations to establish rules for good medical practice for their respective members. As a result, the concepts of life-long learning and continuing education have been accepted and viewed as a component of any quality assurance system.

Patient empowerment is a new and important approach to improving the quality of health services in the country. Different methods are used to give patients a greater say over their medical care, such as in choice of provider and improved access to information. A process for patient complaints and appeals is also enshrined in both the 2004 Health Act¹ and the Act on the Professional Organisations of Physicians and Dentists.²

The 1998 Health Insurance Act³ and the National Framework Contract⁴ also outline the individual's right to choose general practitioner, without administrative or geographical constraints. Individuals can also choose in which hospital to be treated, although most will still be assigned a specific consultant within this hospital. Since 2005, some patient groups have been able to choose their own specialist without general practitioner (GP) referral, as in the case of mothers in respect of paediatricians and gynaecologists. Considerable progress has also been made through the transition from a paternalistic to a more autonomous approach to decision making. Now patients are

informed about the relative risks and benefits of treatment alternatives and can participate in making final decisions on courses of action to adopt.

Contracting to enhance the quality of health services

Enhancing the quality of health services was one key reason for the introduction of contracting reforms. This shift to contracting between the NHIF and health providers was accompanied by a move away from historical or norm-based budgeting to performance related payments.

Quality control mechanisms in contracts between providers and the NHIF oblige providers to participate in a comprehensive quality assurance system. Contracts now specify the process of service delivery, as well as the medical standards and guidelines to be followed by providers; all of which are expected to lead to quality improvements.

Both public and private sector providers can enter into contracts with the NHIF to deliver services. The NHIF specifies the requirements that providers must meet in order to be eligible to participate in the provider selection process; an initial quality assurance measure in theory excludes those providers that do not meet minimum structural quality requirements. However, these measures of selective contracting are not applied fully in practice, thus the potential to facilitate quality improvements has not been fully realised.

Methods of provider payments and incentives to achieve better quality

New methods of paying providers were intended to increase efficiency and ensure the high quality of services. Case-based payments (clinical pathways) for public and private inpatient providers were introduced in 2001. Although there are discussions regarding the efficiency of NHIF

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payments, in particular these are thought to have improved the continuity and coordination of care across different disciplines and sectors, as well supporting clinical effectiveness and clinical audit.

In Bulgaria, inpatient public sector health personnel are, in the main, salaried; however, the incentives of additional performance-related bonuses have since 2002 been included in provider contracts with the NHIF. These bonuses link the promotion of quality to the reimbursement process.

The question of how to provide incentives to achieve high quality in primary care remains an open issue. The establishment of independent (private) practices for primary care physicians and the creation of a system of general practitioners (GPs) was one of the most successful steps in the reform process. This reform changed the environment in which GPs now operate, from a system of salaried physicians into a system based on capitation, adjusted for age and gender, with the payment of bonuses dependent on the evaluation of activity indicators and quality parameters. Higher levels of remuneration have also been made available to those working in sparsely populated and/or harsh remote regions, as well as for the provision of so-called 'socially important' services, such as preventative services and child immunisation. Introducing this capitation payment mechanism into the reimbursement system also has given GPs an incentive to invest in improvements in the quality of their services, in order to attract patients who now are 'shopping around' for the best primary care services.

Improving quality by generating competition

Privatisation was seen as the most powerful tool in Bulgaria to increase both quality and competitiveness. Competition between GPs encouraged by this privatisation process might, it was thought, force less productive GPs out of business. However, this potential for productivity improvement has been limited, due to the lack of competition between providers in some rural areas, as well as the continued existence of incentives for cream skimming and supplier induced demand.

Private practice was legalised in 1991 and has expanded significantly: private outpatient facilities now account for about 30% of all medical centres, 95% of all specialised individual and group practices and 16% of all hospitals.⁵ In 1992, the municipalities were also given ownership of most health care facilities. Following the legal framework of the Health Establishments Act,⁶ state and municipality-owned facilities were transformed into private state and municipality-owned enterprises. By making use of the economic instruments of competition and private property, it was hoped to set in motion a process that would result in better quality services and more successful management of health care facilities' resources. Despite this, the private market has remained limited, since providers that do not have contracts with the NHIF must rely on out-of-pocket payments by patients.

Voluntary health insurance (VHI) in Bulgaria now supplements coverage of the state's basic benefit package by offering variety in providers, waiting times, quality

and other amenities that are often otherwise paid for out-of-pocket. Yet, the market for voluntary health insurance remains limited due to financial barriers to access that most individuals must contend with. So far it has not contributed significantly to quality improvements in health services for the general population, except for those services provided by health professionals reimbursed by both the public and private sectors who are thus able to treat public and private (including VHI funded) patients differently.

The mixture of approaches implemented in Bulgaria, with the goal of promoting the quality of health care services, has both advantages and limitations. Regardless, it can be viewed as a substantial undertaking, that has been complemented by changes in the organisation and financing of health care, coupled with a commitment to efficiency and the needs of patients.

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Health Economics, Policy and Law

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Mythbusters

Myth: Early detection is good for everyone

Sometimes patients schedule annual visits to health professionals even if they do not have any symptoms, because clinicians might discover something with their specialised knowledge and technologies that enable ‘early detection’ of illness. Doctors and advocacy organisations often encourage this screening of healthy people, in the belief it is good practice.

Unfortunately, many widely used tests are not very accurate, or they find conditions for which there is no effective treatment. At their worst, they leave patients worse off than they were before.

No clear answers

Evidence-based guidelines suggest that instead of an annual health check-up, for which there is no evidence, doctors should tailor screening to individual patient health profiles and move to ‘opportunistic’ screening – taking the time to talk about prevention and screening when patients come see them for an acute problem.¹⁻⁴

According to some researchers, doctors should also focus screening on people who can benefit the most, provide follow-up treatment, and monitor their patients’ compliance with medical recommendations. Finally, they should screen only for conditions that cause serious illness or functional difficulties, and only when an accurate test and effective treatments are available.⁵

Of course, no test is 100% accurate. If a condition is very rare in the population being screened, the false-positive rate will

be high. Even with common conditions, prevalence will still be low enough to lead to many false positives. These false results cause stress and anguish for patients who do not actually have the condition.^{6,7} A test that provides a false negative result is also problematic, as it can lead to complacency and a false sense of security – for example, a common urine dipstick test to detect diabetes could fail to do so in four of every five patients who have the disease.⁶

Another problem with many screening tests is ‘leadtime bias’ – the test could discover a disease before the patient feels ill, but it does not actually extend the patient’s life. This early detection can artificially inflate survival time by moving up the diagnosis date, making the test appear to be useful even though mortality does not in fact change.^{8,9}

Exhibit A: The PSA test

Early detection is often an important strategy in the fight against cancer, particularly with cancers that are aggressive and must be found early to improve the patient’s odds of survival. However, one of the more widely used tests – to detect prostate cancer, a relatively slow-growing form of cancer – is quite problematic.

The prostate-specific antigen (PSA) test does not detect cancer itself – only a biopsy can do that – but rather levels of a protein produced by the prostate gland which is associated with prostate cancer. The test leads to treatment for many cases of cancer that, if left alone, would never become life-threatening.

Advocates often claim that since the PSA test was introduced, deaths from prostate cancer have dropped, but mortality rates started falling well before the PSA test could have had an effect.¹⁰⁻¹² The test is not recommended for widespread screening of men without symptoms,

Mythbusters are prepared by Knowledge Transfer and Exchange staff at the Canadian Health Services Research Foundation and published only after review by a researcher expert on the topic.

The full series is available at www.chsrf.ca/mythbusters/index_e.php. This paper was first published in 2006. © CHSRF, 2006.

largely because of its high false-positive rate. Patients receiving a false-positive result can suffer anxiety, and they could have to undergo painful and unnecessary follow-up treatments that can have severe side effects, such as impotence and incontinence.^{10–11,13–14}

More importantly, research to date shows that patients with prostate cancer who take the test have no better odds of surviving than patients who do not. This includes a recent study of more than 71,000 men, which found similar mortality among screened patients compared to unscreened patients.¹⁵ A Canadian study also estimated only 16% of tested men with prostate cancer would have their lives extended by treatment. The rest would have died of another cause before the cancer had a chance to become lethal.¹⁶

Exhibit B: Prenatal diagnosis of genetic abnormalities

Not all early detection strategies are about prevention. In some cases, they can instead provide advance knowledge about a medical condition that already exists. However, sometimes this information can raise a series of difficult or uncomfortable decisions for some patients.

One example is the practice of examining fetuses early in the pregnancy to provide early knowledge about birth defects and other problems. This can be accomplished through many forms of non-invasive testing, including combinations of blood test and ultrasound.

In the case of genetic abnormalities such as Down's syndrome, women considered by health professionals to be of advanced age for childbirth (usually over age 35) are often offered invasive tests such as chorionic villus sampling in the first trimester and amniocentesis in the second trimester.¹⁷

The accuracy of these diagnostic tests is not in question. However, they may often raise a number of difficult decisions for mothers-to-be, including whether or not to terminate the pregnancy. Although many mothers may appreciate this information, for others this early

detection may result in increased anxiety and even regret at having consented to the test.¹⁸

Conclusion

Before any specific test is put into widespread use, patients and practitioners need to consider whether it is worthwhile and accurate, and whether they would be empowered to do something with the results.

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The Case for Chocolate

Bandolier obviously has chocolate lovers among its readers, but chocolate lovers who want a healthy lifestyle. Can it really be true, they ask, that chocolate can be good for you? Henry's mother's hairdresser's friend was always of the opinion that a little of what you fancy does you good, but here a systematic review¹ promised some evidence to support any prejudices.

Stearic acid

Observational studies of stearic acid (dietary, or serum levels) generally show that it is associated with higher levels of heart disease, either as incidence or mortality. Stearic acid comes predominantly from meat and dairy products, so there is little surprise there. Stearic acid from chocolate is a small contributor to stearic acid intake, of about 5% in the average western diet.

Flavonoids in chocolate

Chocolate, dark or milk, has higher levels of flavonoids or oxygen radical absorbance capacity than almost any other food, based on weight (Figures 1 and 2) or on energy. Only apples come close.

Chocolate and mechanisms

Over 20 small trials have studied the effects of chocolate on physiological and biochemical parameters over the short term. The quality of the studies and the magnitude of the effects cannot be seen from the review. Several reported lower blood pressure, decreased low density cholesterol oxidation, decreased platelet aggregation, improved endothelial function, and greater antioxidant capacity.

Flavonoids and heart disease

The review reports 11 prospective observational studies of the association between flavonoid consumption and heart disease or stroke. Studies were conducted in populations of 500 to 40,000 (about 190,000 people in total), followed up for 5 to 28 years. Most reported some reduction in coronary heart disease mortality. A meta-analysis indicated a significant protective effect between flavonoid consumption and risk of coronary heart disease mortality, with a relative risk of 0.81 (95% confidence interval 0.71 to 0.92).

Comment

Many different polyphenols contribute to antioxidants in the diet. There is no absolute need to eat chocolate to get antioxidants. But chocolate has

Figure 1: Flavonol and procyanadin content of chocolate compared with other foods high in antioxidants

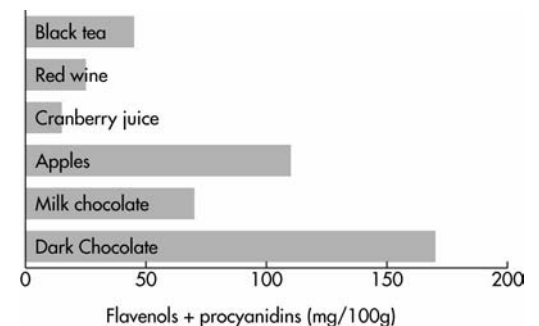
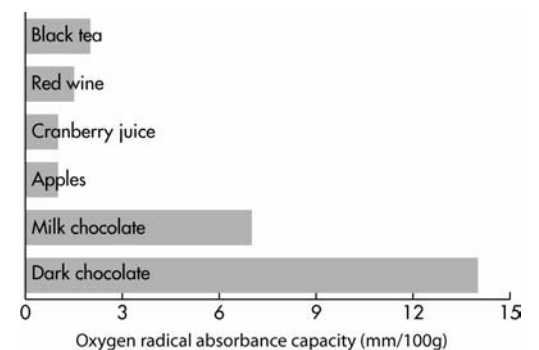


Figure 2: Oxygen radical absorbance capacity of chocolate compared with other foods high in antioxidants



lots of them, and different ones, and is pretty nice on the whole for most of us. Eating too much chocolate is not a good idea, though, because of the sugar and stearic acid it contains. Like so many other things, a little chocolate taken regularly is likely to be a good thing; a little of what you fancy.

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Systematic review

The search was limited to English language studies found in MEDLINE to mid-2005, which examined at least one of several aspects of the relationship between chocolate and cardiovascular health.

Results

The review covered about 140 publications and looked at several different aspects.

Bandolier is an online journal about evidence-based healthcare, written by Oxford scientists. Articles can be accessed at www.jr2.ox.ac.uk/bandolier

This paper was first published in 2006. © Bandolier, 2006.

Eurohealth aims to provide information on new publications that may be of interest to readers. Contact Sherry Merkur at s.m.merkur@lse.ac.uk if you wish to submit a publication for potential inclusion in a future issue.

National strategy to reduce social inequalities in health

Norwegian Ministry of Health and Care Services



Report No. 20 (2006–2007) to the Storting, February 2007

99 pages

Freely available at:

http://www.regjeringen.no/pages/1975150/PDFS/STM200620070020000EN_PDFS.pdf

Translated from Norwegian, this Report to the Storting (Parliament) lays down guidelines for the government and ministry's efforts to reduce social inequalities in health over the next ten years.

It forms part of the government's broader policy for the reduction of social inequalities, promotion of social inclusion and combating poverty. The strategy aims to govern the ministry's work on: annual budgets; management dialogues with subordinate agencies and regional health enterprises; legislation, regulations and other guidelines; inter-ministerial collaboration; organisational measures; and other available policy instruments.

The report first describes social inequalities in health in Norway. Then, policy instruments to reduce social inequalities in health-related behaviours and health care access, as well as economic inequalities in society are discussed. Particular attention is given to children and young people, the labour market and workplace. The report

then goes on to argue that targeted, user-oriented and specially adapted public services are necessary to ensure that the whole population has access to equitable services.

Finally, steps towards reducing social inequalities in health are highlighted, such as: an inter-sectoral review; reporting system; awareness-raising among decision-makers in all sectors and on all administrative levels; cross-sectoral tools (i.e. health impact assessments, social and land use planning); stronger partnerships and local competencies for public health; and strengthened research.

Contents: Introduction; Part 1: Reduce social inequalities that contribute to inequalities in health; Part 2: Reduce social inequalities in health behaviour and use of health services; Part 3: Targeted initiatives to promote social inclusion; Part 4: Develop knowledge and cross-sectoral tools; Appendix: International experiences.

Hearts and Minds at Work in Europe: A European work-related public health report on cardiovascular diseases and mental ill health

Wolfgang Boedeker and Heike Klindworth



Federal Association of Company Health Insurance Funds, 2007

ISBN 978-3-9800600-0-4

137 pages

Freely available at:

http://www.enwhp.org/fileadmin/rs-dokumente/dateien/Hearts_and_Minds_at_Work_in_Europe.pdf

This report was prepared as part of a European Commission project entitled Workhealth, that began in Germany in 2002.

It begins by reviewing the European literature on disease and the workplace, arguing that although work is recognised as a risk factor for two of the most important disease groups in Europe – cardiovascular diseases (CVD) and mental ill health – data on the occurrence of these diseases across occupations and economic sectors are rare. The report also draws attention to the reverse of this relationship; the impact of disease on work.

Adding to the complexity are the links between CVD and mental ill health, as both diseases are potentially causes and consequences of each other.

The report concludes that because stress is known to be the most important work-related risk factor for CVD and mental ill health, sustainable stress prevention is the most effective way to tackle these

problems in the workplace. It argues that these interventions show a positive return on investment. Furthermore, these interventions are most effective when work health and public health aspects are addressed together.

Finally, the report provides recommendations to policy-makers and others, pointing out that effective and sustainable health promotion and prevention calls for collaboration across different professions and policy fields.

Contents: Introduction; The burden of CVD and mental ill health on work; Relationship between CVD and mental ill health; The impact of work on CVD and mental ill health; Strategies for healthy hearts and minds at work; Policy recommendations; Annex A – Structure of the workforce in the EU; Annex B – Further readings; Annex C – The WORKHEALTH II Consortium.

WHO International Clinical Trials Registry Platform

<http://www.who.int/ictrp/en>

The objective of the WHO Registry Platform is to provide a complete view of research that is accessible to those involved in health care decision-making. It also advocates for the public availability of a minimum amount of results information from clinical trials. The web site provides several resources including: The Clinical Trial Search Portal, which enables users to search a central database that contains trial registration data sets; The WHO Network of Collaborating Clinical Trial Registers that provides a forum for registers to exchange information and work together to establish best practice for clinical trial registration; and a list of primary registers that meet certain requirements and contribute data directly to the WHO Search Portal. These web sites are available in English.

Innovative Medicines Initiative (IMI)

<http://www.imi-europe.org>

The IMI is a proposed public-private partnership between the European Federation of Pharmaceutical Industry and Associations (EFPIA) and the European Commission with the overall goal of making Europe the world leader in pharmaceutical research. A key feature of the IMI project is the way different stakeholders work together across Europe, establishing a new type of collaboration between industry, academia, regulators, health care professionals and patients. The IMI web site is available in English and provides details of the organisation, its objectives, news and events, publications for download and relevant links.

Healthcare Cost and Utilization Project (HCUP)

<http://www.hcup-us.ahrq.gov/home.jsp>

Based in the United States, HCUP is a collection of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ). HCUP databases bring together the data collection efforts of State and private data organisations, hospital associations and the US government to create a national information resource of patient-level health care data since 1988. These databases enable research on a broad range of health policy issues, including cost and quality of health services, medical practice patterns, access to health care programmes, and outcomes of treatments at the national, State, and local market levels. The English language web site provides descriptions of and reports from the databases, related software, fact books and reports for download, news and events, as well as technical assistance.

Alliance for Health Policy and Systems Research (HPSR)

<http://www.who.int/alliance-hpsr/en>

The Alliance for HPSR is a WHO-led international collaboration that aims to promote the generation and use of health policy and systems research as a means to improve the health systems of developing countries. Its activities are conducted through a secretariat and over 300 partners worldwide under priority themes including: health workforce, health financing and the role of the non-state sector in health. The Alliance supports the development of national processes for evidence-informed policy-making and capacity for the generation, synthesis, dissemination and use of health policy and systems research knowledge. They regularly publish a newsletter, working papers and reports, all of which are available on-line.

Canada Health Infoway

<http://www.infoway-inforoute.ca>

Launched in 2001, the Canada Health Infoway Incorporated is an independent, not-for-profit organisation whose members are Canada's fourteen federal, provincial and territorial Deputy Ministers of Health. Infoway and its public sector partners have over 100 projects aimed at delivering electronic health record (EHR) solutions to Canadians. The goal is to have an interoperable EHR covering 50% of Canadians by 2010. Details and documents about projects, annual reports, news and events and a newsletter for subscription are available from the web site in both English and French.

News

EUROPEAN MONITOR

International Health Regulations enter into force

In the early twenty-first century, demographic, economic and environmental pressures have created a unique combination of conditions that allow new and re-emerging infectious diseases to spread as never before. The experience of recent decades shows that no individual country can protect itself from diseases and other public health threats. All countries are vulnerable to the spread of pathogens and their economic, political and social impact.

The emergence and rapid spread of SARS in 2003 was a clear indication of how globalisation has made the world much smaller, creating a need for collective defences and for shared responsibility in making these defences work. This is the underlying principle of the revised International Health Regulations that entered into force on 15 June. The Regulations consist of a comprehensive and tested set of rules and procedures which are intended to help make the world more secure from threats to global health.

“SARS was a wake-up call for all of us. It spread faster than we had predicted and was only contained through intensive cooperation between countries which prevented this new disease from gaining a foothold,” said Margaret Chan, Director-General of the World Health Organization. “Today, the greatest threat to international public health security would be an influenza pandemic. The threat of a pandemic has not receded, but implementation of the IHR will help the world to be better prepared for the possibility of a pandemic.”

Agreed by the World Health Assembly in 2005, the Regulations establish an agreed framework of commitments and responsibilities for countries and for WHO to invest in limiting

the international spread of epidemics and other public health emergencies while minimising disruption to travel, trade and economies. Under the IHR, countries will be required to report all events that could result in public health emergencies of international concern, including those caused by chemical agents, radioactive materials and contaminated food within 24 hours of assessment.

The regulations also require that every country designate a National IHR Focal Point, charged with providing to and receiving information from WHO on a 24 hour basis, seven days a week. Each country is also committed to develop and maintain core public health capacities for surveillance and response. These capacities also include outbreaks of chemical, radiological and food origin. Countries are required to establish these capacities as soon as possible and within a deadline of five years after entry into force of the revised IHR.

The IHR also recognises that international travellers be treated with respect for their dignity, human rights and fundamental freedoms when health measures are applied. However, they also allow for examinations and other required health measures to protect against the international spread of disease. Existing international disease control programmes, addressing infectious diseases, food safety and environmental safety will also be strengthened. These programmes make a vital contribution to the global alert and response system as they allow the development of generic and threat-specific capacities.

The IHR also build on the recent experience of WHO and its partners in both responding to and containing disease outbreaks. Recent experience shows that addressing public health threats at their source is the most effective way to reduce their potential to spread internationally. The Regulations will

help to ensure that outbreaks and other public health emergencies of international concern are detected and investigated more rapidly and that collective international action is taken to support affected countries to contain the emergency, save lives and prevent its spread.

WHO has already developed and built an improved events management system to manage potential public health emergencies. It has also been working with its partners to strengthen the Global Outbreak Alert and Response Network (GOARN), which brings together experts from around the world to respond to disease outbreaks.

David Heyman, WHO Assistant Director-General for Communicable Diseases, noted that while “implementing the IHR is a collective responsibility and depends on the capacity of all countries to fulfil the new requirements, WHO will help countries to strengthen the necessary capacities to fully implement the Regulations. This is our responsibility and we expect that the entire international community is committed to the same goal of improving international public health security.”

More information on the revised IHR can be viewed at <http://www.who.int/entity/csr/ibr/en/index.html>

World Health Report 2007

More than at any previous time in history, global public health security depends on international cooperation and the willingness of all countries to act effectively in tackling new and emerging threats. That is the conclusion of this year's World Health Report published by the WHO in Geneva on 23 August. Entitled *A Safer Future: Global Public Health Security in the 21st Century*, it concludes with six key recommendations to secure the highest level of global public health security: full implementation of the revised International Health Regulations

Press releases and other suggested information for future inclusion can be e-mailed to the editor
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by all countries; global cooperation in surveillance and outbreak alert and response; open sharing of knowledge, technologies and materials, including viruses and other laboratory samples, necessary to optimise secure global public health; global responsibility for capacity building within the public health infrastructure of all countries; cross-sector collaboration within governments; and increased global and national resources for training, surveillance, laboratory capacity, response networks, and prevention campaigns.

According to WHO, new diseases are emerging at an unprecedented rate, often with the ability to cross borders and spread rapidly. Since 1967, at least 39 new pathogens have been identified, including HIV, Ebola haemorrhagic fever, Marburg fever and SARS. Other centuries-old threats, such as pandemic influenza, malaria and tuberculosis, continue to pose a threat to health through a combination of mutation, rising resistance to anti-microbial medicines and weak health systems.

“Given today’s universal vulnerability to these threats, better security calls for global solidarity,” said Margaret Chan, Director-General of WHO. “International public health security is both a collective aspiration and a mutual responsibility. The new watchwords are diplomacy, cooperation, transparency and preparedness.”

World Health Report 2007 traces the history of efforts to contain infectious diseases (including plague, cholera and smallpox). It describes the evolution of outbreak surveillance and response activities of international partnerships of agencies and technical institutions. These include GOARN (Global Outbreak Alert and Response Network), the chemical and environmental health incident alert and response system, and the Global Polio Eradication Initiative, which is supporting surveillance of many other vaccine-preventable diseases.

It shows how and why diseases are increasingly threatening global public health security. High and rapid mobility of people is one factor. Airlines now carry more than two billion passengers a year, enabling people and the diseases that travel with them to pass from one country to another in a matter of hours. The potential health and economic impact was seen in 2003 with SARS,

which cost Asian countries an estimated US\$ 60 billion in gross expenditure and business losses.

Some of the human factors behind public health insecurity identified in the report, include inadequate investment in public health resulting from a false sense of security in the absence of infectious disease outbreaks; unexpected policy changes such as a decision temporarily to halt immunisation in Nigeria, which led to the re-emergence of polio; conflict situations when forced migration obliges people to live in overcrowded, unhygienic and impoverished conditions heightening the risk of epidemics; microbial evolution and antibiotic resistance; and animal husbandry and food processing threats such as the human form of bovine spongiform encephalopathy (BSE) and Nipah virus.

The report also sets out the WHO strategic action plan to respond to an influenza pandemic, drawing attention to the need for stronger health systems and for continued vigilance in managing the risks and consequences of the international spread of polio and the newly emerging strain of extensively drug-resistant tuberculosis (XDR-TB). New health threats have also emerged, linked to potential terrorist attacks, chemical incidents and radionuclear accidents.

World Health Report 2007 is available in English, French and Spanish at <http://www.who.int/entity/whr/2007/>

New country specific data on impact of environmental factors on health

On 13 June the World Health Organization released the first ever country-by-country analysis of the impact environmental factors have on health. The data show huge inequalities but also demonstrate that in every country, health could be improved by reducing environmental risks including pollution, hazards in the work environment, ultraviolet radiation, noise, agricultural risks, climate and ecosystem change.

The new data show that 13 million deaths worldwide could be prevented every year by making environments healthier. In some countries, more than one third of the disease burden could be prevented through environmental improvements. Measure might include using cleaner fuel such as gas or electricity, using better cooking devices, improving the ventilation or modifying

population behaviour (such as keeping children away from smoke) could have a major impact on respiratory infections and diseases among women and children. Reducing levels of air pollution, as set out in WHO’s *Air Quality Guidelines*, would save an estimated 865,000 lives per year.

Low income countries suffer the most from environmental health factors, losing about twenty times more healthy years of life per person per year than high income countries. However, the data show that no country is immune from the environmental impact on health. Even in countries with better environmental conditions, almost one sixth of the disease burden could be prevented, and efficient environmental interventions could significantly reduce cardiovascular disease and road traffic injuries.

Commenting on the publication of the new country estimates, Susanne Weber-Mosdorf, WHO Assistant Director-General for Sustainable Development and Healthy Environments said that they were “a first step towards assisting national decision-makers in the sectors of health and environment to set priorities for preventive action.”

Meantime, in a presentation at the Inter-governmental Midterm Review of Child Health and Environment Action Plans in Vienna on 13 June, Roberto Bertollini from the WHO Regional Office for Europe’s Special Programme on Health and Environment, made use of this data to report that there are 5,000 preventable deaths every day in the European region. Well tested environmental health interventions, he argued, could reduce total deaths in Europe by almost 20%, some 1.8 million lives every year. The range of years of life lost to environmental factors varied fourfold across the continent, with the lowest levels of risk reported in northern and western European countries. The highest rates are all in the eastern part of the region: in the Russian Federation 54 disability adjusted years of life are lost per 1,000 population every year with similarly high rates of 49,48,47 and 46 years of life lost per 1,000 population in Kazakhstan, Turkmenistan, Tajikistan and Kyrgyzstan respectively. Within the EU the highest rate of years of life lost, 39 per 1,000 population is to be found in Estonia, closely followed by its neighbours Latvia and Lithuania with 38 and 34 years of life lost respectively.

Dr Bertollini emphasised that children were particularly vulnerable to these environmental factors. The importance of taking more action to protect children was also emphasised in a prior meeting in Vienna where Lisette Van Vliet, Toxics Policy Advisor, at the non governmental Health and Environment Alliance, stated that development of the foetal brain can be disrupted by exposure to hazardous chemicals at levels that would be less damaging for adults.

Priorities for health under the Portuguese Presidency

The centre piece of actions for health under the Portuguese Presidency will be the issue of migration. A conference entitled *Health and Migration in the EU – better health for all in an inclusive society* will be held in Lisbon on 27–28 September. It has the aim of mobilising Member States, national and international organisations and non governmental organisations to discuss and work on proposals of intervention strategies and policies, in order to promote health, prevent disease and improve access to health care for migrants.

Specifically, the Conference's objectives will be: to assess the twenty-first century international migration moves and their impact on EU demography and the economy; to improve knowledge on migrants' health status and health determinants (accounting for the demographic dynamics of the migratory process and its impact; the specific political and legal frameworks at both national and international levels; the socioeconomic integration of migrant families); to identify best practices about migrants' access to health services (health promotion, prevention and access to care), encompassing formal and informal care, as well as social and cultural activities aimed at facilitating inclusion; and to contribute to the definition of health policies and strategies aimed at improving migrants' integration, which could be implemented at both EU and Member States levels.

Another priority is the European Health Strategy. A round table on health strategies in Europe was held on 12–23 July in Lisbon with the aim of furthering the debate. The programme included parallel sessions on disease specific strategies: cancer, cardiovascular,

diabetes, gender-sensitive strategies, obesity, oral health and tuberculosis.

At a global level, the Presidency has pledged to pay special attention to a range of global health issues, in particular in what concerns the World Health Organization, coordinating community positions in the field of tobacco control (at the 2nd Conference of the Parties of the WHO Framework Convention on Tobacco Control), at the 2nd Meeting of WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, at the meeting of WHO's Intergovernmental Working Group on sharing of influenza virus samples and on the implementation of the International Health Regulations.

The Presidency themes are consistent with the focus on health promotion, disease prevention, access to health care and innovation agreed as part of an 18 month programme with the Slovenian and German presidencies. It has also pledged to continue to develop the 'Health in All Policies' initiative established under the Finnish presidency.

To this end a meeting of the working group on Health and Health Systems Impact Assessment (HIA/HSIA) will take place in Lisbon on 5–6 November. This is one of the subgroups of the High Level Group on Health Services and Medical Care of the European Commission. It aims to develop measurement tools on the impact of EU policies on health and health systems. Following up the work of this group and the Kuopio Conference on Health In All Policies during the EU Finnish Presidency, a network of experts, recently established, will be strengthened. The main themes to be covered will include HIA and HSIA methodologies of implementation and procedures in Member States of the EU; as well as planned or ongoing HIA and HSIA, including Commission funded projects. It is hoped to further develop a European network on HSIA and publication and dissemination of the conference results.

Work begun under the German presidency on both HIV/AIDs and pharmaceutical innovation will continue. On 12–13 October, a meeting of EU national AIDS coordinators will take place in Lisbon with a focus on consolidating the collaboration between European countries, with regards to the fight against

infection in both the WHO European Region and the EU Neighbouring Countries. The meeting will also be open to all countries of WHO Europe Region and other Neighbouring Countries.

Again this meeting is linked into the overarching theme of migration and health in the Presidency programme. Key objectives include reporting on the present situation in the EU, WHO European Region and neighbouring countries, identifying incentives and barriers to HIV prevention, treatment and support to migrant and mobile populations, namely national legislation, policies and practices. Furthermore, it is hoped to reach a consensus on the existing gaps and obstacles when reporting HIV impact on migrant and mobile populations and to agree on priorities and processes to address identified shortcomings.

A conference on pharmaceutical innovation will take place in Lisbon from 19–20 November. The Conference programme will focus on the discussion of the current pharmaceutical research and innovation model at EU level, analysing innovation's main current challenges related to its definition and quantification, financing and new R&D technologies. How regulators will adapt regulatory environments to the new scientific changes, promote cooperation among stakeholders, namely through partnerships, as well as the main reason for the loss of competitiveness of Europe in comparison with the US, will also be discussed. It is envisaged that this will result in the release of a set of concrete recommendations and solutions for the future of the pharmaceutical innovation sector.

More on the health priorities of the Portuguese Presidency can be viewed at <http://www.eu2007.min-saude.pt/PUE/en/conteudos/programa+da+saude/presidencys.htm>

European Commission, businesses and NGOs create forum to battle alcohol-related harm

On 7 June in Brussels, over forty businesses and non-governmental organisations signed the Charter establishing the Alcohol and Health Forum. The Forum, scheduled to meet twice a year, is to focus in particular on actions to protect children and young people and to prevent irresponsible commercial alcohol communication and sales. EU

Member States, European Institutions, the World Health Organization and the International Organisation of Vine and Wine will participate as observers.

Previously in October 2006, the European Commission adopted a Communication setting out an EU Alcohol strategy to support Member States in reducing alcohol related harm. The priorities identified in the Communication were: to protect young people and children; reduce injuries and deaths from alcohol-related road accidents; prevent harm among adults and reduce the negative impact on the economy; raise awareness of the impact on health of harmful alcohol consumption; and help gather reliable statistics. Ways in which the EU could support Member States' actions to reduce alcohol-related harm included exchange of good practice on issues such as curbing under-age drinking, exploring cooperation on information or tackling drink-driving.

The move to establish the new Forum comes at a time when an estimated 200,000 Europeans die every year because of harmful alcohol use. More than one out of four deaths among young men is attributed to alcohol. According to the recently published special *Eurobarometer on Alcohol*, one in ten Europeans usually drink five or more drinks in one session, which is the widely used definition of binge drinking for men. This figure was particularly high among the youngest respondents. Almost one in five young people in the 15–24 age group (19%) drink five or more alcoholic beverages in one session.

The Forum will establish a Science Group which, on request, will provide scientific advice and guidance on matters under discussion. The Forum can also establish Task Forces. The first two have already been established and cover marketing communication and youth-specific aspects of alcohol.

In order to become a member of the Forum, a business or NGO has to submit a written commitment to take action. In other words, all the members have to present a concrete action plan with objectives and information on how the results will be monitored and evaluated. Participation for the sake of participation will not be possible as members will need to report on what they have done and their achievements.

Furthermore, all action plans and

commitments will be made public and all will be observed within one single monitoring framework. The results will also be made public through DG Health and Consumer Protection's website. This will allow the evaluation of successful initiatives, which, in turn could be examples for the other members of the Forum to follow.

In a speech at the launch of the Forum, European Union Commissioner for Health and Consumer Protection, Markos Kyprianou, welcomed the participation of such an impressive group of partners in the fight against alcohol related harm. He did however caution that more would need to come out of the Forum than the already announced actions to protect children and young people and promote responsible commercial communication and sales.

He noted that all stakeholders had critical roles to play saying that he expected the forum "as representatives of the alcoholic beverages industry to develop, distribute and market your products in a responsible manner. While I know that much has been done already, there is much scope for further actions regarding advertising, server training, product presentation, and so on. I expect you as representatives of other economic operators to take on your part of the work; we all know that media, advertisers, retailers, owners of pubs and bars play an extremely important role in changing attitudes and behaviours, especially among young people. I also expect a broad involvement of NGOs and I would welcome active participations from NGOs outside the public health field; representing social, youth, families and consumer interests; while of course respecting each organisation's scale of resources."

The Charter establishing the European Alcohol Health Forum can be found at: http://ec.europa.eu/health/ph_determinants/life_style/alcohol/alcohol_charter_en.htm

The special Eurobarometer on Alcohol is available at: http://ec.europa.eu/health/ph_publication/eurobarometers_en.htm

Commission consultation on the long term future of pharmaceuticals.

On 19 July Directorate General Enterprise and Industry initiated a public consultation on how to improve the

long-term future of pharmaceuticals in Europe. The consultation is particularly targeted at enhancing the regulatory, non-regulatory and research & development frameworks for the pharmaceutical industry.

The objective is to address the public health, scientific and economic challenges that the Commission believes are being faced by the EU pharmaceutical industry. These include increased globalisation of the pharmaceutical sector and ensuring the smooth functioning of the internal pharmaceutical market in an enlarged EU. The Commission also believes that the pharmaceutical industry will have to adapt in response to advances in science and technology.

According to the Commission, globalisation in the pharmaceutical sector stimulates a need to improve the competitiveness of EU pharmaceutical companies to take advantage of new opportunities and to access foreign markets. Globalisation also reinforces the need to maintain local EU research and development capability; as the Commission document states "the centre of gravity for worldwide R&D investment in the field is gradually moving to the United States and Asia. Europe should strive to regain territory it covered for most of the 20th century, when it used to be the home for pharmaceutical innovation."

The Commission believes that the functioning of the EU internal pharmaceutical market could be improved by better regulation in, for example, the areas of clinical trials or variations to marketing authorisations. It notes that some existing regulations may be overburdening and affect competitiveness without always bringing public health benefits. It also suggests that improvements to the internal market could be made by enhancing the transparency and harmonisation of national pricing and reimbursement schemes. The importance of patient safety is also emphasised with the paper stating that "recent analysis has demonstrated the existence of multiple and sometimes inefficient requirements as regards pharmacovigilance in the EU. The challenge is thus to strengthen and rationalise drug safety monitoring, while avoiding unnecessary requirements that would impair patients' access to treatments." Globalisation of the market can also contribute to increases in counterfeit medicines that,

in turn, produce a greater need to protect the health of EU citizens.

The consultation document includes a list of six key questions that respondents should use as guidance for their contributions. In addition to inviting comments on the main challenges outlined in the consultation document, other questions include a request for concrete measures to ensure the safety of medicines supplied in the EU, addressing in particular counterfeit medicines, and the provision of high quality and affordable medicines to third countries.

The Commission would also like suggestions on how to improve Europe's international competitiveness and foster convergence and transparency as regards pricing and reimbursement in the EU. Views are also requested as to the appropriateness of the current EU regulatory framework for emerging technologies like regenerative and personalised medicine, as well as nanotechnology.

Responses are due by 12 October. Following this public debate, the Commission intends to address a Communication to the Council of the European Union and to the European Parliament on the future of the EU single market in pharmaceuticals for human use, outlining its vision and strategy for the sector, as well as concrete action items. The Communication will build on this public consultation and will outline how its outcome was taken into account.

The consultation can be viewed at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_07/consultationpaper-2007-07-19_en.pdf

European Heart Health Charter launched

On 12 June the European Heart Health Charter was launched at the European Parliament. It was signed on behalf of fourteen European professional and public health organisations in the presence of representatives of Member States, national cardiac societies and heart foundations. European Union Commissioner for Health and Consumer Protection, Markos Kyprianou and WHO Deputy Regional Director for Europe, Dr Nata Menabde, were also present.

Cardiovascular disease (CVD) is respon-

sible for over half (52%) of deaths in the WHO European Region and almost a quarter (23%) of its disease burden (measured in Disability Adjusted Life Years – DALYs).

Heart disease and stroke are leading causes of death in all WHO European Member States, but there are widening gaps between the eastern and western parts of the Region. While CVD mortality rates have been falling in western Europe in recent decades, a rise can be seen in the more easterly parts of the Region, with an almost ten-fold difference in premature CVD mortality (deaths in people under 65 years of age) emerging between countries. CVD mortality is a major contributor to the almost 20-year difference in healthy life expectancy between the countries of the WHO European Region. The economic costs are also substantial: in 2003, CVD was estimated to have cost the EU economy €169 billion.

The aim of the Charter is to substantially reduce the burden of cardiovascular disease in the European Union and the WHO European Region and to reduce inequities and inequalities in disease burden within and between countries. The Charter highlights the importance of governmental action, in partnership with non-governmental and public health organisations, to create supportive policies and environments that help people adopt healthy types of behaviour. An estimated 80% of heart disease, stroke and type 2 diabetes could be avoided if major risk factors were eliminated, but concerted action is needed to reduce the numbers of smokers and reverse obesity trends in countries, as well as to implement best practice in cardiovascular care.

Commenting on the Charter Professor Georgs Andrejevs, a member of the European Parliament's Committee on the Environment, Public Health and Food Safety, said that "it is not aiming at a unified stance on health care; but rather at achieving high standards in tackling CVD throughout the EU. It is a lever for better policies on, for example, the detection and management of people at high risk and on care for those who suffer from CVD. To that extent it represents a real tool in the promotion of public health."

More information on the Charter is available at <http://www.heartcharter.eu/>

European Commission adopts White Paper on Sport

On 11 July the European Commission adopted its first comprehensive initiative on sport. The White Paper recognises the important social and economic roles of sport, while respecting the requirements of EU law. It is the result of extensive consultations over the past two years with sport organisations, such as the Olympic Committees and sport federations, as well as with Member States and other stakeholders, including an online consultation launched in February this year to which the Commission received 777 replies.

Ján Figel, European Commissioner in charge of Education, Training, Culture and Youth, said "this White Paper is the Commission's contribution to the European debate on the importance of sport in our daily lives. It enhances the visibility of sport in EU policy-making, raises awareness of the needs and specificities of the sport sector, and identifies appropriate further action at EU level."

The White Paper proposes concrete actions in a detailed Action Plan named after the founder of the modern Olympic Games Baron Pierre de Coubertin. The Plan, in particular, addresses the social and economic aspects of sport, including public health, education and social inclusion. Specifically it includes proposals to develop new physical activity guidelines and to create a EU Health-Enhancing Physical Activity network. There will also be the award of a European label to schools actively supporting physical activities, while a range of EU programmes and funds including Progress, Lifelong Learning, Youth in Action, Europe for Citizens, the European Social Fund, the European Regional Development Fund and the European Integration Fund will be mobilised to improve opportunities for supporting social inclusion and integration through sport activities.

EU sports directors discussed the White Paper in a meeting that took place in Lisbon on 12–14 July. In response to the health messages outlined in the White Paper, the directors highlighted the importance of physical activity in "improving individual and public health, quality of life and life expectancy, with benefits that range far beyond the struggle against obesity and have a major impact on medical care costs".

The meeting conclusions urged governments, sports federations, the education sector, urban planning, transport and the media to work more actively to promote physical activity and “create a living environment that encourages the largest number of people to become physically active”.

The White Paper on Sport will now be discussed by the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Its findings will also be presented to EU sport ministers.

In October, the Commission will organise a conference to discuss the White Paper with sport stakeholders.

The White Paper is available at http://ec.europa.eu/sport/index_en.html

Commission and UEFA launch TV advert to promote physical activity

The European Commission and the Union of European Football Associations (UEFA) will launch a joint TV advertising campaign that aims to encourage European citizens to make physical activity part of their daily lives. The thirty second advert encourages viewers to get out of their armchairs and be physically active, using the slogan “Go on, get out of your armchair”. It is expected to reach between eighty and one hundred million viewers during each match week of the Champions League, as it will be aired free of charge in more than forty European countries at the interval of each of this season’s 125 televised Champions League football games. This has been possible through a partnership with UEFA which has offered up the thirty seconds of airtime that it retains for social initiatives. It is the latest initiative from UEFA to promote health through football (see news article from Georgia).

The advert is a product of co-operation between the Commission’s Health and Consumer Protection Directorate General, UEFA and the London-based Abbott Mead Vickers.BBDO advertising agency at a total production cost of €515,000. The Commission had asked the European Association of Communications Agencies to invite its member companies to make proposals to work on the project and AMV.BBDO’s submission was chosen. The agency provided all creative and management

services free of charge.

The initiative comes at a time when poor diets and low levels of physical activity in Europe account for six of the seven leading risk factors for ill health. The lack of physical exercise, coupled with unbalanced diets, has turned obesity into a serious public health problem: obesity related illnesses are estimated to account for as much as 7% of total health care costs in the EU. Studies show that one in three Europeans do not exercise at all in their free time, while the average European spends over five hours a day sitting down. In most EU Member States more than half of the adult population is overweight or obese. It is also estimated that almost 22 million children are overweight in the EU and each year this figure is growing by 400,000. Young people tend to retain excess weight throughout their adult lives and are more likely to become obese.

COUNTRY NEWS

UK and Germany announce International Health Partnership

On 22 August, UK Prime Minister Gordon Brown and German Chancellor Angela Merkel announced the formation of a new international initiative, the International Health Partnership, as part of a global campaign to address the Health Millennium Development Goals (MDGs) and equivalent to the coordination process of the Fast Track Initiative on education, between developing countries and, donors, international health agencies and foundations. The aim of the initiative is to accelerate progress towards MDGs 4, 5 and 6, namely, reducing child and maternal mortality, and tackling specific diseases such as HIV/AIDS by increasing access to and use of health services and delivering improved outcomes. The new initiative will be officially launched on 5 September. It will bring together major donor countries, including the UK, Germany and Norway, alongside international agencies including the World Bank and the World Health Organization.

Referring to the G8’s commitment towards the improvement of health in developing countries outlined earlier in the year, in a joint statement the Prime Minister and the Chancellor affirmed that they were “taking steps working

with others to convert our promises into action.”

While acknowledging the progress that has already been made, including more than doubling aid for health from \$6 billion in 2000 to \$14 billion in 2005; a 60% decline in measles-related deaths, and increased access of two million people to HIV/AIDS treatment, the two leaders stated that they recognise the challenges ahead. Much of the increased aid in recent years has targeted specific interventions but has not built strong sustainable health systems that are essential to deal with all the major causes of ill health. And we know that weak systems - the lack of health workers, clinics, supplies of essential medicines and lack of sustainable health financing systems - are the main barriers to making more rapid progress in improving health outcomes.”

They noted that “of the MDGs, those focussing on health are the least likely to be met...half a million women still die unnecessarily every year in childbirth, ten million children do not reach their fifth birthday, and only one in four of those in need of AIDS treatment in Africa is able to receive it.”

They added that “global health assistance is over complex with many different health partnerships and international organisations providing support through separate aid channels, leading in many cases to fragmented health provision on the ground. These compete for limited trained staff and can function outside the recipient countries’ priorities and structures. This fragmentation has undoubtedly reduced the effectiveness of much aid.”

The agreement, developed with bilateral, international health and funding agencies, developing countries, and foundations commits all partners to: working with country owned plans; creating a mechanism to agree donor support to national plans; coordinating their efforts on the ground; and focussing on the creation of sustainable health systems which deliver improved outcomes. It is expected that partners will coordinate their actions in order to ensure that health plans are well designed, well supported and well implemented.

The importance of helping countries develop strong health financing systems was also reiterated by the leaders empha-

sising the G8's commitment to the "Providing for Health" initiative aimed at helping countries develop strong national health financing systems which can ensure universal coverage. They stated that "this process will be closely and systematically linked and provide input to the Health Partnership in order to enhance sustainable structures for accessible and pro-poor health systems."

One major international non-governmental organisation, Oxfam, immediately welcomed this health initiative, recognising that it will help to target aid towards the health needs of poor countries. Alison Woodhead, head of Oxfam's international campaign for health and education, said that it was "a great initiative that deserves widespread international support. Brown and Merkel should be congratulated for following through on their G8 promises to improve health care. The challenge for them now is to make sure other countries get on board to ensure maximum impact. There are women, men and children in developing countries who are dying because they don't have access to health care or any doctors or nurses to attend to them. This Partnership could literally save lives, by coordinating investment in health care that is free, public and well staffed."

The full joint statement of the Prime Minister and the Chancellor can be viewed at <http://www.number-10.gov.uk/output/Page12904.asp>

UK: Inquiry claims mental health services are letting down older people

A mental health pandemic and an inadequate Government response mean that over 3.5 million older people who experience mental health problems do not have satisfactory services and support, according to the final report from the UK Inquiry into Mental Health and WellBeing in Later Life – a major independent inquiry supported by the UK-based NGO, Age Concern.

The Inquiry makes 35 recommendations for ways to improve mental health services for older people. It calls for action to: eliminate age discrimination in mental health; challenge stigma, ageism and defeatism; work on preventing problems; support older people and their carers to help themselves and each other; and improve housing, health and social care services. It also calls for government action to provide leadership and over-

turn what it deemed as "years of under funding" in older people's mental health.

The Inquiry report reveals that mental health problems affect many more people in later life than previously believed and that the nature of these problems is wider than often recognised. It reveals that up to 2.6 million older people, one in four people over 65 and two in five people over 85, are living with depression or serious symptoms of depression and one in five people over 80 have dementia. It also highlights that older people with mental health services are often ignored and receive little support services, and there exists a poor level of services for people growing older with longstanding mental health problems such as schizophrenia. Women over 75 the report claims, are more likely to take their own lives compared to any other age group, while men over 75 have the second highest suicide rate of all men in the UK.

Chair of the Inquiry, June Crown, said that "Mental health problems in later life are not an inevitable part of ageing. They are often preventable and treatable, and action to improve the lives of older people who experience mental health difficulties is long overdue. Current services for older people with mental health problems are inadequate in range, in quantity and in quality."

The report also estimates that older people make a valuable contribution to the economy and this is growing in absolute and relative terms. By 2021, the unmet mental health needs of older people will cost £230 billion per year in lost workers, £15 billion from the absence of older carers, £5 billion from lost volunteers, £4bn from lost grandparents and £245 billion from lost consumers.

The full report can be accessed at <http://www.mhilli.org/>

UK: Government committed to revision of pharmaceutical pricing arrangements

Drugs pricing arrangements between the National Health Service and pharmaceutical companies should be updated, according to Competitiveness Minister, Stephen Timms, publishing the Government's interim response on 2 August to a recent report from the Office of Fair Trading (OFT).

The OFT report questioned whether the existing PPRS (Pharmaceutical Pricing

Reimbursement System), which combines restrictions on profits and price controls, is achieving both value for money and ensuring the contribution of the UK pharmaceutical industry to improved health care quality and economic prosperity. It recommended the replacement of the current system with a new system of value based pricing.

Timms said, "we agree with the OFT that it is time to develop a pricing system which is fit for purpose for the twenty first century. We must ensure that any future pricing scheme delivers value, rewards innovation and ensures a fair deal. The OFT report contained a number of detailed proposals as to how a future pricing regime would work. We are undertaking a continuing programme of detailed analysis of the OFT report's proposals, and will discuss this analysis with the industry, taking into account their strong concerns about a number of the proposals. This is a highly complex area and there are a number of different models for taking work forward. We will take this work forward over the coming months and will discuss proposals with industry. We will then aim to make further proposals as part of the renegotiation of the PPRS."

The government's initial response recognises that since the PPRS was established fifty years ago, significant changes have occurred, both in the pharmaceutical industry and in the delivery of health care. It notes that blockbuster drugs are rare, with innovation now increasingly focused on ever-smaller patient populations, creating major challenges in ensuring affordable delivery of these benefits to patients. Although in agreement that changes need to be made, the government is mindful of the need to ensure that any pricing system will encourage research and reward innovation which delivers valuable new treatments. Any future pricing scheme must also provide stability, sustainability and predictability for industry.

The OFT report on the Pharmaceutical Price Regulation Scheme can be found at: http://www.of.gov.uk/advice_and_resources/resource_base/market-studies/price-regulation.

Ireland: Review finds 13% of patients admitted to hospital unnecessarily

The Health Service Executive (HSE) on 1 June published its *Acute Hospital Bed Use Review*. The review found that 13%

of patients were unnecessarily admitted to hospital and that 39% of the patients in hospitals surveyed could have been treated in an alternative setting on the day of care, if appropriate alternatives had been available. The review was conducted across 37 hospitals and a total of 3,035 patients were randomly sampled out of a patient population of 8,322. Acute medical and surgical inpatients were the focus of the review.

The findings will be used by the HSE to drive hospital performance improvement and the re-configuration of services to achieve an increase in the levels of appropriate placement of patients outside of hospital settings and reduce inappropriate admissions, as well as an over-dependence on the hospital system.

The work was carried out using the Appropriateness Evaluation Tool (AEP) – a method originally developed in the US but widely used in Europe. The principal alternatives to acute admission identified for these patients were: access to assessment/diagnostics without admission to a hospital; access to a non-acute bed with therapy support, for example, physiotherapy; and home-based patient care including general practitioner support, therapy, specialist nursing, community nursing and home care packages.

The findings suggest that change across three main areas would reduce the number of patients deemed ‘inappropriate’ based on AEP criteria. First, better prevention and management of chronic illness within the community to reduce demand on the acute hospital setting. Second, further developing capacity in responsive community based services, to help avoid unnecessary admissions to acute care and to facilitate earlier discharge and a return to independence. Third, changing internal organisational factors within hospitals that can influence length of stay, bed occupancy and bed utilisation.

Dr Marie Laffoy, Assistant National Director for Strategic Planning in the HSE’s Population Health Division, emphasised that “detailed analysis of the data shows that the most important factor influencing appropriate placement of a patient is the system of care delivery rather than factors concerning the patients themselves. It is not the complex nature of the patient condition or the fact that the patient is old or lives

alone, but the way local health systems are configured to treat and care for that patient that results in inappropriate occupancy of an acute bed. A broad range of community and home-based care options are needed to ensure patients are placed in the most appropriate setting.”

John O’Brien, National Director and the manager who headed up the Winter Initiative, observed that the report indicates that “the solution for many of the logjams within our hospitals may actually lie outside those hospitals... there are many patients occupying beds who would not be doing so if there were alternative community-based options.”

The Acute Hospital Beds Review is available at <http://www.hse.ie/en/Publications/HSEPublicationsNew/AcuteHospitalReportsGuidelines/AcuteHospitalBedReview2007/reports/FiletoUpload,7020,en.pdf>

Scotland: New measures to tackle health care associated infections

A task force set up to tackle health care associated infections (HAI) is to step up its work following the publication on 11 July of the most comprehensive study ever undertaken into the extent of infections in Scotland’s hospitals. Scotland now has a more comprehensive picture of HAI than any other country in Europe and armed with this information will be able to target measures to tackle hospital infection where they are most needed.

The National HAI Point Prevalence Survey, carried out by Health Protection Scotland between October 2005 and October 2006, included all 45 acute hospitals and a sample 22 community hospitals, recording the presence of all types of infections on the day of the survey. It found that the prevalence of HAI was 9.5% in acute hospitals and 7.3% in community hospitals. The survey also estimates for the first time the total cost of HAI in acute hospitals – £183 million a year. The study also found that the highest numbers of HAI in acute hospitals were present in the care of older people, medical and surgical wards. Almost all (92%) of the *Clostridium difficile* infections recorded were found in the care of older people and medical specialties.

In response to the report, the HAI Task Force will focus their efforts on a

number of target areas including examining the case for introducing an MRSA screening programme; targeting skin and soft tissue infections; reducing blood stream infections and ensuring additional surveillance data are put to use in the areas of general medicine and care of the elderly

The Scottish Minister for Health and Wellbeing, Nicola Sturgeon, said that the “study is one of the most detailed of its kind in the world. For the first time, we have a true picture of the extent of infections in our hospitals. The comprehensive nature of the survey means that it may appear Scotland’s rates of HAI are worse than elsewhere. This is not necessarily the case – like for like comparisons with other countries, including England and Norway, show that Scotland’s rates are similar. But HAI is a serious problem that must be tackled.”

The Scottish Executive’s HAI task force oversees an extensive, high quality programme of action which so far has included developing a HAI code of practice, developing a national cleaning services specification, introducing a national hand hygiene campaign, introducing targets for board chief executives to meet and the introduction of educational initiatives like the *Cleanliness Champions* programme.

The Scottish government have also stated that new investment in tackling HAI beyond 2007–08 will form part of the spending review announcement later in 2007. The Point Prevalence Survey will also be carried out at intervals in future to evaluate trends in HAI.

More information on the survey at <http://www.hps.scot.nhs.uk/news/spdetail.aspx?id=105>

Russia: New rules for children’s organ transplants

In July the Ministry of Health and Social Development announced plans to develop instructions regulating the transplantation of organs to children. At present, child donors are prohibited, but the Ministry plans to legalise organ transplants from children. The rules are currently being studied by the Russian Academy of Sciences’ Medical Research Institutes. It is expected that the revised instructions will require that organs for transplants are taken from patients after brain death, a diagnosis that must be

confirmed after twelve hours. Such decisions would be made by a team of experienced medics led by the chief doctor of the hospital in question. The permission of the donors' families would also be required.

The new legislation would bring Russian policy into line with most high income countries which allow children to be organ donors after their deaths. Currently Russians are forced to take their children abroad for such operations, although the associated high costs are prohibitive for most individuals. The potential demand for such operations is significant. According to the Moscow Organ Donation Coordinating Centre, 30% of the 5,000 Russians who need organs transplants each year are children. The plans have been welcomed by many health care professionals, but some activists oppose the proposed legislation, arguing that it is immoral and could lead to the mass abuse of rules by doctors.

More information at: <http://en.rian.ru/russia/20070713/68920290.html>

Head of Russian pharmaceutical company Protek charged with bribery

On 17 August, prosecutors in Moscow said that they had charged Vitaly Smerdov, the head of the Protek pharmaceutical company, with bribing health insurance officials in order to receive sales licenses. Smerdov was previously a witness in a high profile inquiry into possible corruption in Russia's Mandatory Medical Insurance Fund (FOMS) which opened late last year. FOMS executives had been accused of accepting bribes from the heads of regional branches of the fund, and pharmaceutical and other commercial companies involved in distributing medication and medical equipment under a state-run programme to provide free or subsidised drugs to low-income population groups. Smerdov's lawyers have appealed against his arrest and the court's refusal to release him on bail of two million rubles (\$78,000).

<http://en.rian.ru/russia/20070817/72149302.html>

Action in Belarus against tobacco

Experts from the Republican Centre for Hygiene, Epidemiology and Public Health in Belarus have drafted a programme against tobacco for 2008 to 2010. This is the first time such a

programme has been developed in Belarus.

The document has been distributed to all relevant ministries and departments. Its main goal is to protect present and future generations from the health, environmental and economic consequences of tobacco smoke. The programme also aims to reduce demand for tobacco goods, and thus related morbidity and premature mortality. The programme includes measures to increase awareness within the population of the dangers of smoking, as well as ways to quit smoking and treat tobacco addiction. It is hoped that by 2010 that the number of smokers aged 15 or under will fall by 20%, those aged 16–20 by 10% and those aged 21–30 by 7%. Experts also predict a decrease in the rates of female and child passive smoking.

More information at <http://www.belta.by/en/news/society?id=171445>

Georgia: Street football used to promote child health

With the help of the Union of European Football Association (UEFA), children from Georgia, Armenia and Azerbaijan have been highlighting the role that sport can play in maintaining a healthy lifestyle. UEFA's partner, Open Fun Football Schools (OFFS), teamed up with the Georgian Heart Foundation to organise street football events in the Georgian capital Tbilisi in May. The OFFS and the Georgian Heart Federation came together as a result of UEFA's support for World Heart Day.

As part of events organised for Heart Week in Tbilisi, more than one hundred children between the ages of eight and twelve played street football and basketball around the theme of 'healthy life through physical activity'. Seven of the children who took part have heart conditions or diabetes. Children from Armenia and Azerbaijan joined local youngsters in street football matches on six temporary football grounds. The Ministry of Public Health and Georgian non-governmental organisations working to combat tobacco and alcohol abuse were involved in other activities during the week.

Open Fun Football Schools are organised by the Danish Cross Cultures Projects Association (CCPA). They benefit more than 30,000 eastern European children of all skill levels each

year and are based on a concept of fun football that downplays competition and is designed to develop confidence and teamwork. "Children and adults across eastern Europe love football," said Anders Levinsen, director of the CCPA. "We use this shared passion to help bring together divided communities, and leave behind equipment and training that helps local football clubs maintain or develop activities for children."

Heart disease and strokes in Georgia, Armenia and Azerbaijan kill more people than all other causes combined. "We hope to motivate youngsters to eat healthy diets, remain physically active and avoid smoking, so that they can avoid the early death and disability that causes much pain, suffering and poverty and which is a barrier to our economic growth," said Dr Merab Mamatsashvili, president of the Georgian Heart Foundation.

More information at <http://www.uefa.com>

Hungary: Investigation into possible price fixing in the pharmaceutical industry

In June, the Hungarian Competition Office (HCO) began an investigation against the Hungarian Chamber of Pharmacists (HCP), the Association of Innovative Pharmaceutical Manufacturers, the Hungarian Pharmaceutical Manufacturers Association, the Generic Medicines Manufacturers and Distributors Association, the Vaccine Manufacturers and Distributors Association and the Pharmaceutical Wholesalers Association, due to an alleged infringement of the Competition Act.

A leading Hungarian newspaper, *Világgazdaság*, reported that HCO began its investigation in response to a complaint from the Hungarian Trade Association. *Világgazdaság* quoted Péter Szolnoki, head of the HCO's cartel unit, who stated that the HCO had already conducted a thorough preliminary investigation regarding the complaint, which alleged price fixing of non-reimbursed medicinal products, as well as an unlawful concerted effort by pharmacies and pharmaceutical companies to prevent the sale of certain over-the-counter medicines outside of pharmacies.

Mr Szolnoki said that preliminary investigations had revealed that the HCP and the other Associations had communi-

cated regularly on the current prices of pharmaceutical products, and that the HCO had therefore decided to launch formal competition supervisory proceedings, in the form of a full investigation. Another Hungarian daily, *Napi Gazdaság*, also reported that the HCO will allege that this communication was unnecessary to ensure the safe supply of medicinal products.

The Associations are claiming that they were not in fact involved in the chain of communication because the pharmaceutical manufacturers sent their manufacturer prices to the HCP directly, and not via the Associations. The HCO may take up to a year to complete its investigation.

More Swedes going abroad for medical treatment

The number of Swedish patients treated in other EU countries at the expense of the Swedish state doubled between 2005 and 2006, according to new statistics from the Swedish Social Insurance Administration (*Försäkringskassan*).

The English language daily newspaper *The Local* reported that 2,000 people had planned treatment abroad in 2006, compared to only 900 in 2005 and just 150 in 2004 when the scheme to fund non-emergency treatment abroad was introduced. Dental treatment was most popular followed by treatment for muscle and joint problems. The majority of individuals were treated in Finland, with Germany the principle destination for specialist care. Spain, Portugal and the Baltic states were the most common destinations for dentistry. The total cost of overseas treatment in 2005 and 2006 was 25 million kronor, which can be contrasted with a total health care budget in excess of 340 billion kronor

The report from Försäkringskassan is available in Swedish at http://www.forsakeringskassan.se/omfkt/styrning/regeringsuppdrag/2007/halso_sjukvard_07

Controversy over new guidance on entitlement to sick leave in Sweden

In August new guidelines on the criteria for sick leave were published by the Swedish National Board of Health and Welfare (*Socialstyrelsen*). The intention of the new guidance is that people with mild or insignificant stress-related problems should not be put on sick leave in the first instance. It was feared that

individuals with fatigue syndrome, more commonly known as burnout, would no longer be able to be signed off as sick by their doctors after the guidance comes into effect from 1 October. In Sweden some 30,000 people a year are estimated to have more than two weeks off work due to exhaustion.

Jörgen Herlofson, who devised the criteria by which burnout is defined by Sweden's National Board of Health and Welfare, writing in an article in the newspaper *Dagens Nyheter*, claimed that stress-related illnesses were not being taken seriously. He said that the National Board of Health and Welfare had chosen an 'anti-humanist' ideology and that the main reason was clearly to save money. "I and many others are deeply disappointed, worried and suspicious," Herlofson wrote.

However as reported by the *Local*, the man behind the scheme, Jan Larsson, said that this had been "a gross misinterpretation. The ambition is to bring forward better and more targeted sick leave practice". Those with fatigue syndrome would still in fact qualify for sick leave benefits, but this would be accompanied by more action from the health care system intended to help these individuals return to work as quickly as possible. Social Insurance Minister, Cristina Husmark Pehrsson, also stated that the new guidelines were one means of helping more people back to work. "I would be sorry if they were misinterpreted. Nobody thinks that a politician can get involved in how long a doctor gives people sick leave. That is entirely up to individual doctors".

The guidelines have caused controversy since they were released. The Swedish Medical Association (*Läkarförbundet*) has backed the new rules, while many patients' groups have been critical.

Spain: Expert group to consider future of nursing in the National Health System

On 10 July the Ministry of Health and Consumers ordered the establishment of an expert working group to help begin a consultation process over the role played by nurses within the National Health Service (NHS).

This initiative continues a direction of work undertaken by the Ministry of Health and Consumers which has been conscious of the importance of the

nursing profession as a fundamental pillar in the sound functioning of the NHS. The government has already introduced measures to develop and make improvements to the nursing profession through the passing of Royal Decree 450 in 2005. This focused on specialities within nursing and approved the recognition of new degree standard qualifications as the basis on which to enter these specialities.

The government will thus publish a draft document on the role of nursing, intended to be the springboard for subsequent consultation with all stakeholders. This initial document will be developed by the proposed expert working group, which itself will be hosted within the National Council of Specialists in the Health Sciences, a multi-disciplinary body considered most suitable for this task.

The work of this expert group marks the beginning of what is anticipated to be a profound debate over the role the nursing profession currently occupies within the NHS, as well as how it can adapt to future demands. The report will assess the current situation, identify new health and social care demands, and determine their consequences for the functions and skill-mix of the nursing profession, as well as the knock on effects for other health care professions. The report is expected to be completed by 15 December, when consultation with all relevant stakeholders will begin.

In addition to the chair, the expert working group will have eight members. The Ministry have given assurances that its composition will be broad in order to be fully representative. It will include one representative of the 17 Autonomous Communities that make up Spain, one each from the Ministries of Health and Consumers and Education and Science, three from the nursing professions and two from other medical professions. The importance of adequate representation, including all facets of nursing on the working group, has been strongly emphasised by the decision to appoint a member of the National Commission on Nursing to the group, with a second nurse coming from a care and welfare background and the third from the world of academia.

More information (in Spanish) at <http://www.msc.es/gabinetePrensa/>

News in Brief

Climate change: Europe must adapt

Climate change poses a double challenge: Europe must not only make deep cuts in its greenhouse gas emissions but also take measures to adapt to current and future climate change, in order to lessen the adverse impacts of global warming on people, the economy and the environment. This is the key message of a Green Paper published by the European Commission which sets out options for EU action to help the process of adaptation to climate change across Europe. Adaptation implies taking action to cope with changing climatic conditions, for example by using scarce water resources more efficiently or ensuring that vulnerable people are properly cared for during heat waves. The Green Paper consultation runs until November and will contribute to future EC proposals.

More information at
http://ec.europa.eu/environment/climat/eccp_impacts.htm

EurLife database of quality of life indicators

The EurLife database, maintained by the European Foundation for the Improvement of Living and Working Conditions, and which deals with the objective living conditions and subjective well-being of European citizens, has recently been updated. New indicators have been added, as well as data for more recent years. National coverage has been expanded to include the 27 EU Member States and Turkey. The database will be updated again in 2008 with results from the second European Quality of Life Survey.

The database can be accessed at
<http://www.eurofound.europa.eu/areas/qualityoflife/eurlife/index.php>

WHO guide to the essentials in prison health

This new publication from the WHO Regional Office for Europe, edited by Lars Møller, Heino Stöver, Ralf Jürgens, Alex Gatherer and Haik Nikogosian outlines some of the steps prison systems should take to reduce the public health risks from compulsory detention

in often unhealthy situations, to care for prisoners in need and to promote the health of prisoners and prison staff. This requires that everyone working in prison understand how imprisonment affects health, what prisoners' health needs are and how evidence-based health services can be provided for everyone needing treatment, care and prevention in prison. Other essential elements are being aware of and accepting internationally recommended standards for prison health; providing professional care with the same adherence to professional ethics as in other health services; and, while seeing individual needs as the central feature of the care provided, promoting a whole-prison approach to care and promoting the health and well-being of people in custody.

The guide is available at
<http://www.euro.who.int/document/e90174.pdf>

EU to study electronic chips for eHealth

In July the Commission launched a tender to examine the options for using Radio Frequency Identification (RFID) technology in healthcare, with applications ranging from the identification of patients in hospitals to tagging pharmaceutical products. The main objective of the study will be to assess the expected features of RFID applications in the health care market and to build future scenarios in the field. It is also set to identify possible obstacles and needs for policy actions or specific research activities on the subject.

More information at
<http://ted.europa.eu/udl?uri=TED:NOTICE:163980-2007:TEXT:EN:HTML>

Impact of video and computer games on child health

The Swedish National Institute of Public Health has undertaken a systematic review looking at the effects of playing video and computer games on the health of children and young people. The review found that there was only limited evidence to suggest that playing violent video and computer games

caused children to choose aggressive toys. It also did not provide any support for a link between video game playing and aggressive feelings, aggressive thoughts or aggressive behaviours, despite all these outcomes having been well studied. Furthermore, the available longitudinal studies of video game playing and excess weight in children did not support a link, while there was, in fact, strong support to suggest that playing video and computer games has positive effects on cognitive abilities.

The report is available at
http://www.fbi.se/upload/ar2007/Rapporter%202007/R200518_video_computer_game.pdf

Windmill 2007: The future of health care reform in England

In a new paper from the independent health think tank, the Kings Fund, Sarah Harvey, Alasdair Liddell and Laurie McMahon report on the findings of the Windmill 2007 initiative. This is named after the 'Rubber Windmill', a simulation modelling process developed in 1990 to explore how the health service was responding to the internal market being developed at the time. The new study included a two-day simulation of a fictional but realistic health economy from 2008 to 2011 and extensive discussions of the emerging findings with a range of stakeholders. Among the key messages of the paper is the need for a clear set of rules for competition within the NHS to ensure that all players, commissioners, providers, public sector and private, can plan for the future and that the emergent market works in the interests of patients.

The report is available at
http://www.kingsfund.org.uk/publications/kings_fund_publications/windmill_2007.html

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