

Eurohealth

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Medical devices: exploiting the potential in Europe



**Procurement of medical devices in
England: application to wound care**

**Reference pricing for medical
devices in Germany**

**Financing medical devices in Italy:
cardiovascular technologies**

COMMENTARY

Medical devices: exploiting the potential

Medical devices, large and small, that are vital to the functioning of health care systems, are the focus of much of this issue of *Eurohealth*. These devices are also significant to the European economy: in 2005 alone the European medical technology industry generated sales of more than €63.6 billion, while investing more than €3.5 billion in research and development and employing 435,000 skilled workers. In their overview article, Elio Borgonovi, Reinhard Busse and Panos Kanavos argue that much more can be done to optimise the value, effectiveness and efficiency of medical devices in Europe. They call for further evidence to demonstrate the numerous benefits arising from investments in such technology, and, in parallel, to look at how the dynamics of coverage, procurement, reimbursement, and diffusion operate across different health systems and regulatory environments. Contributions looking at different approaches and experience in Italy, Germany and England also feature in this issue.

We are also delighted to publish an article by Delia-Marina Alexe and colleagues on the challenges posed by cancer in Europe today and measures available to tackle this problem. They call for a much more integrated approach to cancer control, including the development of national coordinated cancer plans, as well as investment in effective cancer information systems including screening registries. At an EU level the authors note that the Data Protection Directive may impede the effective operation of cancer registries and requires reform, while further steps can be taken to tackle health inequalities and promote strategies to combat aspects of unhealthy lifestyles such as tobacco, alcohol and poor nutrition that are risk factors for cancer.

Among other contributions to the issue are two perspectives on aspects of health reform from outside Europe. One looks at the use of e-Health in Canada and may be of significant interest to European countries considering how best to expand their own e-Health systems. The second describes the challenge of introducing a case mix system to Japan, illustrating the extent to which experience in Europe has helped to shape health policy in the country.

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Financing medical devices in Europe:

Current trends and perspectives for research

Elio Borgonovi, Reinhard Busse and Panos Kanavos

Summary: Medical technologies offer numerous benefits, in both health and economic terms. However, there is concern and a general lack of understanding about how to best realise their ultimate value, effectiveness and efficiency in health care. The establishment of the European Health Technology Institute for Socio-Economic Research (EHTI) aims to create a platform for research and debate around these key issues, bringing together academia, industry, and policy-makers. This article discusses current trends and considerations in the regulation and financing of medical devices in Europe, outlines the principal objectives of the Institute, and reflects upon the first year of research, which focused on the coverage, procurement, and reimbursement of selected medical technologies in six EU countries.

Key Words: Medical Technology, Regulation, Financing, Health Care Systems

Identifying the optimal allocation of available resources in order to maximise population health gains has been and continues to be a key challenge for health care systems. One of the main perceived drivers of rising health care expenditures has been the rapid pace of innovation in medical technology.¹ While medical technology is not always cost increasing and there are significant opportunities to reduce overall costs by adopting new technologies, efficiency savings are frequently realised with a significant time lag. As continued advances in research are expected to produce an ever-increasing number of alternatives for the detection, prevention and treatment of disease, new products will exert increasing pressure on health care policy makers to adopt measures to regulate the medical technology market with regards to access, quality and public funding.

In order to be effective, such actions should take into consideration several 'biases' historically applied to the medical technology sector. The first bias concerns access to innovative technologies. Earlier studies in health economics in the 1950s and 1960s showed that when new devices became widely available there was a general overuse compared to initial calculations or predictions based on approved indications, suggesting potential inappropriate use. These phenomena encouraged notably strict policies, signalling to policy-makers that they should be careful in their decisions regarding the financing of technologies, especially the most expensive.

The second bias is related to the fact that, to date, policy measures applied to medical technology have been in some way considered similar to those pertaining to pharmaceuticals. This is particularly relevant to cost containment policies

applied in the pharmaceutical sector, such as reference pricing, price controls, and price caps, among others.

Medical devices and pharmaceuticals: distant cousins, not twins!

The second bias deserves particular attention. This is especially important in an era in which policy-makers have started to implement measures to ensure the effectiveness and cost-effectiveness, often based on health technology assessments (HTA), of medical devices. HTA and related strategies are often founded on notions of evidence-based medicine (EBM), whereby a range of evidence (for example, costs, efficacy, cost-effectiveness, equity) regarding a given technology is required by decision-makers to support adoption. However, EBM principles in general and HTA in particular, have principally focused on pharmaceuticals. Consequently, experiences with the pharmaceutical sector in this regard are often considered in the development of such methods and processes for medical devices.

However, is this 'export' of pharmaceutical policies justified? The medical technology industry is largely, if not completely, different from drugs. There are several reasons for this departure. First, in terms

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of its structure, the medical technology industry is much more fragmented. Even though there are big multi-national corporations, there are many more medium and small companies in operation and it is true that the development of new medical devices frequently takes place in smaller entrepreneurial companies. This may be a reflection of differences in the two industries in terms of risk perception and regulations, particularly in connection with the clinical development programme (extent, uncertainty and intensity of financial resources) in the pharmaceutical sector compared with medical devices.

Second, the significance of patents as incentives for innovation is influenced by the different nature of Research and Development (R&D) in the pharmaceutical and medical device industries.² In pharmaceuticals, it is very difficult to design a molecule that simulates all the efficacies and side effects of another drug; even if this were possible, patentability for two virtually identical molecules would be nearly impossible. However, this is not the case with medical devices. A further difference between drug and medical device patents lies in which aspects of the innovation lead to patentable claims. In medical devices, the basic principle can be patentable, but specific devices usually are not. In the pharmaceutical industry, it is often just the opposite. Generally speaking, it is possible to design a new device for a specific application in a number of different ways. The innovation often lies in the underlying principle being used in the particular application.

Third, the innovation process differs significantly between pharmaceuticals and medical devices. For the pharmaceutical industry, the key issue is to discover a molecule that, when demonstrated effective for a certain illness, may immediately become a blockbuster in terms of the return on investments made. The R&D process is very long (approximately twelve years), with the overall costs reaching several hundred million euros per marketed drug. The 'me too' phenomenon (i.e. the marketing of drugs with slightly modified molecules, but similar effectiveness), is present but, in general, it has limited effects on product development or within-product differentiation. By contrast, the innovation process for medical technology is incremental. Although there are some cases of breakthrough innovation, it is more typical to iteratively improve existing products in

their performance and safety. Moreover, medical devices often require 'lead users' for their success (for example, operating equipment needs to be accepted and used by certain surgeons); the partnership between technology producers/suppliers and health service delivery organisations assumes an integral role in this process.

Fourth, and building upon the previous points, a further important difference between pharmaceuticals and devices lies in the ability and propensity to make changes in the device product during clinical evaluation and after it has been marketed.² A pharmaceutical product is usually in its completed form prior to marketing and is described by its chemical formula; in most cases, dosage remains stable during the life of the product. In contrast, devices are constantly being modified to remove defects, improve performance and add features throughout the product lifecycle. These changes occur frequently and fuel competition among manufacturers, with a view to offering better product performance and features.

As a result of the continuous product changes that devices undergo, as well as the differences in the R&D process, it is hardly surprising that the product life cycle in the medical device industry is much shorter than that in the pharmaceutical industry, rendering individual medical devices obsolete within a few years, compared with the statutory patent term (twenty years) and marketing exclusivity periods (up to ten years) that apply to pharmaceuticals. For all of the above, there are good reasons to believe that the 'regulatory approach' applied to the medical technology sector should be different from that employed in the pharmaceutical sector. High-quality scientific research on the effects of policy instruments transferred from the pharmaceutical sector will provide the necessary evidence to policy makers to understand relevant differences.

The European Health Technology Institute for Socio-Economic Research

Based on this rationale, the European Health Technology Institute for Socio-Economic Research (EHTI) was established in 2007.³ The idea of the EHTI was based on the aim of forming a collaborative network of highly reputable academic institutions, Bocconi University (BU), Milan, Technical University (TU) of Berlin, London School of Economics and Political Science (LSE), industry and the policy-making community. This is an

innovative model with several tangible advantages, including: (1) creation of synergistic effects between all partners participating in the research process, (2) consideration of policy-makers' needs and, (3) generation of evidence based on robust methodology that may be useful to multiple stakeholders and the research community. The Institute aims to become one of the principal actors in the European health policy arena, leading the debate around key issues affecting the viability and sustainability of the medical technology sector and its link to societal health and wealth.⁴ In this respect, it also aims to fill an important gap relating to the understanding of medical technology, the importance of R&D and the benefits accruing to both patients and society.

Research objectives

From a research perspective, EHTI focuses on conducting and supporting high-quality empirical research on a range of topics relevant to medical technology, including the value of innovation, quality of life, quality of care, productivity, financing and reimbursement. In the first year of activity, the three universities have focused their research on the financing mechanisms for, and access to, medical technology in European countries.

Regulatory policies in general, and financing measures in particular, are considered important factors impacting on the availability of, and access to, medical devices. It is therefore essential to address the issue of how medical devices are currently regulated and financed across different health care settings in Europe, as well as understanding who benefits from investments in medical technology. To that end, the ultimate aim is to provide systematic, comparative evidence on regulatory policies across countries and technologies and to generate data on the impact of adopted policies in terms of technology uptake and diffusion. This research fulfils an important role as the existing literature has not yet sufficiently addressed these issues in a systematic way.

Since the early 1990s, market access for medical devices in Europe has been regulated through several EU directives. These directives must be transposed into national law in each EU Member State. The EU directives specify the conditions that a product must meet in order to obtain the CE mark. With the CE mark a product may be marketed in all EU Member States. The directives speed up the adoption

process per se and, at the same time, provide a uniform definition for medical devices in the European Union. Against this background of European regulation, actual adoption and use in individual Member States depends mainly on whether the medical devices are covered by the (public) benefit baskets and how financial arrangements provide incentives (or otherwise) for their use.

Therefore, initial research by EHTI focused on key issues relating to (a) coverage, (b) procurement and (c) reimbursement of selected medical technologies in six EU countries (Germany, Poland, Italy, Spain, the UK and France), representing both the largest countries and a mixture of North and South, tax-financed and insurance-based, decentralised and centralised systems. The technologies examined were knee endoprostheses, implantable cardiac defibrillators (ICDs), coronary stents, laparoscopic colorectal surgery, urinary incontinence pads and new wound care products (for example, negative pressure therapy).

The technologies were selected to represent three sets of principle markets for medical devices:

1. Medical aids which are mainly given to and used by patients directly, (for example, incontinence products). These technologies potentially constitute health care benefits in their own right;
2. Medical devices which need to be implanted into a patient (for example, stents, ICDs, or endoprostheses). These technologies entail only one component of health care benefit (with hospital or ambulatory services making up the other components); and
3. Medical devices which are used to provide services by physicians or other health care providers (for example, laparoscopic procedures). These are technologies where the service, not the device, represents the health care benefit.

This distinction was developed in order to analyse the key issues of coverage, procurement and reimbursement of devices beyond the peculiarities of the six technologies. In terms of coverage, several issues were investigated: whether the technology was explicitly included in the national/regional benefit basket or statutory insurance schemes; the main decision criteria for the inclusion/exclusion of the technology – separately or as part of a broader service; and, if and how

frequently the inclusion has been updated following progress with the technology.

Financing mechanisms were analysed along two distinct dimensions: procurement and reimbursement. Procurement is concerned with the ‘price’ of technologies established between the producers and providers of health care services (mainly in the cases of 2 and 3 above) and the main areas of investigation were: level of price setting and negotiation (centralised vs. decentralised procurement); existence of ‘reference’ prices to be used in tender negotiations; and criteria used in price negotiation. Finally, analysis of reimbursement systems across countries examined different funding systems (tariff-based versus global budgets) and the decision-making actors and level(s) at which funding is established (national versus regional level).

Results

The accompanying country case study articles present some of the results obtained in this phase of research. One examines the financing of ICDs and coronary stents in Italy, while another explores recent developments in the procurement landscape for medical devices in the UK, with a focus on their applications to wound care. Finally, the use of reference pricing – a typical instrument taken from pharmaceutical policies – is assessed for outpatient medical aids in Germany.

Conclusions and next steps

Technological innovation is perceived to be at the root of the recent cost escalation in health care. However, existing evidence suggests that, on average, increases in medical spending since 1960 and developments in technology have provided value, leading to significant improvements in patients’ quality of life, and reductions in disability levels and mortality rates.^{5,6} Yet, such benefits and the beneficiaries of technological innovation, most notably in relation to medical devices, have not been adequately studied. As a result, evidence is needed to demonstrate the numerous benefits arising from investments in medical technology and, in parallel, how the dynamics of coverage, procurement, reimbursement, and diffusion of medical technology operate across different health systems and regulatory environments.

With regards to the beneficiaries of medical technologies, it is important to bear in mind that a wider group, beyond patients or health professionals, benefit

from medical technology and that this health gain is translated into economic societal gain.⁷ While it is clear that innovation, in general, contributes to economic development and welfare improvements, the process whereby technological innovation in medical technologies leads to growth and welfare gains is not well understood and would benefit from empirical research. Indeed, the social and economic value of medical technology is the current focus of a second stream of research carried out by BU, the LSE and TU Berlin and which, in its initial phase, is aiming to produce a review based on published and unpublished studies and reports made available within Europe and elsewhere in recent years.

It is hoped that EHTI’s research will expand the existing knowledge base regarding the effective uptake and use of, as well as access to, medical technologies. Further, through its efforts, it is hoped that stakeholders – academia, industry, and policy-makers – will collaboratively engage in debate and discussion on the key issues highlighted throughout this article. Indeed, the unique contributions of medical devices, in both health and economic terms, need to be further understood, with the ultimate aim of improving patient lives and supporting continued medical innovation.

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The procurement landscape for medical devices in England:

Recent developments and applications to wound care

Corinna Sorenson

Summary: The process by which the English National Health Service (NHS) purchases and introduces innovation into its system of hospitals and general practitioner practices is crucial to realising the numerous benefits afforded by medical technologies. Several actions have recently been instituted into the procurement landscape for medical devices in England, including development of collaborative 'procurement hubs', National Contracts Procurement and reorganisation of the roles of key purchasing bodies, all principally under the auspices of the Supply Chain Excellence Programme. While most of these initiatives generally focus(ed) on short-term cost containment and efficacy gains, it has been argued that procurement decisions and practices should be increasingly grounded in providing greatest benefits to patients and providing the best value for money for the £15 billion spent each year by the NHS on goods and services.

Key words: Health Care Financing, Medical Devices, England, Wound Care

Numerous programme and policy initiatives have been introduced in England since the late 1990s to support the effective use of National Health Service (NHS) funding in providing accessible and innovative health care. As the 2002 Wanless Report¹ highlighted, investments in innovative medical technology are an important component of NHS planning to maintain an efficient and high-quality health service and drive socioeconomic benefits. Consequently, the process by which the NHS purchases and introduces innovation into its system of hospitals and GP practices is crucial to realising the numerous benefits afforded by medical technologies.

In particular, several actions have been recently instituted into the procurement landscape for medical devices in the NHS. Such change was arguably first initiated by the development of the Supply Chain Excellence Programme (SCEP), which sought to improve methods of both national and regional procurement through various mechanisms, such as

collaborative 'procurement hubs', National Contracts Procurement (NCP), and reorganisation of the role of the NHS Purchasing and Supply Agency (PaSA). The latter now has responsibility for device evaluation and outsourcing of NHS Logistics – a 'joined-up' effort deemed the NHS Supply Chain, which serves as the primary purchasing agent for the NHS. Other changes to the governance structure were realised, with the multi-national company, DHL, and US-based purchasing organisation, Novation, overseeing operation of the Supply Chain, in collaboration with the NHS Business Services Authority (NHSBSA). The SCEP was recently succeeded by the NHS Sourcing and Supply Chain Improvement Programme (NSSCIP), which aims to continue many of the SCEP's key objectives (for example, use of purchasing hubs).²

The legacy of SCEP and associated developments on NHS procurement is uncertain. With a greater commercial orientation, the Programme increased the focus on bulk purchasing and a competitive tendering process. While such practices can have positive implications for efficiency gains and reduced prices, this has led, in some cases, to the purchase of

cheaper and often older equipment from large suppliers, who can more easily accommodate NHS demands for low prices and high volume. This can provide disincentives for innovative products to be developed and available to patients and providers, in addition to disproportionately orienting objectives towards short-term cost-savings, rather than long-term benefits and costs.³ While cost containment is certainly a key objective of any health care system, procurement decisions and practices should be grounded in providing greatest benefits to patients and providing the best value for money for the £15 billion spent each year by the NHS on goods and services.

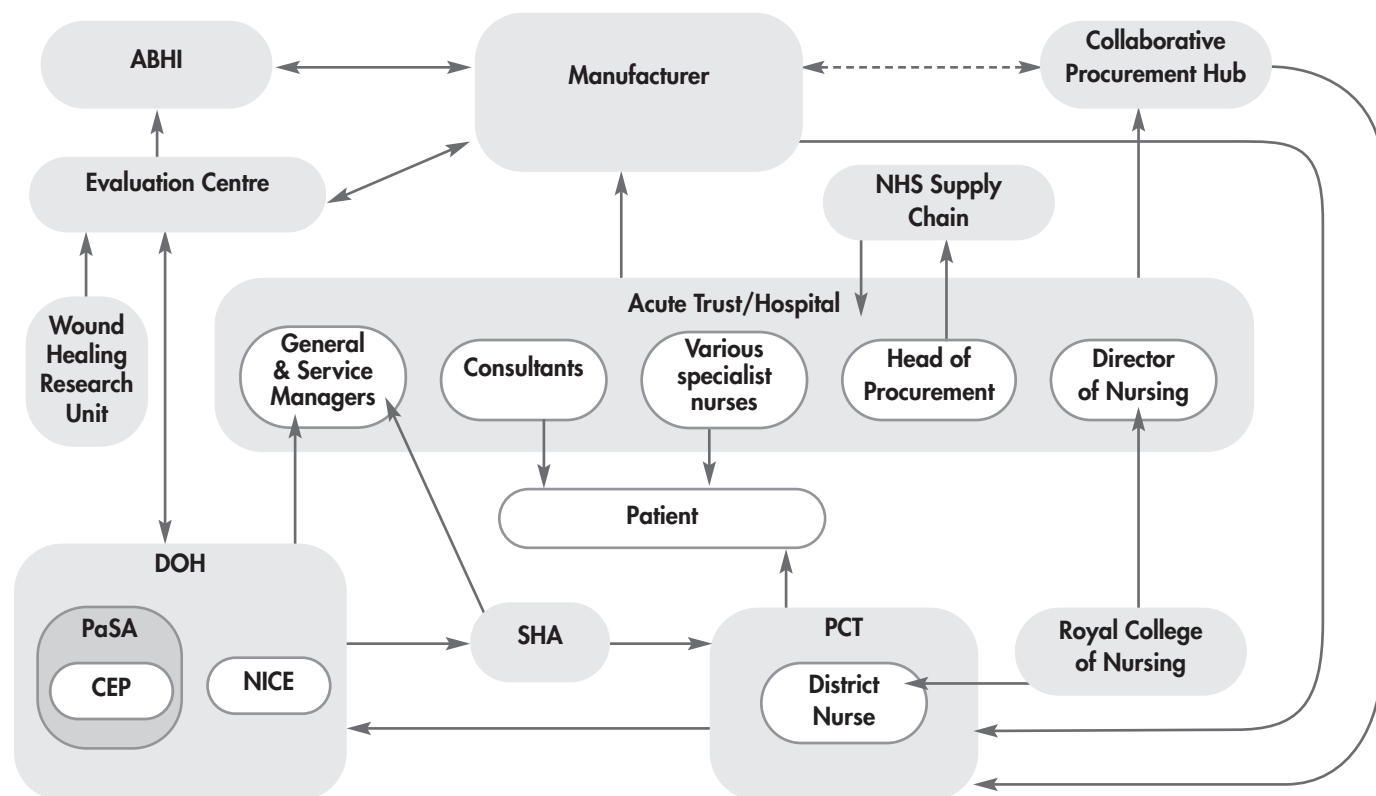
Evidence-based purchasing

To help meet this objective, recent changes encompassed the development of a new device evaluation service, the Centre for Evidence-Based Purchasing (CEP), within NHS PaSA. The Centre was established to provide evidence to underpin purchasing decisions and, more broadly, to support the uptake of effective, safe and innovative products and related procedures in health care. While evaluation of medical technology has historically rested on evidence

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Figure 1: Procurement mapping of Vacuum Assisted Closure (VAC) therapy



of performance and safety, the CEP and its programmes, such as the Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH)*, aim to incorporate considerations of costs, patient outcomes and clinical opinion into a procurement framework. As promulgated by these initiatives, such evidence could be used to inform procurement contract agreements and determine appropriate pricing bands for applicable tariffs.

While the principal objectives of evidence-based purchasing (EBP) are laudable and increasingly needed to support value for money in the NHS, it is still in an embryonic stage of development. Moreover, similar to other procurement developments, EBP presents challenges for highly innovative or new technologies in the early stages of commercialisation. In particular, the data or evidence required for the evaluation of medical devices are often unavailable, as unlike pharmaceuticals, randomised controlled trials are not required for market approval. Even in cases where data are available for early evaluation, evidence is unlikely to appropriately

account for the incremental development of most medical technologies. Indeed, devices are typically developed through a dynamic, iterative process, whereby their functionality is constantly improved upon by user feedback and further research. This results in the evolution of new generations of the initial device, leading to different characteristics, outcomes and cost estimates with each progressive iteration. To this point, evaluation prior to procurement, either at first generation or before user feedback can be assessed, may not fully or accurately capture the true value of a given technology.

Application to wound care

Recent innovations in wound care, particularly Vacuum-Assisted Closure (VAC) therapy**, provide a helpful example to illustrate some of the opportunities and challenges associated with application of EBP in the NHS. VAC therapy is a relatively immature and highly innovative intervention that applies negative pressure to accelerate wound healing. It employs electrically-powered vacuum pumps,

collection canisters, connection tubes and specialised dressings to drain wounds of exudate (i.e. excess fluid and cells) and influence growth of surface tissues. To date, VAC therapy is primarily used for acute (e.g. skin grafts) and chronic (e.g. leg ulcers) wounds of variable size and complexity, and is employed in both hospital and community care settings. While still an early product, the benefits of VAC therapy for wound care patients are considered high, in terms of wound healing, cost-effectiveness, and reduced length of stay. Currently in the NHS, purchasing activity for VAC therapy is predominated by NHS Trusts (devices) and the NHS Supply Chain (consumables). Procurement decisions are primarily comprised of two main choices, purchase or rent, which is mainly determined by specialist nurses and clinicians. Figure 1 maps the procurement landscape related to VAC therapy.

Increased demand and its innovative nature have placed VAC therapy on the procurement agenda in the NHS. However, decision-makers are often

*The MATCH programme constitutes a research collaboration between various UK academic institutions and a group of industry partners. Beyond its scientific aims, MATCH seeks to strengthen key networks and engagement between regulators, industry, and patients – all with their own important perspectives regarding medical technologies.

** Included in general category of Negative Pressure Therapy for wound care.

grounding purchasing activity on mixed or limited evidence. This is principally due to considerations regarding data availability for new and notably innovative therapies and, perhaps, as a result of insufficient resources allocated to adequately assess the existing evidence on the costs and benefits of VAC therapy. Wound care itself also introduces challenges that can impact on their evaluation and, subsequently, EBP. For instance, wound care is highly variable across wound type and characteristics, frequency of dressing changes and duration of treatment. Moreover, there are few 'standard' or 'conventional' products in this therapeutic area, as evidenced by the variety of innovative wound treatments on the market and the presence of inconsistent local clinical guidelines on use in patient care.

Outstanding issues

In order to address some of the issues related to VAC therapy and facilitate the effective use of EBP, especially in highly innovative therapies, there are a number of outstanding issues that need to be addressed. Firstly, systematic review of available evidence and/or economic analyses, including modelling, needs to be pursued. Given it is a fairly immature therapy, there may be limited data and, where evidence is available, methodological issues (for example, small sample sizes, variation in outcome measurement) may be present. This may be exacerbated by the lack of clarification as to what constitutes standard wound care. Such challenges must be acknowledged and addressed through additional evidence and consideration of new data as it becomes available. MATCH is addressing some of these methodological issues by incorporating different analytical approaches, for example, Bayesian techniques, into value-assessment methods for the purposes of procurement.

Secondly, as demonstrated by the example of VAC therapy, there are a vast range of actors involved in the procurement process. To ensure national and local relevance and cross-stakeholder engagement, collaboration is needed amongst key stakeholders, including industry, the Association of British Healthcare Industries (ABHI), the Department of Health (including the National Institute for Health and Clinical Excellence – NICE), procurement actors (for example, collaborative procurement hubs, Trust Managers, Directors of Nursing) and users of the technology. These key stakeholders should be involved in lending valuable multiple

perspectives, in addition to pure cost-minimisation considerations, which currently tend to dominate purchasing decision-making. In particular, stakeholders both inside and outside the NHS could contribute input regarding how: (a) different elements of procurement interact, (b) patient needs can be achieved, (c) innovation can be better integrated into the NHS, and (d) industry can be rewarded for high-value products. In terms of NICE in particular, it will prove important to carefully assess how evidence-based purchasing decisions (and, evaluative processes) may coincide with the Institute's decisions and guidance. The information provided through interactive and iterative communication routes facilitates parallel benefits for improved purchasing decisions, continuous device development and enhanced management of wound care in the NHS.

Thirdly, as the concept and use of EBP develops in England, the unique considerations of innovative devices must be taken into account, many of which have been highlighted throughout this article. These include, but are not limited to, the methodological challenges associated with early evidence and technologies intended for small patient populations; the iterative development curve; and the high cost and resource needs of distribution and user training and education. To that end, devices, as compared to pharmaceuticals, require a significant level of user involvement, which ultimately has implications for the performance (i.e. effectiveness, safety) of the product. The medical technology industry is typified by small companies, who may lack the necessary resources to amass the information required by CEP or other relevant EBP bodies. Fourthly, similar to any evaluative process for determining the value of new health technologies, the transparency of EBP-based procurement decisions must

be upheld. As NHS procurement assumes a commercial element and often involves a vast array of transactions, an open process is necessitated.

The procurement landscape in England has undergone notable transformations, introducing various policies and mechanisms to enhance the value for money achieved in NHS purchasing. EBP, marked by the establishment of the CEP, is one particular strategy to meet this aim. While EBP may help shift focus from short-term gains to sustainable cost and outcomes in NHS purchasing, adequately accounting for innovation and differences between technologies (i.e. devices vs. pharmaceuticals) in its practices and methods is crucial. Furthermore, requisite resources should be invested in the CEP to ensure an effective and robust process and, importantly, one with an impact on procurement. Indeed, purchasing practices and policies should ultimately support the founding principles of the NHS – providing patients with high-quality, effective, and affordable health care.

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Financing medical devices:

The case of implantable cardioverter defibrillators and coronary stents in Italy

Giulia Cappellaro and Aleksandra Torbica

Summary: In the recent years, the financing of medical devices has gained increasing attention from health policy makers in Italy at both regional and national level. The article investigates the current modalities of procurement and reimbursement of cardiovascular medical devices in Italy, as well as their diffusion across the country. Both implantable cardioverter defibrillators and coronary stents are purchased by health care providers through open public tenders and are prospectively reimbursed using Diagnosis Related Group tariffs. Empirical data suggest that these technologies have increasingly been used in recent years in Italy.

Key words: Health Care Financing, Medical Devices, Reimbursement, Italy

The financing of medical devices has only become an important agenda item for Italian health policy makers in the last few years. In fact, with the exception of several laws adopted to simply transpose EU directives on market access regulation, no significant policy measures were taken until 2002. The main reason for the increased attention is undoubtedly linked to the economic and financial sustainability of the system. Medical device expenditure accounts for almost 6% of overall health care expenditure in Italy, or around € 4 billion per annum.¹ Furthermore, the rapid pace of innovation in this area has raised the level of debate over the best ways in which to guarantee equal access to new medical devices and at the same time ensure the long-term financial sustainability of the Italian National Health Service (NHS).

Among several policy measures adopted

between 2002 and 2008, three merit special attention: the creation of the Medical Devices Committee, the development of a national database of medical devices and the implementation of a system of reference pricing. The 2003 Financing Law established the Medical Devices Committee (Commissione Unica sui Dispositivi Medici-CUD). Its main objectives were to create a national database of medical devices currently available on the market (*Repertorio Nazionale*) and to subsequently update this on a regular basis taking account of clinical and economic criteria. This national database became functional in May 2007 and, from January 2009, only devices described therein may be purchased, used or distributed within the Italian NHS. The 2007 Financing Law also introduced reference prices for a list of selected medical devices that should be used in procurement arrangements between medical device producers and health service providers. A Ministerial Decree on 11 October 2007 defined the first medical devices to be affected by reference pricing and includes, for example, coronary stents and hip endoprostheses components.

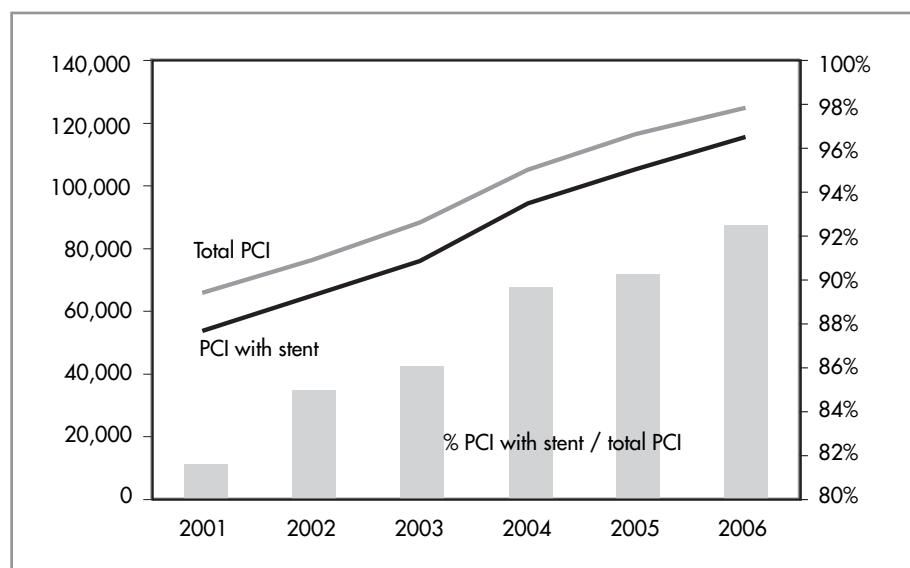
Following this short overview of recent policy measures, we now investigate current procedures for the procurement

and reimbursement of medical devices in Italy. To achieve this we focus on two technologies: implantable-cardioverter defibrillators (ICDs), used for the prevention of sudden death due to arrhythmia in patients with acute myocardial infarctions, and coronary stents used in percutaneous coronary interventions (PCI) for patients with ischemic heart disease. The prevention and treatment of cardiovascular diseases is the most important clinical area to consider, both in terms of impact on overall health care expenditure and the rate of innovation in medical devices used for treatment and diagnosis.

Diffusion of ICDs and coronary stents

Empirical data suggest that the use of both of these technologies has significantly increased in recent years. The recently established National Registry for ICDs revealed that approximately 10,400 ICDs were implanted in 2005, almost 60% more than in 2004.² This equates to a ratio of 179 implants per million population; across Europe this ranges from 67 per million in Portugal to 262 per million population in Germany.³ The significant increase in Italy should be interpreted with caution due to differences in data. It can only partially be explained by the larger use of ICDs in primary prevention. Different types of

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Figure 1: Diffusion of PCI procedures and coronary stents in Italy

Source: Calculations, based on data of GISE (www.gise.it)

Table 1: Reference prices for coronary stents

Description	Technical specification	Reference price (€)
Bare metal stents	Stainless steel	505
Bare metal stents	Chrome or cobalt-chrome	572
Covered coronary stents	Carbon	557
Drug eluting coronary stents	–	1,486

Source: Ministerial Decree 11 October 2007

ICDs can be used, they can vary by the type of pulse generators they use. Looking at first implants and replacement interventions triple chamber ICDs account for 37% of all implantations compared to 32% using double chamber and 30% single chamber ICDs.

Turning to coronary stents, data on activity in catheter laboratories in Italy⁴ highlight the significant increase in the total number of PCI procedures from approximately 65,000 in 2001 to 125,000 in 2006 (Figure 1). This increase can partially be explained by improvements in both diagnostic and therapeutic procedures that have expanded the number of patients eligible for the procedure. Technological innovation (i.e. the introduction of coronary stents) is undoubtedly one key factor. In fact, the increase in PCI procedures with coronary stents has grown faster than the number of total PCIs (with and without stents) during the same period increasing from 81.6% of all PCIs (53,411 procedures) in 2001 to 92.5% in 2006 (114,799 procedures). There

are several types of stents, for example, drug eluting stents (DES) and bare metal stents (BMS). DES now account for 56% of all stent procedures compared with 18% in 2003 when they were first introduced onto the Italian market.

Procurement – financial arrangements between producers and providers

Both ICDs and stents are purchased by health care providers through open public tenders. Negotiations take place at provider level, even though centralised procurement strategies have been enacted at both regional and inter provincial level. Public tenders are usually assessed on the basis of cost, with the price/quality criteria ratio varying from 40/60 to 50/50. Given the rapid pace of innovation in this category of devices, quality criteria are usually based not only on the technical evaluation of the device, but also on the results of clinical studies, research and development programmes and, in case of selected innovative products, the quality of samples provided by the manufacturer.

Before the recent introduction of reference prices, aimed to put a cap on the cost of bids in public tenders, price negotiations were free. Even though both technologies, ICDs and stents, will eventually be affected by this measure, only coronary stents were included in the initial list of devices with reference prices (Table 1).

Reimbursement measures

In Italy, given that all medical devices are implanted on an inpatient basis, ICDs and stents are prospectively reimbursed through DRG tariffs. From 1 January 2006 a new DRG classification system (Grouper 19) was adopted nationwide. This change has influenced the reimbursement of both ICDs and coronary stents, since it defined three new DRGs specific to these devices. ICDs are currently reimbursed through DRGs 514 and 515 – cardiac defibrillator implant with/without cardiac catheterisation. Coronary stents are included in DRG 517 – percutaneous interventions for the cardiovascular system with insertion of stent in the coronary artery without acute myocardial infarction.

The different Italian regions are entitled to adopt different policy measures to regulate reimbursement mechanisms for medical devices.⁵ The variability of regional reimbursement systems plays a significant role in the use of cardiovascular implantable technologies. Some regions reimburse a percentage of the cost of the device (Lombardy, for instance, recognises 30% of the average weighted regional costs of BMS and 50% of DES), whereas other regions, mainly Campania or Sardinia, provide a fixed top-up to DRG tariffs for devices.

Discussion and future perspectives

In recent years, the financing of medical devices has gained increasing attention from health policy makers in Italy at both regional and national level. From the measures adopted, it appears that national policy makers have focused their attention on cost containment policies by establishing the maximum prices for devices that can be used in tender negotiations. It is still too early, however, to quantify the effects of the introduction of national reference prices in Italy. Furthermore, the government has recently recognised the temporary nature of reference prices and the need to identify complementary cost-containment alternatives; nevertheless no official policy measures have, to date, been adopted.

The regional health authorities, on the other hand, have mainly concentrated on defining different reimbursement policies to control costs. Even though significant progress has been made, the current classification system does not allow for differentiation between types of ICD or coronary stent. This could potentially hinder the diffusion of innovative devices. Data highlight regional variability in the diffusion of both technologies, but the hypothesis that this is due to different reimbursement schemes still needs to be tested empirically.

Given the increasing attention of Italian policy makers to the definition of policies in the medical device sector, new measures are likely to follow. The effectiveness of these policies will greatly depend on the success of coordination between the national government and the regions, since the major critical feature of the Italian NHS remains the distribution of powers between the two levels.

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Reference pricing for outpatient medical aids in Germany

Michael Bäumlér, Jonas Schreyögg, Sabine Meissner and Reinhard Busse

Summary: German reference prices define a limit for reimbursement by sickness funds for certain categories of products. In 2005 a nationwide reference price system for six of thirty-three categories of medical aids was introduced. Prior to this, reference prices had only existed for these categories in some of the German Länder. A data sample provided by a large German sickness fund indicated decreasing expenditure in five categories after the introduction of the new system while expenditures for one category increased. However, a judgement on the efficacy of reference prices seems to be difficult as there were both different starting points for reference prices in the Länder and other factors influencing expenditure.

Keywords: Reference Prices; Medical Aids; Germany; Expenditure

Contributions to German Social Health Insurance (SHI) are paid in equal part by employers and employees as a proportion of salary. As the employers' payments are thought to be one of the reasons for high unemployment rates in Germany, endeavours to lower these costs, or at least to fix them at their current level, have been made. In the ambulatory and hospital care sectors, expenditures have generally been contained by tying changes in reimbursement to changes in contributory income. For the cost containment of pharmaceutical expenditure, a range of more and less successful instruments, including regional and physician-specific prescription caps as well as reference prices (since 1989), have been used.

Thus, the temptation was great to also use this reimbursement system in the market for medical aids (i.e. medical devices prescribed in ambulatory care for use by

patients), as the 'sector' medical aids and 'services by non-physicians' (for example, physiotherapy) was one of the few remaining sectors with visible expenditure increases – nota bene, in official statistics on SHI expenditure, the two groups are always given together so that the overall development was extrapolated to both.

We aimed to analyse if there is evidence that the introduction of nationwide reference prices for certain groups of medical devices led to decreasing SHI expenditure, in comparison to what happened in the pharmaceutical market where we judged this to be quite successful.¹ To do this we examined a sample of administrative data on spending on medical aids,^{2–5} of the Gmünder ErsatzKasse (GEK). This is one of Germany's largest sickness funds which insures about 1.65 million people.

Definition of reference prices in Germany

The German reference price system does not set fixed prices but instead limits what may be reimbursed by the sickness funds. For products with prices higher than the reference price, the insured individual has to pay the difference between the reference price and the price set for manufacturer/distributor reimbursement. The reference

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prices include value added tax and all costs arising from the delivery of medical aids.

Reference prices for medical devices demand the same requirements as pharmaceuticals. They have to guarantee a sufficient, appropriate and efficient, as well as quality-assured provision of medical devices. Reference prices aim in principle to mobilise efficiency reserves and stimulate effective price competition. Therefore, the price should preferably be orientated towards reasonably priced goods and services. Sickness funds are requested to make use of public tenders in respect of medical devices that are not subject to reference-pricing.

Introduction of reference prices for medical devices

Reference prices for medical devices were first established under the 1989 Health Care Reform Act.⁶ Visual and hearing aids were reference-priced in all federal states (Länder), whereas devices for decubitus, arch supports, incontinence aids and ostomy procedures only received reference prices in some of them. The prices itself were defined by the different regional associations of the sickness funds.⁷

When the SHI Modernisation Act (GMG) came into effect in 2004, the federal associations of the sickness funds were required to set nationwide reference prices for the first time. The first came into effect on 1 January 2005 for the following six (of a total of thirty-three) categories of the medical aids catalogue: arch supports, technical aids for compression therapy, visual and hearing aids, absorbing and draining incontinence aids and ostomy procedures.

The setting of reference prices

In a first step, reference price groups are formed by the federal associations of sickness funds for products of homogeneous and equivalent functionality on the basis of the classification of the respective product groups within each category in the catalogue of medical aids.⁶ This is clearly an important precondition as groups with heterogeneous products of different functionality would have a clear potential for inappropriately steering the usage of one product over the other. Forming groups with the aim of calculating reference prices is therefore confined to groups where homogeneity can be reasonably safely evaluated or assumed.

In a second step, reference prices are set for each group by the associations of sickness funds. Manufacturers and organisations

representing people with disabilities then have the opportunity to issue statements that have to be taken in consideration in the process of grouping aids for reference pricing and in the process of setting price levels. These reference prices are then assessed at least once a year and adjusted as appropriate to take account of market conditions.⁸ It is important to note that categories may encompass a large number of product groups, i.e. a reference price is not set for a whole category but for each individual product group: for example, ostomy currently encompass thirty-one product groups, with reference prices ranging from €111.47 to just €0.04.

Impact

Figure 1 illustrates relative expenditure per insured person in the GEK between 2003 and 2006 inclusive, i.e. before and after nationwide reference prices were introduced in 2005, with 2004 as the index year. These expenditures decreased dramatically from €9.27 per insured individual in 2003 and €3.81 in 2004 to only €0.91 and €0.81 in 2005 and 2006 respectively.

The expenditures for all categories with reference prices (with the exception of visual aids which are not included in the analysis as reference pricing already existed on a nationwide basis) increased in 2004 by between 10% (hearing aids) and 5% (arch supports). After the introduction of reference prices, expenditure fell both in 2005 and 2006, save for incontinence aids, a category for which reference prices were initially not set for all product groups

(Table 1). In contrast, while expenditure on other medical aids not falling under the reference price scheme decreased between 2003 and 2004, it again increased in 2005. As Figure 1 illustrates while there was a fall in 2006, this group continued to have higher levels of per capita expenditure compared with medical aids in the reference pricing groups.

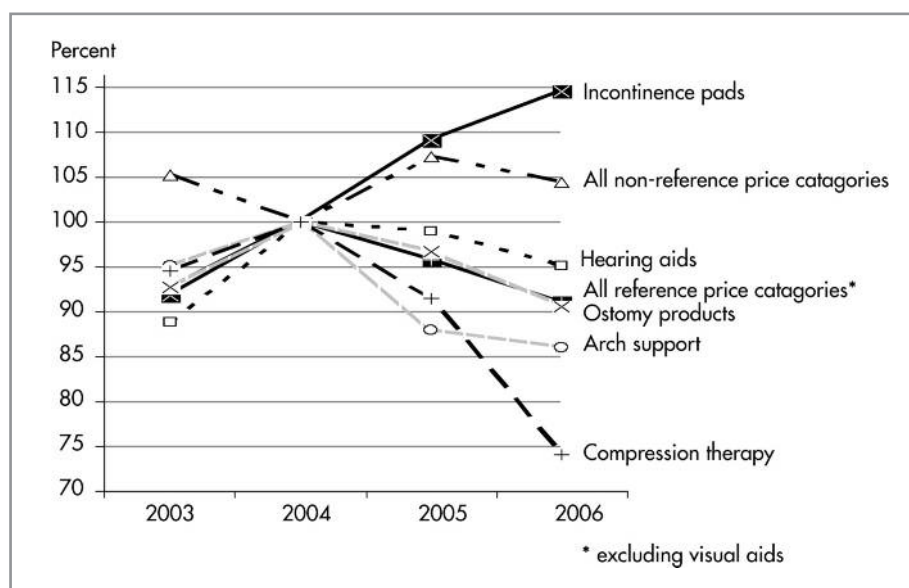
Conclusion and perspectives

It is difficult to judge the success of the introduction of nationwide reference pricing in Germany, since (1) results are not unambiguous, (2) the number of prescribed medical aids switches between products within a group, and actual prices are currently impossible to disentangle and therefore (3) it is not possible to adequately assess the impact on issues such as patients' equity of access, appropriateness and quality of care and the level of innovation of the industry. We therefore concentrate on expenditure per capita data.

With the exception of incontinence products, expenditure per capita decreased for all categories of medical aid with a reference price. The greatest fall in expenditure was observed in those categories of medical aid that had rarely made prior use of reference pricing. In the case of hearing aids, where reference pricing had existed before 2005, only a small decrease in expenditures could be observed.

Compared with all non reference-price categories, which increased after 2004, it is striking that expenditures for categories grouped using reference prices decreased

Figure 1: Expenditures per insured per year (with expenditures for 2004 as the index year)



Source: Calculations, based on data of GEK Heil- und Hilfsmittelreport 2004–2007.²⁻⁵

Table 1: Overview of changes in expenditure for different categories of medical aids

Category	Expenditure per insured individual 2004 (€)	% of total expenditure for medical aids per insured individual 2004	Reference prices in X of 16 Länder in 2004	Expenditure development in 2005 (index year 2004)	Expenditure development in 2006 (index year 2004)
Hearing aids	3.71	8.32%	16	99%	95%
Incontinence aids	2.16	4.85%	10	109%	115%
Arch supports	3.89	8.73%	7	88%	86%
Ostomy products	1.79	4.02%	2	97%	91%
Compression therapy aids	2.66	5.97%	2	91%	74%

Source: Calculations, based on data of GEK Heil- und Hilfsmittelreport 2004–2007.

within two years to 91% of their 2004 expenditure levels. Nevertheless, these decreases are much less pronounced than those seen after the introduction of reference prices for pharmaceuticals.^{1,9}

It should however be noted that the demand for medical aids is influenced by many other factors that are difficult to control. Price elasticities for co-payments may vary between categories and thus may cause expenditure change. Distribution of market power may also influence the levels at which reference prices are set. In categories where manufacturers have strong market power, the reference price could be set rather high, whilst in other categories the strong influence of the sickness funds may lead to markedly low prices and thus to lower expenditures. Moreover, we have not been able to incorporate epidemiological factors, such as change in the incidence of disease associated with certain medical aids, into this analysis.

Looking at our results from a macro system-perspective, one overall conclusion at this stage is that while the reference price system has contained expenditure within the SHI system, it cannot automatically be equated to increased efficiency as this would require more detailed analysis of the precise changes in product price and use. Even if such data were to become available, careful analysis of the impacts on population health, appropriateness and equity of care, as well as efficiency, would require more of the types of data that are commonly used within the health technological assessment of pharmaceuticals.

It may be that because of these difficulties, Germany is already experimenting in new ways of organising both access to and financing of medical aids, such as through

public tenders. Under this policy, introduced in 2007, sickness funds are required to use public procurement procedures. They invite tenders from distributors (not manufacturers unlike the situation for pharmaceuticals) for providing certain medical aids to their insured populations in a specified area. Taking a closer look at the results of this new instrument will be well merited as soon as they become available.

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Cancer control in Europe today: challenges and policy options

Delia-Marina Alexe, Tit Albrecht, Martin McKee and Michel P Coleman

Summary: In spite of the advances in cancer control, cancer remains a huge problem in Europe, in terms of both morbidity and mortality. This article summarises the challenges posed by cancer in Europe today and the measures available to tackle them. It is based on 'Responding to the Challenge of Cancer in Europe', a collaboration between internationally recognised public health institutes in the European Union, under the umbrella Fighting Against Cancer Today (FACT).

Keywords: Cancer, Cancer Control, Inequalities, Prevention, Policy

Introduction

Cancer has been known and researched since antiquity, but substantial progress in cancer control has only been made in the last few decades. Greater understanding of the causes of cancer has had a major impact on both *primary and secondary prevention* of cancer, as well as on *treatment and rehabilitation*. In terms of reducing human exposure to cancer risk factors, one of the most important discoveries of the twentieth century was the role of tobacco smoking as a cause of cancers of the lung and various other organs.¹ The outcome of anti-smoking measures is now becoming visible. Lung cancer incidence and death rates among men are decreasing steadily where they have been effectively implemented, such as in western and northern European countries.²

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A more recent achievement in *primary prevention* is the identification of the Human Papilloma Virus (HPV) as the cause of cervical cancer, and the development of vaccines against carcinogenic types of HPV; some vaccines were licensed in 2006 in the European Union.

Secondary prevention, and specifically early diagnosis of breast and cervical cancers through organised mass-screening programmes, has led to a reduction in cancer mortality and an overall improvement of the quality of life of cancer patients. A more recent opportunity for cancer control is faecal occult blood testing, which has been shown to reduce mortality from colorectal cancer.³

Although pharmacological *treatment* is responsible for a small proportion of cures in patients with cancer overall, its contribution in tackling some types of cancer (testicular and breast cancer, leukaemia and Hodgkin's disease) has led to an impressive increase in survival from these cancers and a significant reduction in the number of deaths.⁴ All these developments, along with major innovations in imaging, surgery, and radiotherapy, have radically changed the perception and management of cancer. Some cancers can now be cured, while others are increasingly seen as a 'chronic' condition rather than a fatal disease, which means that a patient is more likely to die *with* a cancer, rather than *of* it. Advances in genetics and in genetic epidemiology and

the Human Genome Project (<http://www.genome.gov>) now offer new perspectives for diagnosis, treatment, and soon maybe prevention, of many diseases, including cancer.

Life expectancy has increased dramatically. A century ago, life expectancy in Europe was less than forty-five years and the main causes of death were infectious diseases and diseases related to poor nutrition. The control of infant mortality in western countries produced the first significant gains in life expectancy; then, the introduction of penicillin, sulfa drugs and streptomycin yielded another significant reduction, this time in adult mortality. From the 1960s onwards, an increasing array of drugs has made it possible to control a growing number of chronic conditions, such as hypertension and asthma. The result has been a downward trend in morbidity and disability.⁵

However, these impressive gains have coincided with, and indirectly contributed to, an increase in the burden of disease attributable to cancer. In the WHO European Region, only 5% of cancer deaths occur in people less than forty-five years of age. The majority of deaths from cancer occur after this age, three-quarters of which are in people aged sixty years and older.⁶ The inevitable consequence of ageing and population growth in Europe has been a very large increase in the burden of cancer.

For these reasons, in spite of the advances in cancer control, cancer remains a huge problem in Europe, in terms of both morbidity and mortality. This article summarises the challenges posed by cancer in Europe today and the measures designed to tackle them. It is based on 'Responding to the Challenge of Cancer in Europe', a collaboration between internationally recognised public health institutes in the European Union, under the umbrella *Fighting Against Cancer Today (FACT)*.^{*} FACT is co-funded by the Government of Slovenia and the European Commission's Health and Consumer Protection Directorate. Participating institutions include the National Institute of Public Health of Slovenia as the co-ordinators, the London School of Hygiene and Tropical Medicine, the Institute of Oncology in Ljubljana and the European Observatory on Health Systems and Policies.

Cancer: current challenges and cancer control

The burden of cancer

Worldwide, about ten million people are diagnosed with cancer each year. A sharp increase of 50% in the incidence of cancer has been predicted by 2020, mainly due to ageing populations in both developing and developed countries, but also as a result of current trends in smoking prevalence and the growing adoption of unhealthy lifestyles.⁷ One-third of the global burden of cancer is recorded in Europe: in 2006, there were 3.2 million new cases of cancer and about 1.7 million cancer deaths. In the 25 EU Member States (EU25 – pre-2007), one out of four deaths was attributed to cancer. Most cases and most cancer deaths are due to four common cancers, those of breast, prostate, lung and large bowel.⁸

The number of new cases and cancer deaths in Europe has increased and is likely to rise further. The accompanying improvement in survival has led to an even greater increase in prevalence. Projections of future cancer incidence indicate that even if the risk of getting cancer at each age does not change, the number of new cancer patients diagnosed each year in the pre-2007 EU25 Member States will rise by 20% in the eighteen years between 2002 and 2020, simply due to population growth and ageing. Incidence rates would have to fall by more than 1% every year over that period in order to counterbalance

the upward pressure of these demographic changes on the numbers of new patients that health systems will have to manage.² Cancer patients will be older than today, and many will have several co-existing illnesses, so the health needs of cancer patients will become even more complex. This upward demographic pressure on the cancer burden is one of the biggest challenges in cancer control.

Implementation of effective strategies for cancer control is essential to counteract these trends. These measures must include primary, secondary and tertiary prevention. In particular, measures are needed to tackle tobacco smoking, the most preventable cause of cancer; to promote mass (population-based) screening programmes for cancers of the cervix, breast and large bowel (colon and rectum), and to extend the adoption and accessibility of effective treatments to all patients within an 'integrated care' system. Lastly, adequate provision for greater numbers of cancers among older people is essential.

Inequalities in cancer in Europe

Europe has some of the richest countries in the world, but also some of the poorest. In 2002, 168 million people were living below the poverty line, about 46% of the European population.⁹ These socio-economic differences are reflected in significant health gaps not only between and within the countries of the European region, including the European Union. They are seen in both the burden of cancer and the range of survival. Differences in the burden of cancer result mainly from international differences in exposure to cancer risk factors (for example, prevalence of smoking, unhealthy diet, obesity) and socioeconomic characteristics; however, they are also an indicator of the overall delivery of services for the prevention and treatment of cancer, including organised screening programmes, the existence and accessibility of health care facilities and technological infrastructure, and the availability of human, financial and material resources for health and economic development. A survey by the European Society of Clinical Oncology, designed to assess the status of medical oncology in Europe (MOSES, Medical Oncology Status in Europe Survey, www.esmo.org/resources/surveys/mosesII_survey/?get_resource=241), has found significant discrepancies in the provision of cancer care throughout Europe, including access to surgery, radiotherapy and cancer drugs.

Progress in cancer control can be seen in most countries, but in some, cancer control is still in its infancy. Efforts to tackle cancer in northern and western European countries during recent decades have resulted in decreasing mortality and increasing survival from those cancers that are amenable to either primary or secondary prevention (for example, lung cancer, breast and cervical cancers). By contrast, in some countries that have joined the EU since 2004, the lack of financial and human resources, along with uncoordinated efforts in the organisation of cancer control, has been associated with an increase in mortality and a poor prognosis for cancers that could have been prevented, or detected in an early phase. Furthermore, at the population level, a lack of cancer awareness in central and eastern European countries has been described, especially in regard to prevention as a means of cancer control.¹⁰

A dramatic contrast in mortality from cervical cancer has been described between EU Member States in western Europe and those in central and eastern Europe. Death from cervical cancer is now relatively uncommon in western European countries, but in Latvia, Bulgaria, Lithuania and Romania there is a continuing increase in cervical cancer mortality. In Romania, mortality from cervical cancer has reached levels that have never been seen before in Europe.¹⁰ In the late 1990s, there was a greater than tenfold difference between the highest cervical cancer death rate, in Romania, with no organised mass-screening programme, and the lowest death rates in Finland and Sweden, where population coverage of cervical cancer screening is almost 100%.¹¹ The treatment environment for cancer patients is also extremely difficult in Romania, as the concept of integrated care is non-existent. Another dire example is that of Estonia, where population-based medical registries and epidemiological research are still seriously hampered by data protection legislation that omits any of the exemptions provided under the EU Directive for the processing of personal data for historical, statistical or scientific purposes. This has completely disabled surveillance of trends in cancer incidence and survival.¹²

Health inequalities between 'old' (pre 2004) and the twelve 'new' EU Member States merit particular attention from both the health authorities of the countries concerned and the EU as a whole. Cancer control must be a priority for the

^{*} website <http://www.projectfact.eu>

European Commission, both now and in future action plans. There is a particular need to support the most severely affected Member States, and scope for this is offered by the Commission's Structural Funds. Exchange of best practices in cancer control across the EU, backed up by substantial funding in countries where the health care system is in 'transition' and cancer control measures are under development, could also substantially reduce these inequalities in cancer outcomes.

Within countries, adequate political and financial support is needed to enable the creation and operation of population-based screening programmes and cancer registries. This should include an appropriate legislative framework and stable long-term funding. National education programmes should be implemented to change attitudes towards cancer and cancer prevention, building upon initiatives such as the European Code Against Cancer.

Key risk factors for cancer and prevention policies

Some lifestyle factors, such as tobacco smoking, alcohol consumption, unhealthy diets and lack of physical exercise, or excessive exposure to sun, play an important role in the causation of cancer. The biggest challenge in primary prevention remains tobacco smoking, linked to between 80–90% of lung cancers and between 40–60% of cancers of the oesophagus, larynx and oral cavity.¹³ Despite the significant impact of anti-smoking interventions implemented in some countries since the early 1980s, lung cancer is still the leading cause of cancer death in Europe. Importantly, although lung cancer rates in males have stabilised or have been decreasing in northern and western European countries, lung cancer mortality among women is still rising in many European countries, in particular in southern and eastern European countries.² While some European countries have made impressive progress in tobacco control, others still have much to do. It is remarkable that many countries still allow smoking in public places.

Another challenge in cancer prevention is the excessive consumption of alcohol, twice as high in Europe as the world average. Alcohol is a cause of several cancers, such as those of the upper digestive and respiratory tract, and primary liver cancer.^{13,14} When alcohol consumption is combined with tobacco smoking, cancer risk increases exponen-

tially.¹⁴ Although the role of diet in cancer causation is still relatively under-explored, it has been estimated that about one-third of all cancer mortality may be related to unhealthy diets,¹⁵ while a diet low in fresh fruit and vegetables seems to increase the risk of cancer in those exposed to other carcinogens.¹⁶ There is also evidence supporting the role of obesity as a cause of some cancers.^{13,14} Preventing skin cancer remains equally important, because the incidence of melanoma of the skin in Europe has doubled since the 1960s.

Viruses such as HPV and the hepatitis B and C viruses cause more than 20% of cancers in developing countries but only about 8% of all malignancies in developed countries.⁷ This gap is also apparent in Europe, where cervical cancer is a major problem in central and eastern European countries.¹⁰

A broad policy framework is needed for cancer control in Europe. Policy will need to harness some essential tools for the prevention of tobacco smoking and alcohol consumption, such as the WHO Framework Convention on Tobacco Control and the Framework for Alcohol Policy in the WHO European Region. Effective strategies to reduce tobacco and alcohol consumption include pricing policies, policies to reduce the harm caused by exposure to environmental tobacco smoke and harmful drinking of alcohol, policies to reduce demand and limit access (in particular the locations and times when alcohol can be purchased), and by the avoidance of internal market policies that promote consumption.^{13,17} Unfortunately, both the tobacco and alcohol industries have been successful in preventing effective action in many countries, often promoting campaigns to undermine the evidence about effective health policies.

Another tool is the European Code Against Cancer, an integrated instrument for cancer prevention. It focuses on promoting the adoption by individuals of healthy lifestyles, including participation in screening programmes.¹⁴ It provides an important basis for health promotion by health care professionals and non-governmental organisations.

Most countries in Europe have seen a rapid increase in the prevalence of obesity in recent years: tackling this epidemic should become a priority in the EU.¹³ The Global Strategy on Diet and Physical Activity provides a solid basis for action. Promoting physical activity would help in

reducing average body weight, but it has also been linked to a reduction in the risk of cancers of the breast, body of the uterus and prostate, independently of weight control.¹⁴

Interventions to tackle cervical cancer should be tailored to the particular situation of each country. For example, HPV vaccination would provide a new approach to preventing cervical cancer, particularly in countries with a high incidence of the disease and inadequate screening.¹⁸ To prevent infection with hepatitis B virus in Europe, systematic vaccination is needed as a part of national immunisation programmes. No vaccine is yet available to prevent infection with hepatitis C virus.

Costs of diagnostic and treatment services

Early diagnosis and optimal treatment of cancer is complex. It requires education, prevention, diagnosis, treatment and palliative care. One of the most important challenges in cancer control is to coordinate national plans and services to cover all aspects of the management of cancer.

During the last decade, the diagnosis and treatment of cancer have become increasingly expensive, as a result of rapid advances in technology and drug development. Pressure from the pharmaceutical industry has led to the prioritisation of drugs over other treatment modalities. The oncology drug market is expected to grow steadily as a result of the ageing population, the development of new treatments and advances in cancer genetics. Developments in molecular pathology, imaging, radiotherapy and surgery are at least as important in the management of cancer, and should also be strongly encouraged by the EU, along with long-term investment in the training of staff and the acquisition and/or renewal of equipment.¹⁷

New and expensive drugs that offer no substantial advantage over existing treatments are being promoted. This places a further burden on national health services, insurers and cancer patients. For example, one cycle of temozolomide, used in treating some brain tumours, is 350 times more expensive than the reference drug procarbazine, although these two are largely equivalent in terms of efficacy and safety.⁴

The increase in the cost of cancer care, and in the cost of drugs in particular, is likely to prevent equal access to optimal care to all patients in an economically limited system, with different countries choosing different

thresholds to trigger the availability of drugs for defined groups of patients.¹⁹ A recent example from England concerns the proposal by the National Institute for Health and Clinical Excellence (NICE) for the 'rationalisation' of chemotherapeutic treatment for kidney cancer with four types of drugs, based on their lack of cost-effectiveness for treating patients with advanced or metastatic renal cell carcinoma.²⁰

Health care policy-makers and funders need to examine the cost-effectiveness of new technologies as closely as the efficacy of the drugs themselves. National governments have a responsibility to establish mechanisms to ensure that clinically proven interventions that maximise both the duration and quality of life are available to all their constituents. Robust health technology assessment is essential, followed by equity in the distribution of treatment resources.¹⁹

Cancer control: an integrated approach

It has been estimated that a quarter of cancers could be prevented by applying existing knowledge, while a further third of cancers may be curable using current treatments and technologies.⁷ For fatal cancers, palliative care is an essential component of cancer care. It is aimed both at improving the quality of care for cancer patients and their families, and at helping them both to live well until they die, and to die well.²¹ An integrated strategy for cancer control must thus include all elements of prevention, as well as treatment, palliative care and research.

At a national level, a key requirement for successful cancer control is the development of a coordinated cancer plan. WHO published six guides as a framework for a comprehensive planned approach to cancer control. These can be used to identify priorities for action and research across the entire spectrum of cancer control. Implementation of these activities needs to be monitored constantly, alongside the overall efficacy of the health system, one indicator of which is cancer survival. Cancer information systems such as screening registries and cancer registries are essential tools; their operation requires adequate investment and legal protection.

At the EU level, measures to complement national policies in Member States are needed. For example, the 1995 EU data protection directive has impeded the effective operation of cancer registries. The Directive must be revised to enable and

protect cancer registration.¹⁷ Reducing health inequalities across the EU should also be a priority: more support and investment are needed in the most affected Member States. Measures to control the effects of unhealthy lifestyles have an important potential to supplement health care provisions everywhere. These include strategies to tackle tobacco smoking and alcohol consumption, and those which promote healthy nutrition and physical activity, safe occupational and environmental guidelines, as well as the prevention of infections that cause cancer.

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Lampedusa and pharmaceutical distribution: community pharmacy in the 21st century

Ricard Meneu

Summary: Within the context of the countries belonging to the EU before May 2004 (EU15), regulation of the pharmaceutical industry is currently under close scrutiny. Attempts at reform often attract the attention of various stakeholders and European institutions, who may flag up violations of European Community norms in Member State legislation. Although much of the debate revolves around business issues (i.e., property, planning, mergers and acquisitions) there is a real need to redefine the professional activities of pharmacy personnel whose roles have changed radically over recent decades.

Key words: Community Pharmacy, Regulation, Profession, Incentives, Public Health

*“If we want things to stay as they are, things will have to change”
from *The Leopard*, Giuseppe Tomasi di Lampedusa (1958).*

In 2008, the European Commission initiated infringement proceedings against Germany over its restrictions on the ownership of pharmacies. Similar actions have been undertaken against the regulation of pharmacies in Spain, France, Austria and Italy. These infringement procedures concern a series of restrictions relating to the opening and running of pharmacies including: the incompatibility between the distribution and retail sale of pharmaceutical products; having the ownership of pharmacies reserved exclusively for pharmacists; territorial and demographic limits in the setting-up of pharmacies; and a ban on owning more than one pharmacy.

The distribution and dispensation of drugs is a highly regulated activity in most of the

EU15; however, the pace of these regulations has not kept up to speed with developments in the sector. Since the mid-twentieth century, the activities of the community pharmacy have altered considerably. Pharmacists, who originally operated as drug producers, have now moved towards activities related to the distribution of manufactured products that are already scrupulously labelled by the pharmaceutical industry. These products are delivered directly to the pharmacy through the wide-reaching logistics of wholesale distributors, who centralise purchasing and deliver to individual pharmacies up to five times a day. It is these intermediaries who provide the majority of the value associated with the drug distribution system, since they guarantee pharmaceutical supply and accessibility. Because pharmacies no longer need to hold substantial stocks, they can

save money that would otherwise be tied up in inventory.

Wholesalers perform two broad functions in the supply chain of the pharmaceutical industry: (i) they provide basic logistic functions for pharmaceutical distribution, bridging distances and time, while assuring quality and quantity, and (ii) they provide services that may add value to both pharmaceutical manufacturers and retailers, including sales analyses, marketing assistance and product training, special handling services and product recalls.¹ However, this major shift in the responsibilities and duties of the different players in the sector has hardly been reflected in the design of new governance regulations. Regulations, thus, have become outdated and no longer correspond to the current parameters of a sector which has changed substantially since the laws to regulate it were originally put in place.

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The views expressed are those of the author alone.

The regulation of drug distribution and dispensation has become a battle ground with each player vying to draw the regulator to his own corner, and boost his share of the pie. However, the whole process has progressively neglected to provide any added value to population health improvement.

One analysis of the major features of pharmacy regulation reveals that, as a professional collective, the European Community's pharmacists have managed to maintain a long-standing monopoly over the supply of drugs, both prescription and over-the-counter products, and to control the number and location of pharmacies, while limiting the right to ownership of these establishments.² It is more difficult to explain the frequent alignment of health care authorities with the pharmacists' interests. Some would argue that such regulatory capture is, overall, against the interests of society as a whole.

The laws governing pharmaceutical distribution have been reiteratively examined in European countries to verify the 'rent seeking' hypothesis. Results coincide in showing that, for the most part, legislation is oriented towards restricting the entry of players, or limiting competition between existing players, thus reinforcing the pre-eminence of private interests at the expense of the public good.³

As a result of these tensions, in most of the EU15 countries, regulatory aspects of debatable efficiency are continuously being challenged. Particular attention is paid to the four 'Big Ps' – property (ownership), planning, payment and professional services. Regulations governing *property* translate into the accepted monopoly whereby only pharmacists can own pharmacies. They involve the control mechanisms on access to ownership and restrict its scope. Added to this is the questionable congruence of reserving for these establishments a monopoly on sales of all drugs, including those that do not require a medical prescription.

There are limitations on the number of pharmacies that may be opened in keeping with *planning* criteria related to demographic or geographic features that would guarantee accessibility. Reimbursement or *payment* systems, with various fees, constant margins, capped margins and rebates may be questioned. Though the object of less heated debate (although

central to the problem), are the *professional* activities conducted in pharmacies. It is precisely these activities that justify a requirement for certain technical qualifications to dispense what are none other than manufactured, pre-labelled products. These issues are now discussed in more depth.

Property

Access to ownership of pharmacies varies throughout Europe, although in ten of the EU15 countries, it is limited to qualified pharmacists. This restriction, together with another that limits the number of pharmacies that one proprietor can own, can make it difficult to develop strategies that would have a favourable impact on efficiency, such as certain types of horizontal integration to obtain economies of scale or scope or other (cost) advantages.²

Most Member States allow horizontal cooperation. Both partnerships with other pharmacies and integration with druggists are allowed in a majority of cases. Vertical integration is restricted. Seven Member States allow pharmacists and wholesalers to integrate; while only six Member States allow integration between pharmacists and producers. Countries with no chains of pharmacies include Denmark, Spain, France, Germany and Austria.^{2,4}

Prohibiting non-pharmacists or legal entities not consisting of pharmacists from having holdings in pharmacies goes beyond what is necessary to achieve the objective of public health protection, since it would be sufficient to require the presence of a pharmacist to dispense medicines to patients and to manage stocks. Since compliance with professional standards is guaranteed independently of the presence of the owner on the premises, requiring owners to be qualified pharmacists is a redundant measure.

The champions of this model, i.e. current owners and their professional 'guilds' claim that "rules on the ownership are established by national legislation to guarantee the independence of the profession, to ensure that decisions are not taken solely for commercial reasons and to guarantee the provision of high quality pharmacy services".⁵ This, however it might be argued, fools no one, as it is unlikely that a businessman's professional qualifications will lead him to act against his own interests. On the contrary, professional qualifications can supply the owner with the knowledge and skills necessary to implement practices just this side of what is acceptable.

Furthermore, if "pharmacists must be independent from major market entities or other parties that might influence professional decisions"⁵ it does not seem reasonable that in some countries it is pharmacists who are the owners of most distribution companies, established under the format of 'cooperatives'. This type of bottom-up vertical integration leaves them open to the same risks of "commercial pressures" as the opposite, prohibited, top-down integration under which wholesalers can, in turn, be owners of pharmacies.

Under scrutiny, limiting ownership of pharmacies to qualified pharmacists is not justified in operational terms. It clashes with both the regulation of some national markets and rules governing other health care establishments. Even in the case of complex organisations providing health care services (for example, specialised hospitals) there are no similar rules limiting ownership to specific professionals, as there are no limitations on shareholder composition.

Planning

In order to ensure that pharmacy services and medicines are conveniently accessible to all citizens and to avoid the situation where pharmacies are concentrated in highly populated urban areas, several Member States have criteria on the establishment of new pharmacies.

Seven of the EU15 countries studied set requirements on their location. The most common restrictions are related to a minimum number of potential customers and a minimum distance between pharmacies. In general, these planning measures translate into relatively simple rules that may be based on arbitrary figures which leave a wide berth for discretionary decisions.

A reasonable distrust of the efficiency of these mechanisms is reflected in some of the 'infringement proceedings', that indicate that some of the measures adopted do not in fact achieve their intended objectives. They can be counterproductive to the goals of ensuring a good supply of medicines across a country.

Another concern is that these mechanisms may lead to the creation of artificially protected monopolies which then use cross subsidies to support activities that are not profitable. Alternative solutions have been proposed, such as the establishment of transparent subsidies to pharmacies, provided on the basis of sound public

interest objectives, in situations where activities could not be performed on a profitable commercial basis.⁴ Versatile distribution systems are needed to help ensure access for both people living in remote rural areas and those who may find it difficult to travel to a pharmacy. One option, to date under-exploited because of legal restrictions in many EU-15 countries, could involve dispensing drugs over the internet.

“To define the objectives essential to a 21st century community pharmaceutical sector, it is necessary to promote the interests of demand over those of supply. This will require redesign of regulation and incentive systems”

Payment

Payment systems provide an efficient way to orient any sector's agents towards a specific role, and pharmaceutical distribution is no exception. Depending on the system adopted, a pharmacy's income is linked to a greater or lesser extent to the price and number of products dispensed, or the professional services it provides. There are three basic financing categories:⁶ those that are product oriented, those that are patient oriented, and those that are a combination of the two. While the latter two are similar to the payment schemes usually adopted to remunerate other professional health care providers – fee for service, capitation and salaries – ‘product oriented’ schemes are more similar to retail reimbursement models.

Pharmacists usually receive a fee related to the number of transactions they conduct. More specifically, they receive a fixed fee and/or a percentage (fixed or variable margin) of the drug price per dispensed prescription drug. The fixed fee is supposed to reimburse pharmacists for their provision of pharmaceutical services. However, the fact that this reimbursement is related to the number of prescriptions rather than to the actual provision of pharmaceutical services has been criticised by some authors.¹

Systems based on the payment of margins are undesirable in an environment where there is a wide variability in the pricing of

products that have similar costs in terms of supply, storage, conservation and dispensation. There is a clear need to redefine the criteria for remuneration of pharmacies, as is stated in the *Resolution of the Council of Europe ResAP (2001) 2* concerning the pharmacist's role in the framework of health security. This recommends that “the system under which (pharmacists) are remunerated must be reviewed to reflect the professional service they provide rather than the profit margin or volume of their sales, in accordance with Resolution AP (93)1 on the role and training of community pharmacists”.⁷

Professional activities

Other concerns less frequently addressed, although central to this discussion, relate to whether professional activities justify the need for specific qualifications. Today, pharmacists largely dispense manufactured products that are carefully labelled against a prescription document, which generally includes specifications about the product, dosage, person for whom the product is intended, along with a justification of the indication.

Although “common medicinal products, such as paracetamol and aspirin, can be dangerous if they are not taken in appropriate quantities and in the appropriate way”,⁵ this does not mean that every dispensing act requires professional advice and counsel. When an individual patient buys aspirin time and time again, it is not usually necessary for the pharmacist to remind him or her of the risk of stomach bleeding associated with its analgesic and cardio-protection properties. Current legislation obviously does not require the provision of such services.

Any redefinition of the professional role of pharmacists will necessarily incorporate claims of the need to pay for ‘Pharmaceutical Care’ (PC), a concept that has not been clearly defined. So pending the demonstration of the overall efficiency of PC, the implementation of programmes to review utilisation for the purpose of developing schemes for professional development, while a difficult task, is one that will no doubt benefit all stakeholders. The flashy promises of PC, a concept that has not even reached an embryonic stage, may be making us forget the fact that the mere verification *ex ante* of therapeutic compliance and avoiding certain interactions and counter indications would provide substantial added value that is currently absent in the current situation.

Conclusions

The discourse over the regulation of the pharmaceutical distribution sector invokes public safety and consumer protection. It generally masks the desire to preserve *in statu quo* and thus inhibit any development that may actually benefit the users of distribution services over pharmacy owners.⁸ There is no doubt that public health must be guaranteed through the distribution of drugs; however, in order to do this, clear objectives must be defined and mechanisms established to meet the goals sought, followed by careful evaluation of their empirical efficiency. This is very different from what is happening today when out-dated strategies, designed for a time when the activities of pharmacists were very different, are being preserved.

The sector also invokes the nebulous notion of ‘public health’, even though the effects of the current system can include the preservation of unfair monopolies that only enhance revenues for pharmacists, the evident capture of the regulator by the objects of regulation and the maintenance of unsuitable payment schemes. All of this can be set against the absence of a clear definition of both the desirable professional services to be rendered and their contribution to population health improvement.

Any analysis of current regulation must clarify whether current laws promote or inhibit efficiency in the sector, and whether they translate into real benefits for consumers instead of acting as a mechanism to hike up prices unnecessarily. An adequate evaluation of sector regulation would require, on the one hand, a country by country comparison, accompanied, above all, by an exhaustive analysis of the tensions that exist between the pharmacy, a venue that not only retails drugs, but that should also provide professional services, and all of the other stakeholders participating in the drug-provision cycle.

To define the objectives essential to a twenty-first century community pharmaceutical sector, it is necessary to promote the interests of demand over those of supply. This will require redesign of regulation and incentive systems, in an effort to align the interests of (i) professional pharmacists, as providers of valid specialised services and not only as mere drug retailers, (ii) the health care system in which this sector has been integrated until now in an anomalous position and (iii) the public which it supposedly serves. Any

measures adopted should pursue the goal of improving the health of the population by tapping into the professional qualifications of pharmacists that are currently wasted on task of lesser importance. This is not so much a question of improving economic benefits, but of moving towards a sector design that corresponds with the current drug-provision cycle. This approach would thus account for the changes that have taken place in recent years, rather than continuing to perpetuate what is now an outdated image of the sector.

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The over-the-counter pharmaceutical market – policy and practice

Christine Bond

Summary: The European non-prescription medicines and consumer over-the-counter (OTC) self-medication market is today worth some €29 billion at consumer prices and represents 36% of world sales.¹ In this personal reflection from a UK perspective, I consider the background to and changing context of OTC medicines, the implications for the pharmacy profession and patients, and the benefits and challenges.

Keywords: Over-the-counter Pharmaceuticals; Pharmaceutical Policy, UK

In most of the world, access to and supply of medicines is governed by a regulatory framework which is based on perceptions of the risks and benefits of the medicine to the population. In the UK, for example, there are three broad categories of medicines: POM (prescription only medicines), P (pharmacy supervised sale), and GSL (general sales list).

POM medicines are primarily only available to the public when prescribed by a medical practitioner, although historically dentists have long been able to supply from a limited Dental Formulary. More recently in the UK, full prescribing rights have also been accorded to other health care professionals such as nurses and pharmacists, as long as certain specified conditions are met. P medicines can only be sold under the supervision of a pharmacist from premises registered with the Royal Pharmaceutical Society of Great Britain (RPSGB), and GSL medicines are available from any retail outlet. When moving from POM through to P then GSL there is an increasing ease of public access to medication and an equivalent decrease in professional control and vice versa. Within this framework are ‘controlled drugs’

(CD) which are subject to additional controls, and herbal medicines which are least controlled (see Table 1).

Although this paper is about the OTC market, which is traditionally understood to be P and GSL medicines, it is important to be aware of POM medicines as the three categories together contribute to the pharmaceutical market which is in dynamic equilibrium. When a new medicinal compound is first licensed for use by the public in the UK, and depending on the evidence of safety and efficacy in the pre-marketed period, it is classified as POM. After two years this classification defaults to P unless there is a specific application to retain the POM status, which is the more normal practice. Subsequent moves to reclassify a medicine require a rigorous process of evidence submission to, and consultation by, the MHRA (Medicines and Health care products Regulatory Agency). In Europe there is also clear guidance on the criteria to be applied when retaining a medicine in the POM category (Directive 92/26/EEC). These are summarised in Box 1.

In general, a large subset of POM medicines and a smaller proportion of P and GSL medicines are supplied within a national state health care system, through systems ranging from ‘no cost’ to the patient (for example, Wales) to co-payment systems based on a range of

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Table 1: UK medicines classification and implications for supply, record keeping and professional control

Classification		Supply controls	Record keeping	Level of control
CD	Misuse of Drug Act schedules	Special supply regulations apply	Records in controlled drugs register and routine records	Most professional control – least patient control. Hardest to access
POM	Prescription only medicine	Prescribed by specified health care professional	Record kept	↑ ↓
P	Pharmacist supervised sale	Sold by or under the supervision of a pharmacist	Record rarely kept	
GSL	General Sales List medicine	Available from any retail outlet	Record never kept	
Herbal	New regulations imminent	Available from any retail outlet and some self appointed specialist shops	Record never kept	Most patient control – least professional control. Easiest to access

different models (for example, France or England). Whilst most of the POM medicines would fall within a state health system, OTC drugs, sold to the public, more generally become part of private health care.

Since the late 1980s in Europe, and more recently in other parts of the developed world such as the USA and Australia, there have been moves to increase the numbers of medicines available OTC, and the above European criteria and re-regulation processes have been extensively applied and adopted. The rationale for these moves has been multifactorial. Firstly, as drug

budgets have continued to rise year on year there has been a wish to transfer drug distribution costs from the government to the individual consumer. It is also said that this shift in responsibility for care from the professional to the individual consumer will empower the public, widen access to medicines² and bring additional financial return to the pharmaceutical industry, particularly for drugs nearing the end of their protected, patent, period.

The trend to deregulation from POM status has also been supported by the pharmacy profession³ as a way of extending the range of effective advice and

treatments they can provide to patients presenting symptoms in community pharmacies. In general, the medical profession have supported the deregulation in principle,⁴ although caveats have been expressed for certain specific medicines. A recurring issue is whether or not, as professionals, pharmacists are qualified to diagnose, a skill which is clearly the first step when considering the patient's symptoms and considering 'prescribing'. This is despite the fact that in the early 20th century, and in the UK specifically before the introduction of the NHS in 1948, many people obtained the vast majority of their advice and treatment from their local pharmacist, depending on what were known as 'Chemist's Nostrums' to cure their various ills.

Bearing in mind these concerns therefore, the first medicines to be deregulated tended to be for conditions that pharmacists had historically diagnosed, such as diarrhoea. Indeed loperamide was one of the first of the recent tranche of deregulations providing a safe and effective remedy in lieu of the traditional codeine or other opiate-based remedies (1983). As time went on, and as the confidence of the public and opinion leaders in health grew, medicines already available for an established diagnosis, for example, hydrocortisone for contact dermatitis, were proposed for deregulation for additional indications such as eczema, and for longer term use. The final and then logical move was to deregulate new medicines for new diagnostic areas, whilst operating within the European framework. Examples of

Box 1: European criteria for retaining a medicine in the POM category

- There is direct or indirect danger to health if the medicine is used without medical supervision (for example the ADR (adverse drug reaction) profile needs a doctor to assess risk-benefit, or misdiagnosis might lead to the patient being put at risk);
- The medicine is frequently used incorrectly leading to direct or indirect danger to health (for example, products liable to misuse);
- The activity of the drug or the side effects require further investigation;
- The drug is parenterally administered.

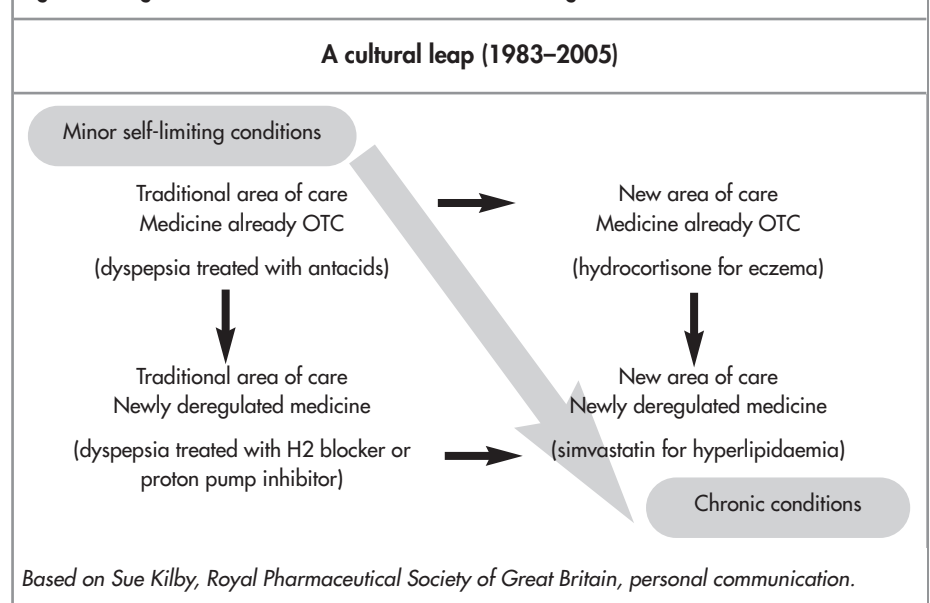
Figure 1: Progress from POM to P and overall cultural change

Table 2: OTC availability in selected countries

	Cimetidine	Omeprazole	Domperidone	Metoclopramide	Simvastatin
Austria	OTC	Rx	Rx	Rx	Rx
Belgium	Rx	Rx	OTC	OTC	Rx
Denmark	OTC	Rx	Rx	NR	Rx
Finland	Rx	Rx	NR	Rx	Rx
France	OTC	Rx	Rx	Rx	Rx
Germany	Rx	Rx	Rx	Rx	Rx
Greece	Rx	Rx	Rx	Rx	Rx
Ireland	Rx	Rx	OTC	Rx	Rx
Italy	OTC	Rx	OTC	OTC	Rx
Netherlands	OTC	Rx	OTC	Rx	Rx
Portugal	Rx	Rx	Rx	Rx	Rx
Spain	OTC	Rx	Rx	Rx	Rx
Sweden	Rx	OTC	NR	Rx	Rx
UK	OTC	OTC	OTC	Rx	OTC

Rx – Prescription only; OTC – available without a prescription; NR – not registered in that country.

Source: <http://www.aesgp.be/Ingredients/EU-15Table.pdf>

such a move in the UK are the deregulation of the Emergency Hormonal Contraceptive pill (levonorgestrel) and the lipid lowering drug simvastatin (Figure 1).

Implications for pharmacy practice

As noted, whilst a large part of the rationale for deregulation came from the industry and health policy makers, the pharmacy profession supported the move because it provided an opportunity for their members to use their skills more fully. The professional pharmacy bodies have played a key role in the deregulation process which has contributed to the paradigm shift of community pharmacists from a technical supply orientated role to a more clinical cognitive role. Indeed, whilst some of the deregulation moves were driven by the industry for specific proprietary products, other moves for deregulation of a general product have come from the profession. This change in role to utilise the profession more fully in an integrated health care service has been increasingly recognised in UK Government policy papers since its early mention in the publication of the Nuffield report on pharmacy on 1986,⁵ culminating in recent pharmacy strategies in the countries of the UK. The better use of

community pharmacy also reflects the shifting balance of care from hospital to community.

One of the other results of the changing paradigm of pharmacy has been the impact on the remuneration of pharmacists. In the UK, as in many other countries, pharmaceutical remuneration has been traditionally linked to the volume of items dispensed against prescriptions. This was initially an appropriate basis, given the skilled compounding required. However, as manufactured proprietary products became the norm, the professional contribution to the dispensing process, whilst still a key component of a safe supply process, in providing a final clinical check on a medicine, became reduced. Other roles, such as general health care and lifestyle advice, also were increasingly delivered either out of goodwill for reasons of professionalism, or formally paid for as part of locally negotiated agreements. Until recently, these were not remunerated on a national basis. New contracts in the UK, introduced in the early 21st century have changed the basis for remuneration to one which recognises these other non-supply oriented services.

Deregulation has contributed to this more

general move for pharmacists to be seen as clinicians in their own right. In the UK, as well as being able to sell a wider range of potent OTC medicines, they have also increasingly acquired a right to supply medicines under the NHS, including OTC products through mechanisms such as the Minor Ailments Schemes, Patient Group Directors and direct prescribing rights. Further discussions of these are outwith the scope of this paper, but are mentioned as an important illustration of how it is not possible to change one component of a complex professional remit without affecting other components.

European perspective

Whilst the detail of this paper is drawn from experience in the UK it can be regarded as a proxy for the rest of Europe. However, there are variations across Europe despite initiatives to achieve a general harmonisation of pharmaceutical regulations. In most, if not all, countries the concept of deregulation of medicines for OTC sale has been replicated although there are interesting differences in detail of what is, and is not, available across the different countries as Table 2 illustrates. This is despite the fact that the principles of retaining a drug with a POM status are,

as previously stated, guided by European standards. However, in general, policy on pharmacy and access to medicines is probably more visionary in the UK than in most, if not all, other European countries.

Other European differences include the exact nature of the POM, P and GSL categories. In the UK and France, medicines in the P category can only be sold 'under the supervision' of a pharmacist from a registered pharmacy, but GSL products are available from any retail outlet, including pharmacies. In Italy, the equivalent of P and GSL medicines exist as SOP (*senza obbligo di prescrizione*) and PDB (*prodotto di banco*), but both are only available in pharmacies. The difference between the categories is that the GSL equivalent category, the PDB, is available for customer self selection and can be advertised directly to the public. In the Netherlands, as in USA, there are only POM and OTC categories. Dutch pharmacies focus much more on POM medicines and have a minority role in the sale of OTC products, 75% of which are sold from 'drogisten' (chemists). These intermediate outlets are neither registered pharmacies nor general retail outlets.

Benefits and challenges of wider availability of OTC medicines

As noted earlier the rationale for deregulation of medicine is said to have been driven by government, the profession and the industry. The success of deregulation from these interlinked perspectives will now be considered.

From the government's perspective deregulation is part of a philosophy to increase safe and convenient access to medicines, empower the public and encourage them to take greater responsibility for their own health. This is also part of a wider agenda recognising that most people actually understand their own needs and symptoms better than the professional and that the best way to treat them is in partnership with the health care professionals. Thus, the 'expert patient' programme⁶ and medicines partnership initiatives (see http://www.npc.co.uk/med_partnership) have emerged. Whilst the focus of the former is more on prescribed medicines, the latter encompasses both prescribed and OTC medicines, and for OTC medicines sold from pharmacies the health professional who provides the advice and guidance is the pharmacist, or the pharmacy assistant. Increasingly in the UK the previously untrained pharmacy

assistant is becoming professionalised. Mandatory training has been in place since 1996, and more recently encouragement to become qualified as a pharmacy technician and registered with the RPSGB.

The role of pharmacists and their staff with respect to OTC medicines is therefore to ensure, as far as possible, that medicines are sold within the conditions of the OTC licence (which may be more restricted than the indication for prescribed use), that the potential for drug interactions (with both other OTC and prescribed medicines) is assessed and avoided, and that people with contra-indications are not sold the preparations.

Using one of the most frequently sold OTC drugs, ibuprofen, as an example, this non steroidal, anti-inflammatory analgesic should not be used long-term (more than seven days continually), should not be used together with other non steroidal anti-inflammatory drugs or some anti-hypertensive medications, and should not be taken by people with a history of peptic ulcer disease or asthma. Whilst this appears deceptively simple to deliver, in practice we know that this guidance is not adhered to, as a long term follow up study of purchasers of ibuprofen^{7,8} and a general public survey⁹ showed (see next section).

The challenge therefore is to empower pharmacists and their staff to provide more directive advice to people buying medicines, without compromising the principles of increased public access to medicines and public empowerment. Until the recent rounds of deregulations, over the past twenty years, most of the drugs sold OTC did not have any body of published information to support evidence based use. Indeed, there is little evidence at all for many of the much hyped and advertised cough and cold remedies traditionally sold.¹⁰ This is not, however, the case for all OTC treatments, particularly the newly deregulated products such as analgesics, products for gastrointestinal problems (antacids and antiulcer) and dermatological products.

As with prescribed medicines, knowledge of all factors required for 'safe', clinically effective supply does not necessarily translate into practice. For OTC sales the pharmacy staff (pharmacists and non-pharmacists) must have all the knowledge, they must be able to communicate it to the purchaser and also obtain information from the purchaser on relevant medical history to ensure appropriate management

recommendations are made. This is not always easy. Use of algorithmic guidelines summarising the necessary knowledge have been shown to be acceptable to and popular with staff,¹¹ but have not necessarily supported evidence based product supply.¹²

For some years a mnemonic WHAM (Who is the medicine for, What is the medicine for, How long have the symptoms been present, Actions already taken, Medicine taken for other reasons prescribed or otherwise) has been used as an aide memoire to remind pharmacy staff of the generic questions to be asked, and information needed to support every OTC sale. Whilst pharmacy staff state they use the mnemonic and find it useful,¹³ in practice not all the questions are routinely asked.¹⁴ Where more questions are asked, the sale is more likely to be appropriate. Reasons often cited for not asking the questions included lack of customer receptiveness and time.

There should therefore be a policy agenda to raise public awareness of the need to treat OTC medicines with respect. They must be reminded that, despite being advertised to the public (in contrast to POM medicines in many countries including the UK), OTC medicines are not just an ordinary commodity, and that change in regulatory status from POM to P has not changed a drug or its potential to cause side effects. There is early research evidence which suggests that the public perceive OTC medicines to be safer and less effective than POM medicines (unpublished work by the author and colleagues) which could explain the current attitude of many of the public to giving information OTC. Mechanisms could build on the fact that when experiencing symptoms of minor illness such as colds and flu the pharmacist is their first preferred option¹⁵ for advice.

To what extent has deregulation increased the market for medicines no longer protected by patent and to what extent have costs shifted from the government to the patient? Two of the early deregulations, loperamide and topical hydrocortisone, were said to have saved the UK NHS £4.2 million and £2 million per annum respectively in 1987.¹⁶ Similar Swedish research estimated that the deregulation of sixteen different products had saved \$400 million per annum.¹⁷ However, it is not possible to generalise across all drugs from this data, as each product will be different.

For example, consider a product for an acute condition, such as topical acyclovir for the treatment of cold sores (herpes and simplex). This was deregulated in 1993, and routine data indicate that prescriptions for this product fell sharply and remained low.¹⁸ Thus supply was changed from NHS supply to OTC supply. In contrast, this drop in prescribed volume was not observed for the anti-ulcer H2 blockers, such as cimetidine, famotidine and ranitidine. It is suggested that OTC availability widened the target population, and that people transferred from self-treatment of dyspepsia with simple cheap antacids to the more expensive newer products. However, once realising their effectiveness, long term use was translated back into increased prescription use. Thus, in this instance, the overall market increased probably in both the NHS and self care arena. This pattern has also been observed with antihistamines.¹⁹ Economic modelling based on consumer surplus also provides theoretical understanding of the above observed effects. If the acquisition cost of the drug is cheaper over the counter there will be financial benefits for both patient and government.^{20,21}

Disadvantages of deregulation

Whilst the deregulation of medicines has many benefits, as already outlined, there are also some disadvantages. It is important to be aware of and address these issues, rather than allowing them to ultimately result in reversal of the policy.

Firstly, side effects and adverse events from medicines are an important and well recognised consequence of the pharmacological activity of a drug. Although the licensing procedures include requirements for evidence of safety in the context of use, it is only once a medicine is used by people in that context that 'real world' circumstances apply. Thus whilst newly launched POM medicines are deemed safe on the basis of the pre-launch clinical trial data, it is often only after product launch, and use by larger numbers of people with a range of co-morbidities and taking concurrent medication, that rare but potentially fatal side effects are identified.

This is likewise the case when a medicine is deregulated from POM to P and is used by an even wider range of people, without the individualised, normal medical advice that would have supported prescription use. Examples of medicines subsequently needing to be reclassified include the antihistamine terfenadine and the anti head lice

treatment carbaryl. Moreover, as already noted, once a medicine is badged P or GSL, there is emerging evidence that the public no longer respect its potency in the same way that they would if it were a POM medicine. It is therefore no wonder that after purchase of a P or GSL medicine, a significant number of purchasers use it outwith the conditions of the OTC license as described below.

Drug safety depends on appropriate use (i.e. at the right dosage, for the right indication, and in the absence of contraindications), and knowledge of the adverse event profile of the drug and its interactions. Long term follow up studies of purchasers/users of ibuprofen (a proxy for other OTC drugs) shows that if these criteria are applied there may be cause for concern.^{7,8} The current OTC dosage is 1–2g ibuprofen daily, in divided doses, for a maximum of seven days, yet this study found that 38% of purchasers/users (who responded to the study questionnaire) were taking it for chronic conditions (defined as having been experienced for more than thirteen weeks). Nearly a quarter had been using ibuprofen regularly for more than eight weeks, 8% had exceeded the maximum OTC daily dose (and 1% the maximum prescribed dose). People were, in general, using it for appropriate conditions but not in the absence of contraindications. 4% had a history of stomach ulcer, 7% a history of asthma, 4% had sought advice about gastro-intestinal symptoms during the week after purchase, 7% were using concurrently with a gastro-intestinal medicine and 4% with an asthma medicine. Finally 38% were using it with a medicine with a potential for interaction: 27% with another analgesic, 11% with an antihypertensive and 8% with a diuretic.

Ways to avoid these drug interactions need to be considered, such as enhanced NHS record keeping, access for pharmacists to selected parts of the medical records, and increased public and professional awareness. So whilst most OTCs probably are theoretically safe, we need to be sure that this is the case in practice, and have systems in place to prove this. We also need to consider whether the level of side effects experienced is commensurate with the benefit. A side effect profile which is acceptable for a treatment which prolongs life in advanced cancer will be quite different from one for a lifestyle medicine.

Pharmacovigilance systems, designed to monitor and identify side effects also need to take these different criteria into account.

At present in the UK the main system of pharmacovigilance, the Yellow Card System (<http://yellowcard.mhra.gov.uk/the-yellow-card-scheme>), only requires all adverse events to be reported for newly launched medicines; only life threatening events are invited for established medicines. As more medicines are deregulated it may be necessary to change these criteria so that unacceptable prevalence levels of unpleasant, but not severe, side effects are detected. This requires public and professional campaigns. Whilst there is a danger of overwhelming the routine pharmacovigilance system, increased automation in reporting (for example on-line) and improved analysis should mean this can be accommodated. A problem with the signal generation system which depends on spontaneous reporting is that the reporter has to make the association between the drug (the cause) and the effect, before thinking of reporting it. Once again the perceived safety of OTC medicines becomes an issue and people, both professional and the public need to be reminded that today's OTC drug was yesterday's prescription speciality.

In prescription drug monitoring, dedicated follow up exercises are an alternative method of pharmacovigilance using routinely held records to identify people who have taken a drug and then reviewing records for any evidence of side effect or drug interactions. However as no records are routinely kept of medicines supplied OTC this is not possible, other than as a dedicated follow up exercise, such as the ibuprofen and hayfever follow up studies reported above, and similar.^{7,19,22}

So, the lack of record keeping of OTC purchases is a problem, and one which it may be hard to resolve. Although in the UK, where community pharmacies are increasingly being linked to NHS IT systems, a future mechanism to link OTC purchases to a single patient record is technically possible, this is not the case for all countries and/or for GSL medicines sold from non-pharmacy outlets. Again, as IT develops, it may ultimately be possible to automate this, with individual purchaser consent, for example, through bar coding and swipe cards.

Finally, making medicines available over the counter is inextricably linked to private purchase and therefore is an inequitable policy. Whilst there are cheaper 'value for money' equivalents of well established medicines such as paracetamol available for OTC purchase this is not the case for the

newer deregulated medicines. Thus, those who are less affluent are disadvantaged.²³⁻²⁴

A national initiative to address this has recently been introduced in Scotland, based on earlier research in England²⁵ as part of a revised community pharmacy contractual framework. In this new framework a Minor Ailment Service (MAS) is one of the four core services delivered by all community pharmacies. People, who would normally be exempt from prescription charges (on the grounds of income, age or morbidity) can access, free of charge on the NHS, a range of OTC medicines from the pharmacy. This therefore removes the inequity of access introduced by private purchase but runs counter to any cost shifting from the public to the private purse. The MAS scheme has been carefully developed and includes computerised registration of the patient at a particular pharmacy with NHS records maintained containing the patient's unique NHS identification number (the CHI – Community Health Index). A current shortcoming of the system is that it does not link to other health records, such as the general practitioner (GP) held medical record, although there are longer term plans to address this. Therefore, in the short term GPs need to continue to remember to ask about, and patients need to report, use of OTC medicines. At the moment this does not always happen.²⁶

Conclusion

Recent moves have increased the range of medicines available without a prescription. This move has potential benefits for all stakeholders. However for these benefits to be fully realised issues of record keeping, pharmacovigilance and public and professional attitudes all need to be resolved. Whilst many of the potential risks can be contained within a pharmacy environment, this is more complex in a general retail environment, and in countries where the P and GSL categories are distinct, the secondary stage of deregulation from P to GSL should be considered extremely carefully.

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Development and use of the Japanese case-mix system

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Summary: The Japanese government introduced a case-mix system, known as the Diagnostic Procedures Combination (DPC), for acute care hospitals in 2003. Covering more than 90% of acute in-patient care, it has become one of the important sources of information for health policy. Using this dataset, the authors have analysed the impact on chemotherapy regimens.

Keywords: Case-mix, Diagnostic Resource Groups, Chemotherapy, Japan

Japan has a Bismarck-type compulsory social health insurance system.¹ The universal system, which covers 122 million people, is divided up according to type of employment and place of residence. Although thousands of independent insurance funds exist, they are all integrated within a government mandated framework. For employees, the type of

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company determines the insurance fund in which they are enrolled and the level of contributions that they must make. The self employed and retired are covered by a community-based health insurance scheme.

The Japanese health financing system has long been based upon fee-for-service (FFS) reimbursement using a national price schedule. The health insurance funds, both public and semi-public, gather premiums from their members and reimburse the costs of treatment according to type and volume of services provided (Figure 1).

Health care expenditure in Japan has steadily increased (Table 1), and there has

been continuing discussion over several decades on how to contain these costs. While payers argue that costs are exorbitant, service providers insist that the government does not allocate enough resources to services, pointing to the relatively low level of health care expenditure, 8% of GDP in 2004, compared with 8.3%, 10.6%, 10.9% and 15.3% in the UK, France, Germany and the USA respectively.² One ongoing problem is the lack of transparency in service provision, including a lack of appropriate data to evaluate medical services.

As the health system has been based on a fine tuned FFS system, there are little

Figure 1: Structure of social health insurance scheme in Japan

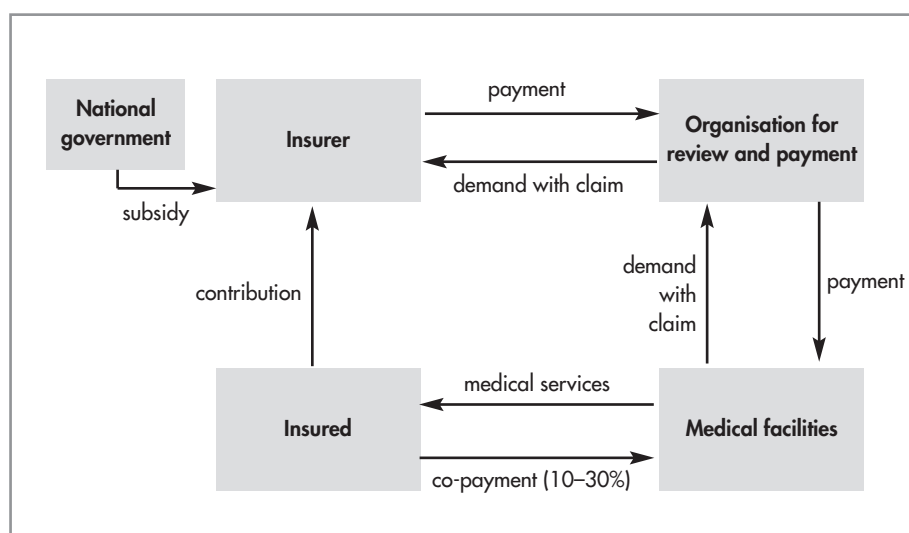


Table 1: Trends in total health care expenditure in Japan

	Total health care expenditure (THE)			National income (NI)		TME/NI	Total health care expenditure for older people			
	Total (billion yen)	Rate of increase (%)	Per capita (000s yen)	Total (billion yen)	Rate of increase (%)	(%)	Total (billion yen)	Rate of increase (%)	Per capita (000s yen)	TME for older people/TME (%)
1955	238.8		2.7	6,973.3		3.4				
1965	1,122.4	19.5	11.4	26,827.0	11.5	4.2				
1975	6,477.9	20.4	57.9	123,990.7	10.2	5.2	866.6	30.3	184	13.4
1985	16,015.9	6.1	132.3	261,089.0	7.4	6.1	4,067.3	12.7	499	25.4
1995	26,957.7	4.5	214.7	374,277.5	0.1	7.2	8,915.2	9.3	752	33.1
1996	28,454.2	5.6	226.1	386,793.7	3.3	7.4	9,723.2	9.1	782	34.2
1997	28,914.9	1.6	229.2	391,341.1	1.2	7.4	10,278.6	5.7	790	35.5
1998	29,582.3	2.3	233.9	379,264.4	3.1	7.8	10,893.2	6.0	801	36.8
1999	30,701.9	3.8	242.3	373,340.3	1.6	8.2	11,804.0	8.4	832	38.4
2000	30,141.8	1.8	237.5	379,065.9	1.5	8.0	11,199.7	5.1	758	37.2
2001	31,099.8	3.2	244.3	368,374.2	2.8	8.4	11,656.0	4.1	757	37.5
2002	30,950.7	0.5	242.9	362,118.3	1.7	8.5	11,730.0	0.6	737	37.9
2003	31,537.5	1.9	247.1	368,659.1	1.8	8.6	11,652.3	0.7	753	36.9

detailed claim data, containing information such as diagnosis, procedures conducted, drugs prescribed etc. Claims data have not been standardised or coded electronically, limiting their use in health policy making. One key objective of the new case-mix system (DPC – Diagnostic Procedures Combination) is to implement a standardised electronic claim system, with keywords that provide transparency and accountability. In future, it should be possible to evaluate the cost and quality of medical services. This article, explores how the new DPC can be a tool for greater transparency in the provision of medical services.

Case-mix system development

From the late 1990s, the Ministry of Health, Labour and Welfare (MHLW) and its affiliated research institute, the Institute of Health Economics and Policy (IHEP) explored the feasibility of introducing a case-mix classification system as a tool of standardised medical profiling and payment. A number of case mix systems were tested for validity. While some US Diagnostic Related Group systems were thought to be applicable to Japanese acute-care hospitals, they were criticised as being too rough to correctly reflect practice

patterns by the physicians association. They did however acknowledge the necessity of case-mix profiling as a tool to improve transparency. It was therefore decided to develop an original classification system that fits with practice patterns in Japan, while allowing comparative benchmarking nationwide and with systems in other countries.

The use of DRGs in eight western European countries was also investigated. As a result it was decided to develop the new case-mix system as a profiling tool for medical services in line with the principles of the Dutch *Diagnose Behandelings Combinatie* (DBC). Also of great influence were the French and Austrian approaches to case-mix applications for regional health planning, and the Belgian and English approaches towards the incremental development process.

The structure of DPC

The DPC Project team made use of a DBC-like data gathering process and a PMC (Patient Management Category)-like severity setting.³ The first step in development was to construct a definition table (see Table 2). For the diagnostic category ‘Malignancy, Respiratory System’ a

number of specific indications are listed, for example, ‘Malignant neoplasm of Trachea (C33)’ or ‘Carcinoma in situ of bronchus and lung (D022)’. After consultation with an expert panel on typical procedures for each diagnosis, as well as potential co-morbidities and complications, the research team constructed the DPC groups.

In the DPC algorithm, diagnosis, procedure, and co-morbidity/complication are the three key variables for classification. Additional information (for example, birth weight in the case of neonatal intensive care) is also referred to in some groups. Diagnosis and co-morbidity/complications were coded using the International Classification of Disease Version 10 (ICD10) scheme, with procedures coded in the Japanese Procedure Code, as defined in the fee schedule of the national health insurance system.

The structure of DPC version 3 has eight components (Figure 2). This includes the Major Diagnosis Category (MDC) and DPC serial number (DX) corresponding to ICD10 category, which indicates the type of admission. It should be noted these components are for profiling, and not all

Table 2: Example of DPC definition table – Malignancy, respiratory system

Base DPC	Principal diagnosis		Principal surgery			Additional surgery			Adjuvant therapy			Co-morbidity/ complication	
	Diagnosis	ICD	Procedure	JPC *	Code	Procedure	JPC	Code	Procedure	JPC	Code	Diagnosis	DPC6/ ICD10
Malignancy, respiratory system	Malignant neoplasm of trachea	C33	No procedure		99	Bronchoscopy, rigid	D301	01	Chemotherapy without radiation *		04	Brain tumor	010010
	Malignant neoplasm of bronchus and lung	C34\$	Other procedure		97	Bronchoscopy, flexible	D302	01	Chemotherapy with radiation		03	Respiratory failure	040130
	Secondary malignant neoplasm of lung	C780	Lobectomy	K511\$	01	Needle biopsy	D412	01	Radiation without chemotherapy		02	Malignancy	070040
	Carcinoma in situ of trachea	D021	Lobectomy, endoscopic	K513	01	Thoracotomy	D415	01	Hemodialysis	J0382	01	Disorder, leucocyte	130070
	Carcinoma in situ of bronchus and lung	D022	Tracheostomy	K5182	01				CVI	G005	01	Chronic pain	R522
	Carcinoma in situ of respiratory system, unknown	D024	Lung cancer procedure	K514\$	01				Respirator	J045\$	01		
			Lung cancer procedure, endoscopic	K514-2\$	01								

*: JPC = Japan Procedure Code

** : For chemotherapy, there is a special list in which a specific MHLW code is allocated to each drug.

Figure 2: Structure of DPC code

<u>04</u> <u>0040</u> <u>x</u> <u>x</u> <u>01</u> <u>x</u> <u>4</u> <u>x</u> <u>x</u>	
04	MDC
0040	Code for Dx
x	Type of admission
x	Age, birth weight, Japan Coma Scale
01	Sub-code for principal surgical procedures 01 etc: code for surgical procedure in definition table 99: no surgical procedure
x	Sub-code for additional surgical procedures 0: none 1: exist
4	Sub-code for adjuvant therapy 0: none 1 etc: code for adjuvant procedures
x	Sub-code for CC 0: none 1: exist
x	Sub-code for severity

x = not applicable

are necessarily for the reimbursement schedule.

DPC Reimbursement Scheme

The DPC based reimbursement scheme is quite different to that in other countries. Payment to hospitals has both a DPC component and a FFS component. The DPC component relates to the hospital fee, comprising hotel fee and costs incurred in hospital wards for pharmaceuticals, supplies and diagnostic procedures cheaper than 10,000 Yen (US\$10). The FFS component refers to tariffs for surgical procedures and anaesthesia, pharmaceuticals and expensive devices used in operating rooms, and procedures of more than 10,000 Yen. For the DPC component, a per diem payment schedule is set for each DPC group.

Figure 3 provides an example of a DPC payment. For each DPC grouping, the standard per diem payment is defined, and three periods are set for reimbursement: period I, period II and 'upper limit' for

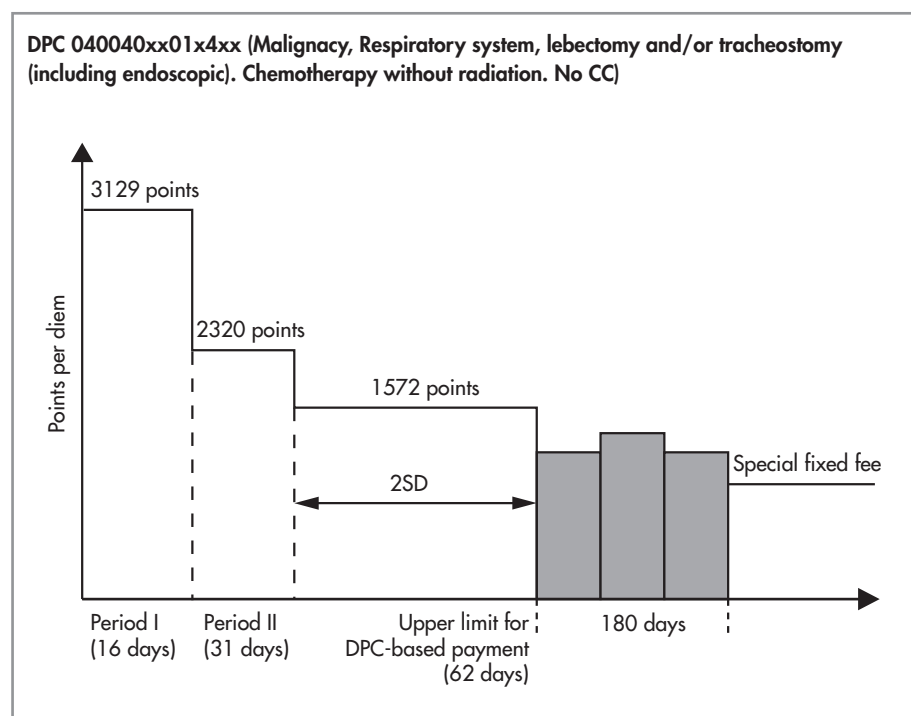
Table 3: Top ten chemotherapy regimens for lung cancer in Japanese hospitals (2006)

Regimen	Number of hospitals	Share of total hospitals (%)	Cases	Share of total cases (%)	Cumulative share of cases %
1 carboplatin + paclitaxel	189	78.1%	3243	18.9%	18.9%
2 Gefitinib	186	76.9%	1164	6.8%	25.6%
3 etoposide + carboplatin	166	68.6%	1069	6.2%	31.8%
4 docetaxel hydrate	148	61.2%	906	5.3%	37.1%
5 cisplatin + irinotecan	123	50.8%	652	3.8%	40.9%
6 carboplatin + gemcitabine	114	47.1%	585	3.4%	44.3%
7 etoposide + cisplatin	105	43.4%	560	3.3%	47.6%
8 cisplatin + vinorelbine	85	35.1%	544	3.2%	50.7%
9 Amrubicin	117	48.3%	540	3.1%	53.9%
10 carboplatin + docetaxel hydrate	79	32.6%	510	3.0%	56.8%

DPC-based payment. These periods are linked to average length of stay. In period I, per diem payment is set for 50% more than the standard per-diem payment. Furthermore, the hospital coefficient is calculated for each facility according to its function and characteristics. From period II to the upper limit day, per diem payment is set at 15% less than the standard payment. Over the upper limit day a reduced FFS payment scheme will be applied. The system has been fully computerised given its complex nature, including special computerised software for ICD coding to aid clinicians completing DPC information sheets for their patients.

Making use of the DPC database for health policy

Cancer has been a leading cause of death in Japan, with one person in three dying from the disease. More people are dying of cancer as the population gets older. Combating cancer is an increasingly serious issue for health policy makers. However, analysts have criticised the wide variations in the accessibility and quality of cancer care among the different regions and institutions. In order to further ameliorate cancer, the MHLW established a 'Comprehensive Ten-Year Strategy for Cancer Control' in 2006. One of the most important objectives of the Strategy is to assure the equal access to quality cancer treatment for the entire population. This

Figure 3: Example of DPC-based payment for hospital

requires analysis of the current use of treatments – something that can now be achieved making use of DPC data. This can help facilitate a movement towards greater use of evidence based medicine and quality assurance in cancer care.

Table 3 shows, ten of the thirty most widely regimens used for chemotherapy in lung cancer patients in 242 acute care hospitals in the DPC system between July

and October 2006.⁵ The data indicates that 17,200 lung cancer patients received chemotherapy using 659 different regimens, with the most frequently applied regimen being carboplatin plus paclitaxel, which was used by 3,243 patients in 189 hospitals. The same data set was also used to identify frequency of drug use in lung cancer patients (Table 4). Carboplatin was the most frequently used drug: 6,754 cases

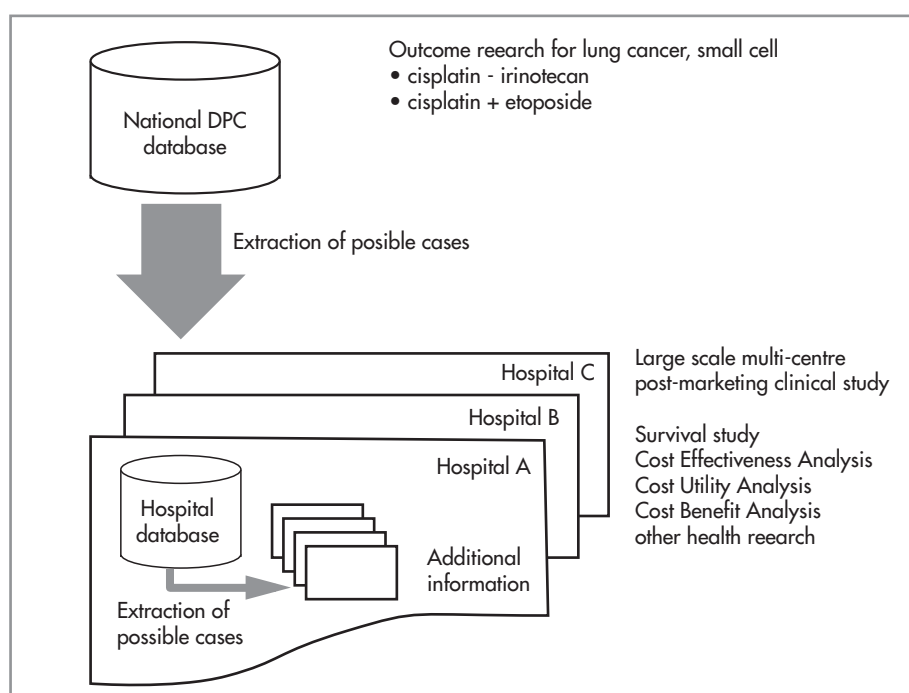
Table 4: Top fifteen chemotherapy drugs for lung cancer in Japanese hospitals (2006)

Drug	Number of hospitals	Percentage by hospital	Number of cases	Percentage by case	Number of used regimens	Percentage by used regimens
1 carboplatin	219	90.5%	6,754	39.3%	216	32.8%
2 paclitaxel	195	80.6%	4,014	23.3%	130	19.7%
3 cisplatin	189	78.1%	3,369	19.6%	199	30.2%
4 gemcitabine	190	78.5%	2,333	13.6%	124	18.8%
5 docetaxel hydrate	187	77.3%	2,227	12.9%	117	17.8%
6 vinorelbine	181	74.8%	2,098	12.2%	103	15.6%
7 irinotecan	192	79.3%	1,807	10.5%	95	14.4%
8 etoposide	185	76.4%	1,801	10.5%	57	8.6%
9 gefitinib	194	80.2%	1,548	9.0%	95	14.4%
10 OK-432	183	75.6%	788	4.6%	119	18.1%
11 vinorelbine	150	62.0%	722	4.2%	77	11.7%
12 5-fluorouracil	135	55.8%	709	4.1%	41	6.2%
13 amrubicin	130	53.7%	677	3.9%	34	5.2%
14 levofolinate	98	40.5%	590	3.4%	11	1.7%
15 nedaplatin	30	12.4%	465	2.7%	28	4.2%
Total	242	100.0%	17,200	100.0%	659	100.0%

(39.3%), followed by paclitaxel (23.3%) and cisplatin (19.6%). Among the 659 regimens, 216 regimens contain carboplatin (32.8%), 199 regimens contain cisplatin (30.2%) and 130 contain paclitaxel (19.7%). This indicates that carboplatin and cisplatin are the main elements of chemotherapy for lung cancer in Japan.⁵

Conclusion

Today the DPC programme covers more than 90% of acute in-patient care, including cancer, cardio-vascular disease and injuries. In 2007, 1,426 hospitals participated in the DPC programme, covering approximately 450,000 acute care beds. It was expected that another 200 hospitals would join the project in 2008. The same methodology, using the DPC framework, is now being applied to out-patient services.⁶ This implies that use of the DPC database, can allow one to analyse the whole process of treatment from a clinical and economic viewpoint.

Figure 4: Example of DPC based clinical study Lung cancer, chemotherapy (040040xx01x4xx)

The DPC database can also be used for large-scale multi-central post-marketing clinical studies as shown in Figure 4. In 2008, the DPC research programme has clinical studies for several disorders, including chemotherapy for lung and breast cancer.

With limited resources available in the health sector, not all medical innovations can be covered by the public medical insurance scheme. In order to make the Japanese health system sustainable, evidence for the rational distribution of resources is needed. This requires information about medical procedures and their outcomes.

As the English National Health Service experience has shown, under-financing of the health sector can damage the health system. On the other hand, over-financing the health system can damage the general economy, because the Japanese health system depends on contributions from the general economy. Thus, there needs to be a balance between the health spending and the needs of the broader economy.

The new DPC system can help provide detailed situation analysis of the use of health care interventions among regions, in-patient and out-patient services, as well as between acute and chronic care. At its heart are the concepts of transparency and accountability. By using this framework, researchers will in future be able to evaluate the quality of the health system from both micro and macro perspectives.

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e-Health in Canada: Lessons for European health systems

Denis Protti

Summary: This paper provides a status report of health information technology and electronic health record (EHR) initiatives in Canada. It also candidly discusses the difficulties Canada is facing in moving the EHR agenda forward. Particular emphasis is placed on describing the unique role of Canada Health Infoway, a unique, federally-funded, independent, not-for-profit organisation whose members are Canada's fourteen federal, provincial and territorial Deputy Ministers of Health. The interesting lesson learned is about a national organisation being successful in an environment whereby health care is a provincial responsibility.

Key words: Electronic Health Records, Funding Health IT, National Oversight, Electronic Medical Records, Canada

Perhaps the single most potent lesson for other countries to learn from Canada is its unique, federally-funded, independent, not-for-profit organisation called Canada Health Infoway (Infoway) whose members are Canada's fourteen federal, provincial and territorial Deputy Ministers of Health. Created in 2001, Infoway invests in a common, pan-Canadian framework of electronic health record systems where best practices and successful projects in one region can be shared or replicated in another. Infoway is Canada's catalyst for collaborative change to accelerate the use of electronic health information systems and electronic health records (EHRs) across the country. It recognises and has to function in an environment whereby health care is a provincial responsibility.

As in many countries, though the health care sector depends upon accurate, up-to-date information, it has been slow to exploit information technology (IT) – mainly because of cost and resistance to change. For years, IT was a low priority in

health care and it is only recently that governments have begun to realise that technology can improve the quality of care and actually save money in the long run.

As a strategic investor, Infoway works in collaboration with health ministries, regional authorities, other health care organisations and information system vendors to best align Infoway's investments with jurisdictional plans and to leverage existing solutions. Once investment decisions are made, public sector partners lead the development and implementation of EHR solutions. Infoway views an EHR as a secure and private lifetime record of an individual's health and care history. Available electronically, it provides authorised health care professionals with immediate access to their patients' accurate health histories, including laboratory and radiology test results, past treatments, prescription drug profiles and immunisations, while protecting privacy and confidentiality. The EHR supports improved clinical decision-making leading to more effective diagnosis and treatment, greater patient safety, increased efficiency and improved access to services.

It is worth noting that in Canada, a distinction is made between the above

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Table 1: Projects that have received Infoway funding

Area	Completed projects	Active projects
Infostructure	14	10
Provincial client and provider registries	12	17
Provincial drug information systems	8	11
Provincial laboratory information systems	3	4
Regional diagnostic imaging systems	12	17
Telehealth	30	41
Public health surveillance	2	12
Interoperable EHRs	7	19
Innovation and adoption	9	26

Source: Canada Health Infoway, 2007.¹

defined EHR and an electronic medical record (EMR). An EMR generally refers to computer-based clinical data of an individual that is location specific and kept by a single physician office or practice, community health centre, or possibly an ambulatory clinic. Ideally, the two work together, with doctors' EMRs connected to wider EHR systems. Infoway's goal is that by 2010, 50% of Canadians (and 100% by 2016) will have their electronic health record available to those authorised professionals who provide their health care services.

The good news

Working with its federal, provincial and territorial partners, Infoway is attempting to hasten the pace of development and implementation of electronic health records. During 2007–08, Infoway approved \$311.5 million in new projects, bringing the total cumulative value of its investments to \$1.457 billion or 89% of Infoway's \$1.6 billion in capitalisation by the federal government. This capitalisation includes an injection of \$400 million that Infoway was allocated by the Government of Canada in the March 2007 Budget for investment in electronic health information and communications technology.

The investments have brought the total number of projects underway to 254, representing a four-fold increase from the fifty-three projects that were underway in 2004.¹ For instance, in terms of *Infostructure*, there are twenty-four pan-Canadian projects of which fourteen have been completed and ten are active while in terms of *provincial client and provider*

registries, twelve have been completed and seventeen are active. It should be noted however that the information in Table 1 is not an account of all the projects underway in Canada but only those that have received Infoway funding.

As in most countries, Canada can point to its centres of excellence and its crown jewels so to speak. A few of many examples at the provincial level are British Columbia's PharmaNet system which since 1995, have connected all the pharmacies in the province to a centralised medication profile database. As a result, any pharmacy and hospital emergency department in the province has 24/7 access to all the medications any patient has received in the previous fourteen months. An Infoway sponsored project will soon give that same access to physicians who have EMR systems in their offices.

At a regional level, the Capital Health Authority based in Edmonton, Alberta had 'islands' of patient information until April 2004. After only eleven months in development, Capital Health launched netCARE, Canada's first region-wide integrated EHR. For the first time, authorised clinicians had immediate computer access to up-to-date patient records across systems. The creation of the netCARE portal required managers to consider the most efficient use of resources, how to safeguard patient confidentiality and, in particular, how to engage with the clinicians who would ultimately use it. With the success of the netCARE portal, the Alberta Government has selected it as the platform for a province-wide EHR.

At a hospital level, the University Health Network (UHN), a large teaching hospital on three sites in Toronto has successfully implemented CPOE (computerised physician order entry) including over 50,000 medication orders a month – an application most hospitals in North America have been unable to address at this point in time. As a result, UHN has been able to demonstrate a reduction in medication errors and adverse drug events.

At a local level, patients at the Group Health Centre's in Sault Ste. Marie, Ontario have been invited to participate in EMRxtra, a project supported by a \$2 million investment by Infoway. With the patients' consent, EMRxtra extends the centre's electronic medical records to local pharmacists and members of the larger, multi-disciplinary team of care providers. Access to lab results, allergies and other vital information contained in the electronic medical record helps pharmacists avoid dangerous drug interactions and provide sound advice to the patient with the confidence that comes from being fully informed about the patient's medical history. Just as importantly, the pharmacist's expertise becomes an important element in the circle of care provided to the patient.

The less good news

The absence of additional funding in the Government of Canada's 2008 Budget puts the 2010 goal of providing 50% of Canadians with an EHR at risk. Infoway will need significant additional capital to provide the benefits of EHRs to all Canadians and across the continuum of care as recommended in the 2006 Health Council of Canada Annual Report to Canadians. Two studies estimated the ten year total cost of ownership for the pan-Canadian interoperable EHRs at approximately \$10 billion, with a return of \$6 to \$7 billion a year in efficiencies when fully implemented.^{2,3} An estimated investment of \$350 per person, spread over ten years, is needed. This is consistent with what other developed countries have invested.

In addition to the funding issue, a 2006 study by the Commonwealth Fund found that only 23% per cent of Canadian doctors use electronic medical records, compared with 98% in the Netherlands, 92% in New Zealand and 89% in the United Kingdom.⁴ The seven-country survey revealed strikingly different country rates of primary care practice use of IT and the range of functions supported

by office systems. Primary care doctors in Australia, the Netherlands, New Zealand and the United Kingdom have the most widespread and multifunctional systems; Canadian and US doctors lag well behind. Some progress has been made since the 2006 study, particularly in the province of Alberta due to the government's early decision to provide financial support to its physicians.

It seems a key problem is that the cost of EMRs in a Canadian doctor's office falls mostly on the physician, while the benefit goes to the health care system as a whole; this is especially true for the many single handed practices and small clinics that do not have the IT expertise to help them implement and maintain technology. A June 2007 survey identified lack of willpower and cost as the two reasons that account for approximately 80% of the barriers to EMR adoption in the province of Ontario.

A further complication has been the provincial governments' inconsistent and differential approaches to EMR funding which has *de facto* created two tier primary care systems. Physicians who agree to work under particular funding formulas have their EMR costs covered by the province, whereas those doctors attached to other funding schemes must draw from their own resources in order to have EMR in their practice.

Another common problem in most provinces is 'data stewardship', i.e., who shall keep the records and who shall own them. Ownership brings with it an expectation of granting privileges to others to contribute to or gain access to the information. Concern about privacy and access (by both physicians and patients) seem to be among the major reasons why Canada has not adopted electronic records to the same extent as many other countries have. Nevertheless, the Canadian Medical Association believes that the benefits of electronic records clearly outweigh the risks. As Flegel so aptly put it, "it has become clinically counterproductive to allow the risks to continue to delay the necessary development and implementation of technologies. If we can handle the myriad privacy concerns involved in electronic banking, what is holding up electronic medical records? We have the e-technology; all we need is the e-will."⁵

Conclusion

As strategic investor, Infoway has successfully worked collaboratively with jurisdic-

tional partners to develop and share the long-term health infrastructure vision for Canada. They have facilitated national collaboration to ensure that public and private sector stakeholders jointly plan, share best practices and continually improve the deployment of the pan-Canadian health infrastructure. Effective alliances with the private sector have helped Infoway better leverage its investment dollars, and better align the information technology industry's business directions with their goals. Infoway's emphasis on interoperability and vendor-neutral architecture and standards generates interest from many potential IT partners, and has allowed Canada's health care jurisdictions to reduce costs and obtain upfront financing from vendors and suppliers.

To protect future investments, Infoway and the jurisdictions have implemented a collaborative risk assessment approach where project and jurisdiction risks are clearly identified for risk mitigation and reporting purposes. In addition, a Quality Assurance Framework was developed and will be applied to all Infoway investment projects.

In closing, a 2007 Conference Board of Canada study estimated that electronic health record spending will have created 37,000 new jobs by 2010, translating to \$2 billion in new labour income for Canadians.⁶ And every dollar invested by Infoway and the provinces adds \$1.34 (on average) to Canada's gross domestic product. More investment, exports and employment bring more tax revenues for federal and provincial governments – about \$0.36 for each dollar invested. In

short, beyond better health care, all provinces and territories are reaping economic benefits from their EHR projects.

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NEW PUBLICATION

Caring for People with Chronic Conditions

Edited by Ellen Nolte and Martin McKee

Open University Press,
December 2008, 265 pages

This new book systematically examines some of the key issues involved in the care of those with chronic diseases.

Taking an international perspective, it synthesises the evidence on what we know works (or does not) in different circumstances.

Taking a whole systems approach, the book:

- Analyses the prerequisites for effective policies for chronic care
- Examines systems for financing chronic care
- Describes the burden of chronic disease in Europe
- Explores the economic case for investing in chronic disease management
- Examines key challenges posed by the growing complexity in health care including prevention, the role of self-management, the health care workforce, and decision support



Assessment for reimbursement:

Collaboration at EU-level, the MEDEV-experiment

Ad Schuurman

Background

The regulation of medicines in Europe is largely determined by EU legislation. As a consequence, close collaboration has been forged over recent decades between the medicine regulatory authorities in Member States, the European Commission and the European Medicines Agency (EMA).

There has also been a growing interest in enhancing the degree to which the competent health authorities exchange information and share experience on a broad range of pharmaceutical policy matters.

This was a reason why ten years ago, European national competent authorities set up the Medical Evaluation Committee (MEDEV). The experiences of MEDEV to date are discussed in this snapshot article.

MEDEV is an expert group that meets on an informal basis and explores the potential for collaboration in the field of pharmaceutical policies and, in particular, with respect to the evaluation of medicines. It should be clear however that final decisions and possible negotiations (regarding price, certain restrictions on indications, who can prescribe) remain the responsibility of each national competent authority.

Objectives

MEDEV collaborates on exchanging information and sharing experiences among European countries on pharmaceutical policies. The key objectives are to:

- Enhance possibilities for further collaboration among participating countries on the evaluation of clinical research and the cost-effectiveness of medicines as criteria for reimbursement purposes.

– Promote possibilities for further collaboration on the exchange of information on drug prices and concrete steps for making price information available on websites.

Activities

An expert working group has been formed on clinical- and cost-effectiveness evaluations. It is a collaboration of the national competent pharmaceutical authorities that are responsible for assessing (new) medicines for reimbursement and/or for definitions, pricing and reimbursement conditions. It meets on a regular basis (six times a year) to discuss the evaluation of new medicines being considered for reimbursement.

Information on national reimbursement decisions is shared between direct contacts and via the password-protected website.

Timing is of the utmost importance when sharing information, as reimbursement decisions need to be made in relatively short time frames. Several countries may be working simultaneously on the assessment of new medicines, so during that short period they should know which of their counterparts is/are working on the same dossier. On the other hand, other countries may find themselves in the second wave of launch, so that they would benefit from knowing in which countries assessment has already taken place.

The key functions of MEDEV are set out in Box 1. MEDEV reviews existing guidelines for assessing medicines for reimbursement and explores possibilities for harmonising these guidelines, at least in the area of clinical effectiveness. The group also discusses criteria for the re-assessment of medicines for reimbursement in the light of new information on clinical effectiveness and indications, shares information on reviews of national reimbursement decisions and discusses

Box 1: Principal elements of assessment

1. Monitoring (new) drug assessments in all seventeen participating countries and exchanging information on current assessments.
2. Exploring and developing the methodology and criteria for assessing drugs for reimbursement.
3. Reviewing existing guidelines for assessing medicines for reimbursement and exploring possibilities for harmonising guidelines, starting in the field of clinical effectiveness.
4. Discussing criteria for the re-assessment of medicines for reimbursement in the light of new information on clinical effectiveness and indications, and sharing information on the review of national reimbursement decisions.
5. Discussing criteria for therapeutic equivalence and inter-changeability.
6. Collaborating on post-listing reviews (for example, Vioxx, Celebrex) and adjusting indications.
7. Discussing arrangements for reference pricing and (therapeutic) clustering.

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criteria for therapeutic equivalence and inter-changeability. Confidentiality of information is a pertinent concern.

At the moment MEDEV is preparing two pilot studies and will start providing general, informal advice to two small companies producing new orphan drugs. This will include scientific advice, as well as information on procedures and adequate assessment dossiers. If possible, MEDEV will do an (informal) assessment. Small pharmaceutical companies in particular have problems submitting their new drugs to the twenty-seven different reimbursement authorities in the EU. This model could also prove relevant for larger firms.

All of the above represents a pragmatic, informal way for MEDEV to develop a perspective on general, adequate assessments. To date MEDEV has succeeded in performing thirty such assessments; national authorities can then at their discretion make use of these assessments in accordance with the subsidiarity principle.

Conclusion

The MEDEV experiment demonstrates that it is possible to cooperate successfully on the assessment on medicines for reimbursement at an EU-level. The results of the informal assessments can be used in decision making at the level of Member States in accordance with the subsidiarity principle.

Critical is the fact that participants are not forced to work together, but rather it is effective because it facilitates collegial cooperation between individuals working on the same job: the scientific assessment and pricing of medicines. In such a way we can learn from each other, exchange information, methods and develop a common framework. Potentially the benefits of these activities may also accrue to other stakeholders including both the pharmaceutical industry and patients.

Moldova: Using social health insurance to reduce out-of-pocket payments and improve equity

Erica Richardson

Social health insurance (SHI) schemes have been introduced in many countries of the former Soviet Union as a means of opening up the health sector to non-state actors and opening up another stream of funding for health systems which had been dealing with decades of underfunding and falling budgetary allocations. However, the introduction of SHI in countries of the former Soviet Union has not generally been successful in increasing revenues for health funding, or improving transparency, access to services, or overall equity in the system.¹ Historically, the introduction of SHI as a complementary source of funding for the health system has not had a profound impact on the high levels of out of pocket payments (OOPs) experienced in some countries of the former Soviet Union, and financial protection in these countries remains weak.¹

Nevertheless, in order to ensure sustainable financing for the health system and as an equitable means of ensuring broad access to health services for the population, the Government of Moldova introduced a SHI scheme on 1 January 2004.² The more recent introduction of SHI in Moldova would appear to have avoided some pitfalls, and evidence is now indicating that the introduction of SHI has been successful in increasing funding for the health system, providing financial risk pooling, as well as reducing OOPs for poorer households and, thereby, improving access to services and equity.² In this article

the successes of the Moldovan experience are elaborated and areas where further developments are needed are highlighted.

Out-of-pocket payments

According to World Health Organization (WHO) data, OOPs as a proportion of total health expenditure in Moldova peaked in 2000 at 50.5%.³ Such high OOPs were a significant barrier to services for the poorest households and an indicator of serious inequities.⁴ Formal user charges had been introduced in 1999 in order to tackle chronic underfunding in the system and to aid transparency. Prior to this informal payments for services had become widespread and it was hoped that by 'formalising' these payments, issues such as differential pricing according to staff estimates of how much a specific patient could afford, could be addressed.⁵ However, formalising payments did little to reduce the overall cost to patients and it did not address the inequity of the system or provide a financial risk pooling mechanism to protect households from catastrophic health costs.²

Formal co-payments were included as a part of the SHI package for certain services, and OOPs as a share of total health expenditure did fall from 45.8% in 2003 to 41.4% following the introduction of SHI in 2004, although creeping up to 42.9% in 2005. However, the structure of out-of-pocket payments has changed much more significantly, as costs for the uninsured are significantly higher than for the insured. On average in 2005, for example, the cost of hospitalisation for insured patients was 83% lower than for uninsured patients.⁶ This means that many of the poorest households now have better protection from catastrophic health costs

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as the non-working population is covered by government contributions to the SHI scheme.

SHI in Moldova

SHI was first introduced on paper in 1998, but was not possible to implement at the time due to severe fiscal difficulties faced by the Moldovan government. However, this break between the introduction of SHI and actual implementation allowed the government time to learn from the problems faced in other countries which had Semashko systems but had introduced SHI. The new system was eventually introduced nationwide on 1 January 2004.

In Moldova, the introduction of SHI involved the recentralising of health financing to the independent non-profit National Health Insurance Company (NHIC) rather than the introduction of competing funds. This helped to 're-integrate' financial pooling. The NHIC contracts with public and private health service providers, where possible on a competitive basis, to purchase health services covered under SHI. General taxation revenues cover a limited number of basic services as part of a universal package of benefits. All other services, including those for the uninsured, are purchased out of pocket.

Payroll contributions from the working population were set at 2% of wages for both employees and employers. Although a 2% reduction in income tax helped to offset the cost for employees, the overall tax burden in Moldova is high so the benefits of this were not necessarily felt by the working population. The self-employed are responsible for paying their own contributions at a fixed rate. However, there is cause for concern as most of those considered self-employed are engaged in subsistence farming, most do not pay their contributions and are consequently not covered under SHI.²

Significantly, government contributions paid on behalf of the non-working population are equivalent to contributions from the working population and both are linked to real costs. This is important as it has ensured that health care funding covers health care costs. An inadequate government contribution on behalf of the non-working population is one reason why the introduction of SHI has not been as successful in providing equitable cover and reducing OOPs in other countries.¹ The more accurate reflection of real costs in the pricing of services paid for by the

NHIC reduces pressure on service providers to 'make up' funding shortfalls by charging patients informally. It has also meant an increase in both health care expenditure as a percentage of Gross Domestic Product (GDP) and as a share of total health expenditure from public sources.

The balance of public and private expenditure on health has shifted. According to WHO estimates, in 2003, 51% of total health expenditure came from public sources, but this jumped to 56.8% in 2004, falling to 55.5% in 2005. Overall, total health expenditure as a proportion of GDP has also risen significantly since the introduction of SHI; according to WHO estimates, from 6.8% in 2003 to 7.4% in 2004 and 7.5% in 2005.³ Total health expenditure in terms of purchasing power parity reached its nadir in 1999 at \$71 per capita and, although still low by regional standards, it grew to \$170 per capita in 2005.³

Future challenges

Coverage of the rural 'self-employed' poor population needs to be improved to allow the working poor to benefit from SHI. This is currently the main challenge to equity in the Moldovan health system, as paying full costs for health care out of pocket is a significant barrier to accessing health services not covered by the limited universal package. Estimates of coverage levels also need to be more sensitive to ensure the poorest rural regions are not left with the least funding for services. Currently, in providing funding for services, the NHIC assumes that 20% of the population are uninsured. However, in 2004, 24.3% of the population were uninsured and there were significant regional variations – from 58% in the rural Cahul region to 85% in Chisinau municipality.²

More generally, the main out-of-pocket cost to patients is pharmaceuticals, very few of which are covered either by the state-funded universal package or SHI contributions. Following the introduction of SHI in 2004, spending on pharmaceuticals from private, as opposed to public sources, fell to 63.3%, however the proportion has since returned to a higher level, 79.9% in 2005 and 79.5% in 2006.³ Therefore it is necessary to gradually increase the number of products covered by SHI and reduce the OOP burden for pharmaceutical spending; although this needs to be achieved without jeopardising current fiscal successes.

Conclusions

The main lesson that could be learnt from the Moldovan experience is that SHI is not a cheap option for governments; in order to reduce OOPs and improve financial protection for the population, it is necessary to increase pre-payment for services. If the system is going to function adequately, there needs to be equivalence between contributions from the central budget for the non-working population and payroll contributions from the working population.

The credibility of the system rests on its ability to actually fund the services it purports to cover. Therefore, it is important that allocations from the third-party payer do indeed cover costs to the service provider, so there is less need to make up the difference by charging patients directly. However, it is also important to review the benefits package covered by SHI, in order to ensure that important aspects of the health system that are not covered do not act as a barrier to accessing care and thus threaten equity in the system.

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OZONE AND MORTALITY – AN UPDATE

Joel Schwartz

While it has long been accepted that ozone can produce morbidity, as clearly demonstrated in chamber studies, the evidence that ozone kills people is relatively new, and more controversial. In particular, a number of questions have been raised that are central to translating that literature into risk assessment and benefit analyses. Is the ozone-associated mortality just short-term mortality displacement? Does risk vary by individual? If so, what characteristics define the at-risk individual? Are the associations confounded by temperature? By other secondary air pollutants? How are any early deaths associated with ozone exposure to be valued? Recent work by Harvard Center for Risk Analysis faculty and staff has addressed these questions, and is summarised below.

Background

While many studies have reported adverse responses to ozone, a highly oxidising gas, reports that ozone exposure might hasten deaths have been more recent. The first large-scale report came from Europe, where seven cities were studied using identical methods and the results combined.¹ Studies from Europe during that period (the 1990s) have the advantage that use of air conditioning was quite low. Open windows ensure that day-to-day changes in outdoor ozone concentrations are more highly correlated with day-to-day changes in personal exposure, and hence reduce exposure error. This may limit generalisability to North America, however. Since then a number of studies have reported similar results, including three large meta-analyses commissioned by the United States Environmental Protection Agency (EPA).²⁻⁴ Moreover, a large multi-city study has found no evidence of a threshold down to very low levels.⁵

The implications of these findings for ozone risk assessment are enormous. In cost-benefit analyses of air pollutants, mortality risks, when monetised, dominate the benefit calculation. Because of this, a National Academy of Sciences committee was commissioned to review the evidence. Its report, recently issued, concluded that the evidence for a mortality association is

strong.⁶ Among the questions raised to the committee are those in the introduction. These address the potential for confounding (i.e., that other exposures may actually be responsible for the observed association), as well as questions about who is being affected that have importance for health impact assessments and benefit analyses. Because of the critical role these might play in estimating an appropriate level for the standard, we have been active in addressing these issues. A recent Risk in Perspective article (RIP) has focused on the valuation issue, which of course generalises to other exposures.⁷ This RIP will focus on results addressing the other questions.

Are the ozone-associated deaths due to other exposures?

The major concern of observational epidemiology studies is that some other exposure, correlated with the exposure of interest, may explain the observed association, which is not causal but due to that correlation. To confound studies of short term changes in ozone and daily deaths, such confounders must co-vary with ozone over the same timescale. There are two obvious candidates for such a confounder – temperature and other secondary pollutants.

Are the ozone-associated deaths due to the association of ozone with high temperature?

Ozone is not directly emitted by polluting sources. It is produced by chemical reactions in the atmosphere between nitrogen oxides and volatile organic compounds (VOCs), and those reactions are driven by sunlight and temperature. Hence ozone co-varies with temperature. All studies of the effect of ozone on daily deaths have

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therefore controlled for temperature. However, the association of temperature with death is highly non-linear, with heat wave conditions associated with much larger increases in deaths than temperatures just a few degrees cooler. How can we be sure that those studies correctly captured that relation, and that the ozone association is not due to ozone capturing the remaining effect of temperature?

I addressed this in an analysis of over one million deaths in fourteen cities.⁷ Rather than examine the correlation between daily ozone and daily deaths, I converted the analysis into a case-control study. Using a variant called case-crossover analysis, I matched each decedent with him or herself, on a control day in the same month of the same year that they died, which also had the same temperature (rounded to the same degree). This matching controlled for season and time trend, by choosing a control day in the same month and year as the date of death, and since the temperature was the same on the control day as the case day, it could not explain which day the death occurred on. I then compared the ozone levels on the two days to see if they predicted which day was the date of death. I found the same association with ozone that I found analysing the data using the more traditional time series analysis. This indicates that confounding by temperature is unlikely to explain the observed ozone mortality association.

Are the ozone-associated deaths due to other secondary pollutants?

The same processes, chemical reactions driven by light and heat, that produce ozone also produce other secondary pollutants (secondary because they are not directly emitted). Among these are sulphate particles, from the reaction of sulphur oxides with ammonia, nitrate particles, from the reaction of nitrogen oxides with ammonia, and organic particles, which like ozone derive from reactions of hydrocarbons. In addition, other gaseous pollutants, such as peroxyacetylnitrate (PAN), are produced by the same type of reactions that produce ozone. These pollutants are rarely measured, and hence previous studies have not controlled for them. To the extent that the control measures adopted to reduce ozone, such as reductions in emissions of nitrogen oxides

and hydrocarbons, also reduce these other secondary pollutants, such as PAN, it may not be critical for policy analysis to distinguish among them. However, all strategies do not reduce these secondary pollutants equally, and secondary sulphate particles would be reduced by a completely different strategy, the control of sulphur oxide emissions. Hence this is a key remaining uncertainty.

To address this, Franklin and Schwartz turned to the EPA's speciation* monitoring network.⁸ Unfortunately, this network which has only been operating since 2000, usually monitors only one in three or one in six days, and only measures particles and not other oxidant gases. Nevertheless, using data from eighteen cities with speciated particle measurements, we showed that control for nitrate particles or organic carbon particles did not change the estimated effect of ozone on mortality. In contrast, control for sulphate particles reduced the estimated ozone effect by about 25%, although the confidence interval in that estimate was wide, and included the possibility of no change in the ozone effect. Hence some of the effect attributed by past studies to ozone may have been due to sulphate particles, but organic and nitrate particles do not appear to be confounders.

Are the ozone-associated deaths advanced by only a small amount?

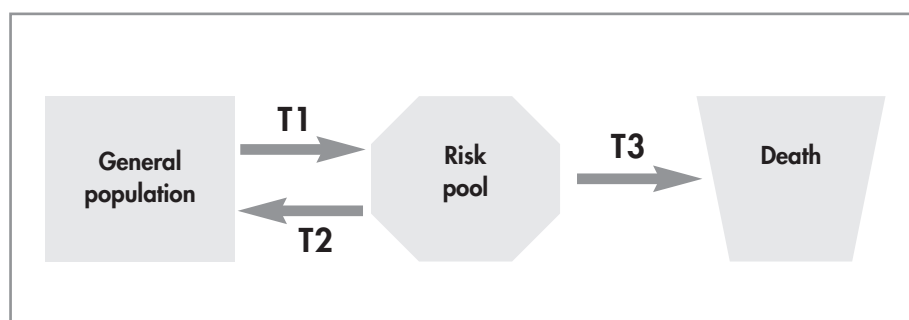
One possible explanation of the observed associations is that they are causal, but that only extremely sensitive individuals, who are on the brink of death, are affected by this exposure. If ozone is merely bringing forward deaths among people who would have died in the next week anyway, the public health impact of the observed ozone mortality association is much reduced. Recently, we addressed this question in a large, multi-city study.

To understand this question, it is useful to consider the schematic below. In it, we imagine that there is a pool of persons who are highly susceptible to dying in the short

run. This could, for example, include people with severe pneumonia, or with acute inflammations that have decreased the stability of atherosclerotic plaques that are temporarily at much higher than normal risk of rupturing and producing a heart attack. Individuals in this high-risk pool can recover and return to a more normal risk, or they can die. Each day some die, some recover, and some new people enter the high-risk pool. Conceptually, air pollution might affect all three transition rates. If air pollution only increased the rate of dying out of the pool, then we would expect the pool to be depleted by an ozone episode, resulting in fewer deaths in the next week. In this case, the deaths associated with ozone exposure are only being brought forward by a short period. However, if ozone affects the recruitment rate, the size of the pool could actually increase, and excess deaths could continue well after the ozone episode occurred.

If ozone's primary effect is on the death rate from the risk pool and deaths were only being brought forward by, for example, seven days, then, *ceteris paribus*, we would expect a negative correlation between ozone exposure today and deaths a week from now. Zanobetti and Schwartz used this insight to look at the correlation between ozone levels and death counts in forty-eight US cities for time periods up to twenty-one days after exposure.⁹

They found that there was no negative correlation between ozone and mortality up to twenty-one days later, and that the positive association persisted over several days but fell to zero within a few days. The overall effect of ozone over the period was an increase of 0.5% in daily deaths (95% C.I.: 0.05–0.96) per 10 parts per billion (ppb) increase in eight hour average ozone, compared with an increase of 0.3% (95% C.I.: 0.2–0.4) when deaths on only one day were considered. Hence the deaths associated with ozone are not just being brought forward by a few weeks, and previous studies may have underestimated



* Speciation analysis is the identification and/or measurement of the quantities of one or more individual chemical 'species' in a sample.

the overall effect of ozone on mortality by just considering the effect of the ozone on deaths the same day.

Who is susceptible to the effects of ozone?

The question of who is dying on high-ozone days affects many areas of risk assessment and health policy analysis. The presence of chronic conditions or the age of the individuals at risk may affect the benefit values associated with delaying the ozone-associated deaths. In addition, since the age pyramid and prevalence of certain conditions are changing in the United States and elsewhere, understanding of the relative risks in different subpopulations will be important. To address this, we conducted a case-only study. A case-only study is focused on identifying factors that modify risk, and does not examine what the baseline risk is. It is based on the following idea. Suppose some personal characteristic, for example diabetes, modifies the risk of dying on a high air pollution day. Then one would expect, on average, more of the deaths on high-ozone days to be among diabetics than the deaths on low-ozone days. Therefore, one can test this hypothesis (greater susceptibility of diabetics to ozone) by doing a regression on the people who died over a period of years, with the outcome whether or not they were diabetic, and the predictor the ozone concentrations on the day they died. This approach has the advantage that things that only predict whether or not a person died are not confounders in this analysis, since they don't predict the outcome (diabetes, not deaths).^{10,11}

Our analysis examined 2.7 million deaths in forty-eight cities between 1989 and 2000.¹² We found, as expected, increased susceptibility among people aged sixty-five and older (~2.7 fold higher percentage increase in deaths per 10 ppb of ozone). More interestingly, the black population had roughly 1.8 times the percentage increase in deaths as the non-black population, and women over the age of sixty had about 1.9 times the percentage increase in death as men. Below age sixty, however, there was no difference between the risk in men and women, suggesting some protection by hormonal status. Among chronic diseases, atrial fibrillation was associated with 1.7 times the percentage increase in deaths per 10ppb of ozone. Previous studies have suggested that atrial fibrillation also increased the risk of dying on very hot days,¹³ or as a result of particle exposure.¹⁴

Analyses of mortality data are limited to looking at modifying factors that are shown on the death certificate. Examination of other potential markers of susceptibility requires other techniques. One approach is to look at a surrogate outcome. Lung function is a continuous outcome which is highly predictive of mortality rate. We examined the short term association between ozone and decrements in lung function (forced expiratory volume in 1 second, FEV1) in a cohort of elderly men in the Boston area. We found that ozone was associated with reduced FEV1, but that the effect was larger in obese subjects.¹⁵ Since obesity is a growing problem all over the world, this suggests that in the absence of contravening changes in other risk modifiers, the susceptible pool may grow over time.

Conclusions

While uncertainties still remain, a significant fraction of the questions have been resolved. The ozone-associated deaths do not appear to be short-term mortality displacement and aggregate effects over several days may increase the risk estimates. There may be some confounding by sulphate particles, but not by other secondary particles. This may reduce the risk estimates. Most of the ozone-associated deaths are in the elderly, but the differences by race and sex may be important. Major chronic diseases such as chronic obstructive pulmonary disease (COPD) and diabetes that provide significant reductions in quality of life are not modifiers of the ozone-association. However, while diabetes is not a modifier, obesity may be. Given trends in obesity over time, this will also be relevant for risk assessments.

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Pharmacy care in older patients

We know that many people do not take medicines prescribed for them, and that adherence rates are often low. We also know that older people have problems with their medicines, often because they are prescribed many medicines, to be taken at different times of the day. Finally, we know that major influences on admission to hospital with adverse drug reactions include older age, being a woman and having lots of tablets to take.

It does not need a brain the size of the planet to see that there are some problems here

needing to be solved. A trial from the USA¹ suggests that extremely good adherence results can be had from some simple interventions from pharmacists that help older people understand and manage their medicines.

Trial

This is an interesting example of a randomised withdrawal trial design outlined in Figure 1.

1. All patients entered a two month run-in period used to ascertain baseline adherence and measure blood pressure and cholesterol.
2. After this, all patients entered an intervention phase, during which they received their drugs individualised in blister packs with tablets labelled for time of day. This was supplemented with individualised education visits, and follow up with a pharmacist every two months. These visits taught patients about their drugs, their names and indication, strengths, adverse events and usage instructions.
3. After six months, patients were randomised to continuing the intervention or usual care.

Adherence, blood pressure, and cholesterol were measured during the run-in period and at the end of each six-month period.

Results

Initially, 200 patients entered the run-in period and 159 were eventually randomised. Their average age was 78 years (minimum 65 years), 77% were men, 57% had four or more health problems, with an average of nine chronic medications. There were high levels of use of statins and blood pressure medicines.

Results for adherence are shown in Table 1. The pharmacy care programme resulted in a large increase in adherence, with the proportion of patients more than 80% adherent to all medicines increasing from

Figure 1: Randomised withdrawal design of study of pharmacy care in older patients with multiple health problems

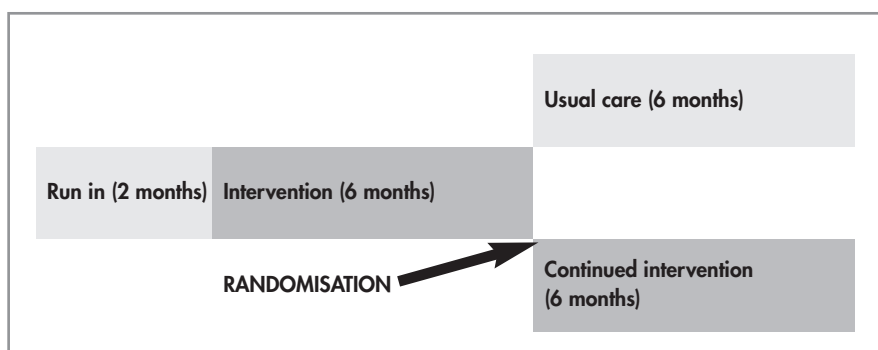


Table 1: Median adherence (% of all tablets taken) and percentage of patients taking at least 80% of all medicines

	Run-in	Intervention	Randomised to	
			Usual care	Intervention
Month	2	8	14	14
Median adherence (%)	62	99	68	96
>80% adherence to all medicines	5	99	22	97

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just 5% in the run-in period to 99%. After randomisation, the intervention group maintained these high levels of adherence, while return to usual care resulted in a large decrease in adherence, approaching rates seen in the run-in period.

Increased adherence resulted in large reductions in systolic and diastolic blood pressure during the intervention period; for LDL (low density lipoprotein) cholesterol useful reductions in both groups were maintained after randomisation, with no significant difference between them.

Comment

This is a very important study, which shows that to achieve high adherence in older people with multiple health problems and medications continuing intervention is needed. The paper, and especially the thoughtful discussion, should be read by anyone wanting to do better.

The benefits of high adherence are potentially large, given the generally low adherence usually seen in these circumstances, and given that low adherence is associated with increased rates of hospital admission. This is not a simple answer to a simple problem, but an indication that with insightful pragmatic action much better outcomes can result.

After all, the pills are better in the patient than in a bottle. If the latter we pay twice, in unused medicine and more health care costs. Given the acknowledged size of the problem, the implication is that this is a topic area that requires some sensible research and action.

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New series of policy briefs launched at WHO European Ministerial Conference 'Health Systems, Health and Wealth'

A new series of policy briefs on health systems and health policy issues was launched at the WHO European Ministerial Conference on Health System held in Tallinn, Estonia in June 2008. A joint project between the Health Evidence Network and the European Observatory on Health Systems and Policies, this new series aims to meet policy-makers' requirements in two ways. First, it presents a rigorous review of the available research evidence, and second, the briefs are written in a language accessible to non-specialist policy-makers and follow a consistent format.

Appropriateness and implementation are key considerations for the series. Countries have different requirements and demands and a given policy option is unlikely to be relevant or appropriate to all systems and approaches. As such, the briefs do not aim to provide an ideal 'model' or recommended approach. Instead, they cover and synthesise available research evidence and potential policy options for best practice, such that policy makers can consider means and strategies towards innovating in their respective systems.

The briefs bring together key evidence underlining the central themes of the Conference: health and wealth, public health, governance, coordinated care, human resources, and financing. Given the focus of the Conference, the underlying concern of all the briefs was to improve health system performance.

Nine joint policy briefs have been published:

- How can European health systems support investment in and the implementation of population health strategies?
- How can the impact of health technology assessments be enhanced?
- Where are the patients in decision making about their own care?
- How can the settings used to provide care to older people be balanced?
- When do vertical (stand-alone) programmes have a place in health systems?
- How can chronic disease management programmes operate across care settings and providers?
- How can the migration of health service professionals be managed so as to reduce any negative effects on supply?
- How can optimal skill mix be effectively implemented and why?
- Do lifelong learning and revalidation ensure that physicians are fit to practice?

The briefs are available in English, French, German and Russian at http://www.euro.who.int/HEN/policybriefs/20080814_2



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Health for all? A critical analysis of public health policies in eight European countries

Edited by Christer Hogstedt, Henrik Moberg, Bernt Lundgren and Mona Backhans



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358 pages

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This study compares the evolution of national public health policies in eight European countries with attention to their character and contents concerning social and lifestyle determinants; the involvement of non-health sectors (for example, education, labour market, environment); and experiences with different strategies. A detailed literature review is also presented on comparative studies of policies on health inequalities.

For each country, the public health situation is examined by a local expert making use of a comprehensive template. Findings include: development of society and the present policy environment; magnitude, trends and analysis regarding social inequalities in health; public health

strategies focusing on specific health determinants; disease-specific strategies; group-specific strategies; arena approaches; implementation methods, resources and main actors; as well as monitoring and evaluation. Also considered are behavioural risk factors and measures taken to tackle lifestyle factors, such as tobacco, alcohol and overweight.

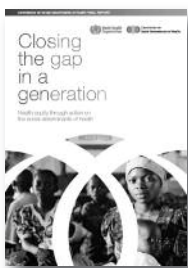
The ultimate objective of this study was to identify common experiences, notable differences and lessons. One of the main findings of the publication is that “the way health inequalities are explained is closely related to the way they are dealt with, i.e. to what extent governments try to make people behave differently or attempt to change their living conditions.”

Contents:

Foreword; Contributors; Comparative Studies of Policies on Health Inequalities – A Literature Review; Health Inequities – Concepts, Measures and Pathways; Denmark; England; Finland; Italy; The Netherlands; Norway; Spain; Sweden; Summary Chapter; Concluding Remarks and Recommendations.

Closing the gap in a generation: Health equity through action on the social determinants of health

Commission on Social Determinants of Health



Geneva: World Health Organization, 2008

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247 pages

Freely available at:

http://www.who.int/social_determinants/final_report/en/index.html

Many of the differences in health between and within countries result from the social environment where people are born, live, grow, work and age. These so-called ‘social determinants of health’ have been the focus of a WHO Commission established in 2005, which aimed to marshal evidence and make recommendations on reducing health inequities. Their final report was published in August 2008.

The report goes beyond measuring health inequities between countries, and documents ‘health gradients’ within countries as well, for example, by showing differences in life expectancy and maternal mortality for different cultural groups within the same country. On the topic of health and wealth, the report shows that wealth alone does not have to determine the health of a nation’s population. Some low-income countries such as Cuba, Costa Rica, China,

the state of Kerala in India and Sri Lanka have achieved levels of good health despite relatively low national incomes.

The Chair of the Commission, Sir Michael Marmot, commented that an “effective way of increasing life expectancy and improving health would be for every government policy and programme to be assessed for its impact on health and health equity”. The report cites the Nordic countries as providing outstanding policies that have encouraged equality of benefits and services, full employment, gender equity and low levels of social exclusion, that should be adopted everywhere.

The full report in English and the executive summary in six UN languages, along with supporting press release, country examples, figures, tables and graphs and podcast are available for download.

Contents:

Executive Summary; Setting the Scene for a Global Approach to Health Quality; Evidence, Action, Actors; Daily Living Conditions; Power, Money and Resources; Knowledge, Monitoring and Skills; Building a Global Movement; List of Recommendations.

Northern Dimension Partnership in Public Health and Social Well-being (NDPHS)

<http://www.ndphs.org>

The NDPHS brings together thirteen governments, the European Commission and eight international organisations, to focus on northern Europe. The English, Polish and Russian language web site provides information about events, an e-newsletter, and presentations. It also provides access to the work of expert groups on HIV/AIDS, prison health, primary health care, social inclusion, healthy lifestyles and work ability. An online database contains information on projects, papers and contacts. It also contains a 'project pipeline', a multi-agency on-line project funding coordination tool.

Baltic Sea Network on Occupational Health and Safety (BSN)

<http://www.balticseaosh.net>

The BSN brings together occupational health and safety institutions from all the countries bordering the Baltic Sea, ranging from Norway to Russia. The site contains a modest amount of information including the annual workplan, meeting reports, contact information for participants, links to other occupational health and safety organisations, as well as access to relevant reports stored in the NDPHS database.

Eurosafe

<http://www.ecosa.org>

The English-language web site of the European Association for Injury Prevention and Safety Promotion (Eurosafe) contains information on various activities including the consumer safety programme, EU Injury database and European Child Safety Alliance. It also contains the archives of *Eurosafe Alert*, the organisation's regular newsletter, including a special edition on the recent 2nd European Conference on Injury Prevention held in Paris in October 2008. A 'knowledge base' section is a plethora of information on topics such as measurement and risk assessment.

DETERMINE

<http://www.health-inequalities.eu>

DETERMINE is an EU consortium for action on socioeconomic determinants of health. It hosts an English-language European Portal for Action on Health Equity. This contains: country health inequality profiles; a database of good practices; an EU Policy Section with case studies; a health in all policies section with examples of how other policy areas can contribute to greater health equity; relevant links to other health inequalities related resources on the web; events information; and publications.

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

<http://www.emcdda.europa.eu>

EMCDDA is one of the European Union's decentralised agencies. Established in 1993 and based in Lisbon, it is the central source of comprehensive information on drugs and drug addiction in Europe. Most of the web site's content is in English but some pages are available in twenty-four European languages. It provides drug related statistics, as well as country profiles, information on EU law on drugs, news and publications. Evidence for policy is available in a 'best practice portal'.

Foresight Project on Mental Capital and Wellbeing

<http://www.foresight.gov.uk/OurWork/ActiveProjects/Mental%20Capital/Welcome.asp>

The aim of the Foresight Project on Mental Capital and Wellbeing has been to advise the UK government on how to achieve the best possible mental development and mental wellbeing for everyone in the future. The Project has collated high quality scientific evidence and involved the collaboration of a large number of expert advisors. The recently launched final report, as well as a large number of background documents, CD ROMs, and an article published in *Nature*, can be freely accessed at the English language web site. Topics include analysis of future challenges for mental health, as well as the complex relationship between wellbeing and work.

EUROPEAN MONITOR

WHO Commission: Inequities killing people on a "grand scale"

The final report of the WHO Commission on the Social Determinants of Health *Closing the Gap in a Generation: Health Equity through Action on the Social Determinants of Health* was published on 28 August in Geneva. The report is the result of a three-year investigation by an eminent group of policy makers, academics, former heads of state and former ministers of health.

Stark findings include the observation that children born in a Glasgow suburb can expect a life twenty-eight years shorter than those living only thirteen kilometres away, while a girl in Lesotho is likely to live forty-two years less than another in Japan. In Sweden, the risk of a woman dying during pregnancy and childbirth is one in 17,400; in Afghanistan, the odds are one in eight. Biology does not explain any of this. Instead, the differences between – and within – countries result from the social environment where people are born, live, grow, work and age. "(The) toxic combination of bad policies, economics, and politics is, in large measure responsible for the fact that a majority of people in the world do not enjoy the good health that is biologically possible...Social injustice is killing people on a grand scale."

"Health inequity really is a matter of life and death," said WHO Director-General Dr Margaret Chan while welcoming the report and congratulating the Commission. "But health systems will not naturally gravitate towards equity. Unprecedented leadership is needed that compels all actors, including those beyond the health sector, to examine their impact on health. Primary health care, which integrates health in all of government's policies, is the best framework for doing so."

Commission Chair, Sir Michael Marmot, said that "central to the Commission's recommendations is creating the conditions for people to be empowered, to have freedom to lead flourishing lives. Nowhere is lack of empowerment more obvious than in the plight of women in many parts of the world. Health suffers as a result. Following our recommendations would dramatically improve the health and life chances of billions of people."

The Commission found evidence that demonstrates, in general, that the poor are worse off than those less deprived. They also found that the less deprived are in turn worse than those with average incomes, and so on. This slope linking income and health is the social gradient, and is seen everywhere – not just in developing countries, but in all countries, including the richest. The slope may be more or less steep in different countries, but the phenomenon is universal.

Wealth is not necessarily a determinant

Economic growth is raising incomes in many countries but increasing national wealth alone does not necessarily increase national health. Without equitable distribution of benefits, national growth can even exacerbate inequities.

While there has been an enormous increase in global wealth, technology and living standards in recent years, the key question is how it is used for fair distribution of services and institution-building, especially in low-income countries. In 1980, the richest countries with 10% of the world's population had a gross national income sixty times that of the poorest countries with 10% of the population. After twenty-five years of globalisation, this difference has increased to 122. Worse, in the last fifteen years, the poorest quintile in many low-income countries have shown a declining share in national consumption.

Wealth alone does not have to

determine the health of a nation's population. Some low-income countries such as Cuba, Costa Rica, China, the state of Kerala in India and Sri Lanka have achieved levels of good health despite relatively low national incomes. But, the Commission points out, wealth can be wisely used. Nordic countries, for example, have followed policies that encouraged equality of benefits and services, full employment, gender equity and low levels of social exclusion. This, said the Commission, is an outstanding example of what needs to be done everywhere.

Solutions from beyond the health sector

Much of the work to redress health inequities lies beyond the health sector. According to the Commission's report, "Water-borne diseases are not caused by a lack of antibiotics but by dirty water, and by the political, social, and economic forces that fail to make clean water available to all; heart disease is caused not by a lack of coronary care units but by lives people lead, which are shaped by the environments in which they live; obesity is not caused by moral failure on the part of individuals but by the excess availability of high-fat and high-sugar foods." The health sector – globally and nationally – needs to focus attention on addressing the root causes of inequities in health.

"We rely too much on medical interventions as a way of increasing life expectancy" explained Sir Michael. "A more effective way of increasing life expectancy and improving health would be for every government policy and programme to be assessed for its impact on health and health equity; to make health and health equity a marker for government performance."

Recommendations

Based on this compelling evidence, the Commission makes three overarching recommendations to tackle the "corrosive effects of inequality of life

News

Press releases and other suggested information for future inclusion can be e-mailed to the editor David McDaid d.mcdaid@lse.ac.uk

chances". First, to improve daily living conditions, including the circumstances in which people are born, grow, live, work and age. Measures recommended include investment in early childhood services and fairer access to health care services. Second, measures to tackle the inequitable distribution of power, money and resources globally, nationally and locally. Finally, they recognise the importance of monitoring the situation and assessing the impact of intervention.

Acknowledging the challenge of implementation, the Commission noted that, on the basis of a commitment to make progress on the social determinants of health equity, there are now nine country partners, including Sweden and the UK. WHO will make the report available to Member States which will determine how the health agency is to respond.

The report is available at
http://www.who.int/entity/social_determinants/final_report/en/index.html

World Health Report calls for a return to primary health care approach

On 14 October 2008 in Almaty, Kazakhstan, the World Health Report 2008 *Primary Health Care – Now More Than Ever* was launched. The launch commemorates the 30th anniversary of the Alma-Ata International Conference on Primary Health Care held in 1978. That event was the first to put health equity on the international political agenda.

The report critically assesses the way that health care is organised, financed and delivered in rich and poor countries around the world. It documents a number of failures and shortcomings that have left the health status of different populations, both within and between countries, dangerously out of balance.

Speaking at the launch, WHO Director General Dr Margaret Chan said that "the World Health Report sets out a way to tackle inequities and inefficiencies in health care, and its recommendations need to be heeded," adding that "a world that is greatly out of balance in matters of health is neither stable nor secure."

In a wide-ranging review, the report found striking inequities in health outcomes, in access to care, and in what people have to pay for care. Differences in life expectancy between the richest and poorest countries now exceed forty years. Of the estimated 136 million women who will give birth this year, around fifty-eight

million will receive no medical assistance whatsoever during childbirth and the postpartum period, endangering their lives and that of their infants.

Globally, annual government expenditure on health varies from as little as US\$ 20 per person to well over US\$ 6,000. For 5.6 billion people in low- and middle-income countries, more than half of all health care expenditure is through out-of-pocket payments. With the costs of health care rising and systems for financial protection in disarray, personal expenditures on health now push more than 100 million people below the poverty line each year.

Data in the report are also indicates a situation in which many health systems have lost their focus on fair access to care, their ability to invest resources wisely, and their capacity to meet the needs and expectations of people, especially in impoverished and marginalised groups. As the report notes, conditions of "inequitable access, impoverishing costs, and erosion of trust in health care constitute a threat to social stability."

To steer health systems towards better performance, the report calls for a return to primary health care, a holistic approach to health care formally launched thirty years ago. When countries at the same level of economic development are compared, those where health care is organised around the tenets of primary health care produce a higher level of health for the same investment.

It notes that in far too many cases, people who are well-off and generally healthier have the best access to the best care, while the poor are left to fend for themselves. Health care is often delivered according to a model that concentrates on diseases, high technology, and specialist care, with health viewed as a product of biomedical interventions and the power of prevention largely ignored.

Specialists may perform tasks that are better managed by general practitioners, family doctors, or nurses. This contributes to inefficiency, restricts access, and deprives patients of opportunities for comprehensive care. When health is skewed towards specialist care, a broad menu of protective and preventive interventions tends to be lost.

The report is available at
<http://www.who.int/entity/wbr/2008/en/index.html>

Commission acts on excessive working time in Greece

On 16 October 2008, the European Commission sent a letter of formal notice to Greece for failure to comply with EU rules on maximum working time as regards doctors in public health services. Vladimír Špidla, EU Commissioner for Employment and Social Affairs, said that the "Working Time Directive protects workers from being forced to work excessive hours, which can endanger their health and could increase risks for others. The Commission must act when it is concerned that minimum standards are not being adhered to."

The Directive (2003/88/EC) limits working time to 48 hours per week on average. The Commission has received numerous complaints that Greece has suspended some of its working time laws so doctors in public hospitals can be legally required to work excessive hours. The complaints state that specialist doctors are being obliged to work an average of 60–72 hours per week, with doctors in training obliged to work an average of 71–93 hours per week. They also suggest that minimum rest periods are not being respected, with doctors required to work up to 32 continuous hours. The Directive stipulates that a worker is entitled to eleven hours a day of rest and one full day off a week. It should be noted that Greece does not make use of the option to derogate from the 48 hour week.

The Greek authorities now have two months to reply. If further compliance with EU legislation is needed, the Commission can send a reasoned opinion, and again Greece would have a further two months to reply. Ultimately, if there is no satisfactory reply, the Commission can refer the matter to the European Court of Justice in Luxembourg. It can also request that the Court impose a fine on the country if it does not comply.

The Working Time Directive is itself currently being revised under the co-decision procedure. The Common Position, adopted by the Council in June, is now before the European Parliament. Furthermore, the Commission is currently finalising a detailed report on the implementation of the Working Time Directive in all Member States. It is planned for adoption in December 2008.

Further information at
http://ec.europa.eu/employment_social/labour_law/index_en.htm

'Europe for Patients' campaign

On 30 September, Health Commissioner Androulla Vassiliou launched the 'Europe for Patients' campaign in Brussels. The campaign highlights the different health policy initiatives the Commission intends to adopt in the coming six to nine months. All the initiatives are bound by a common goal: better health care for all in Europe. They address patient safety, rare diseases, organ donation and transplantation, cancer screening, the health workforce, influenza and childhood vaccination and antibiotic use. The first initiative, on cross border health care, was adopted by the Commission in July. In launching the campaign the Commissioner stressed the need to increase awareness across the EU of the many positive impacts of EU health policies. She stated that "we need to provide clear information, free of Euro-jargon with real examples that relate to people's lives."

A webpage on the EU Health Portal in twenty-two languages will become an information hub where documents, articles and events will be posted.
<http://health.europa.eu/efp>

Legal instruments underpinning EU's medical device directives adopted

In February 2007, the European Commission proposed a new package of measures which were intended to boost intra-community trade in industrial goods (the 'new approach system'). These measures were designed to ensure that the internal market became a reality for all manufacturers and producers, and to make it easier for companies, especially medium sized enterprises, to trade their products in the EU. On 23 June 2008, the European Council finally adopted this new package of measures. At the same time it adopted measures dealing with the 'mutual recognition principle' that compliments the 'new approach system'.

The principle of free movement of goods is one of the cornerstones of the EC Treaty. Many industrial products are already subject to Community legislation and so can be traded freely within the EU. However, free trade must go hand-in-hand with high safety standards. The 'new approach system' strengthens the framework within which the goods are manufactured and traded, building upon existing mechanisms, to ensure that only safe products circulate. Market surveillance structures will be strengthened to catch unsafe products, to remove them

from the whole Community market and to take action against manufacturers. The testing, certification and inspection bodies that are involved in product checking will be subject to more stringent controls in the form of accreditation, to ensure that there is a level playing field both for manufacturers and the inspection bodies.

Not all goods fall under Community legislation. Many companies have found it difficult to sell their products in other Member States, and are discouraged from venturing outside their domestic market due to the burden of proving that their products fulfilled the technical requirements in the destination Member State. Recognising this problem, the aim behind the 'mutual recognition principle' is that Member States will be prevented from stopping the sale of goods which have been lawfully marketed in another Member State.

EU Drugs Action Plan for 2009–2012

On 18 September 2008, the Commission adopted an 'EU Drugs Action Plan' for the period 2009–2012. The plan comes at a time when the latest available data from the European Commission show that whereas the use of heroin, cannabis and synthetic drugs has stabilised or is declining, cocaine use is rising in a number of Member States. The total number of people in the EU who use drugs – or have at some time taken them – is estimated at seventy million for cannabis, at least twelve million for cocaine, more than nine million for ecstasy and eleven million for amphetamines, while at least half a million people are known to be receiving substitution treatment for heroin. There are up to two million problem drug users in the EU and around 7,500 people die of drug overdoses each year.

The new Action Plan builds on the existing approach of the EU Drugs Strategy 2005–2012 which set out a European model for drug policy based on a balanced approach to reduce both supply and demand for drugs. The five main priorities of the new Action Plan are: reducing the demand for drugs and raising public awareness, mobilising European citizens, reducing the supply of drugs, improving international co-operation and facilitating a better understanding of the drug phenomenon.

Actions proposed include measures to improve the quality, availability and coverage of treatment and harm reduction

programmes for drug users and the establishment of intelligence-led police and customs operations to counter large-scale organised crime groups both in the EU and on the drug trafficking routes from Afghanistan and Latin America.

The Action Plan 2009–2012 will be presented to the Council and is expected to be adopted before the end of the year.

More information at
http://ec.europa.eu/justice_home/fsj/drugs/fsj_drugs_intro_en.htm

COUNTRY NEWS

Swedish focus on suicide prevention

On 14 July it was reported that the Swedish government had decided to make suicide prevention a priority in the recently updated public health bill. The aim is that no one should find themselves in a situation where they see taking their own life as the only way out.

Each year, about 1,400 people take their own life in Sweden, which is about twice as many lives lost as a result of traffic accidents. Suicide is the most common cause of death among people aged 15–44, albeit most suicides are committed by people the aged over of 45. Preliminary estimates for 2007 indicate that 17.3 per 100,000 men and 6.9 per 100,000 women died from suicide.

Given that many suicides are avoidable, the government decided on three schemes to help reduce intentional deaths. The first targets young people. The Swedish National Institute of Public Health (SNIPH), the Swedish National Agency for School Improvement and the National Suicide and Mental Ill-health Prevention Unit at the Karolinska Institute have been given the task of producing information material on suicide prevention and a strategy for disseminating the material to teachers and school employees.

The second scheme targets health care personnel and other professionals, such as police and criminal justice system personnel, who may come in contact with people at risk of suicide. The SNIPH and the National Board of Health and Welfare will propose ways in which to further educate such professionals in suicide prevention strategies.

In the third scheme, the government aims to improve public awareness of suicide prevention. The National Board of

Health and Welfare will produce this information, as well as a strategy for dissemination in cooperation with other organisations.

UNICEF boosts funding to help ensure proper nutrition for Kyrgyz children

The United Nations Children's Fund (UNICEF) will provide \$270,000 in additional funds to help develop a national nutrition strategy in Kyrgyzstan, where more than half of babies and infants are anaemic and many young children suffer from stunted growth as a result of nutrient deficiencies.

"Giving a child a solid nutritional start in life is critical to physical, mental and social development," stressed UNICEF chief Ann Veneman during her visit to the Central Asian nation, the first-ever by an Executive Director of the agency. While in the capital, Bishkek, Ms Veneman also visited the Rehabilitation Centre for Street Children, which provides shelter for some seventy children who have been exposed to violence, exploitation or abuse. She held talks with Prime Minister Igor Chudinov on a range of issues, including the implementation of legislation to protect the country's children, as well as the recent establishment of the new government department to co-ordinate children's issues.

More than half of the population in Kyrgyzstan – the second poorest country in Eastern Europe and Central Asia – lives in poverty and more than one quarter in extreme poverty, affecting more than 60% of children under the age of fourteen. Statistics show that at least 50% of Kyrgyz babies aged between 6–24 months are anaemic and nearly 14% of children under five suffer from stunted growth.

UNICEF has been supporting activities in the country since 1994 in areas such as health and nutrition, clean water and sanitation, quality basic education for all boys and girls, as well as the rights of marginalised children, children in poverty and children facing discrimination.

More information at
<http://www.un.org/apps/news/story.asp?NewsID=28608&Cr=KYRGYZ&Cr1=>

Russia: TB poses security threat in Russia, official says

Tuberculosis (TB) poses a threat to Russia's security and labour force, Mikhail Grishankov, first deputy chair of the security committee of the State Duma,

said during a roundtable at the World Bank office on 22 September in Moscow. Grishankov added that the Russian government plans to allocate twenty-six billion Russian roubles, or about \$1 billion, from 2007 to 2011 for a TB prevention and treatment programme.

According to Grishankov, "social infections" such as TB and HIV "pose a real threat" to Russia's security because they often affect people during their prime working years, at a time when the country is experiencing a labour shortage. In addition, drug resistant TB is increasing in Russia and requires more expensive treatment than drug-sensitive strains of the disease. Treatment for drug-sensitive TB costs 2,500 roubles, or about \$99, for six months, compared with 1.5 million roubles, or about \$60,000, for one year to treat drug-resistant TB.

Grishankov recommended that government branches work together to control TB in Russia, noting that "poor awareness of authorities and people is the main obstacle to development of an up-to-date comprehensive inter-agency programme".

Most TB patients in Russia are classified as 'socially vulnerable', including people who are alcoholics, homeless, migrants or unemployed. More than 300,000 TB cases have been registered in Russia, which has a TB incidence of more than 100 cases per 100,000 people in twenty six regions. Nearby countries such as Finland, Norway and Sweden have a TB incidence of five to six cases per 100,000 people. According to the WHO, Russia ranks 11th out of the twenty two countries with the highest TB burden worldwide and accounts for 35% of all primary TB cases in WHO's European region.

More information at
http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=54604

France: experts discuss integration of TB services within primary care

Tuberculosis experts discussed the integration of TB services into primary health care and global progress in TB control at the 'Stop TB Partnership' symposium at the 39th Union World Conference on Lung Health on 16 October in Paris. Nils Billo, executive director of the International Union Against Tuberculosis and Lung Disease, said that despite the development of stronger health systems and better TB control in developing countries

over the last two decades, there still is a "long way" to go.

According to Billo, inadequate funding, insufficient management of DOTS, an increase in multi-drug resistant (MDR) TB and extensively drug-resistant (XDR) TB, and a lack of infrastructure in developing countries to address MDR- and XDR-TB are presenting challenges in meeting the United Nations' Millennium Development Goals and the Global Plan To Stop TB: 2006–2015 targets. Billo called on France, Germany, the UK and the US to increase efforts to address TB worldwide, saying they should "launch a major financial rescue plan for TB."

Marcos Espinal, executive secretary of the Stop TB Partnership, said that drug-resistant TB, HIV/TB co-infections and a lack of infrastructure are hindering health systems' efforts to control TB. Mario Raviglione, director of the Stop TB Department at the WHO, said that the global TB community needs to work "urgently" to improve health systems in developing countries, adding that global targets on TB control cannot be met without improvement in developing countries' health infrastructures. Raviglione called for increased funding, noting that although concerns about the global economy likely will affect TB funding, the global health community must still increase efforts to link TB services with health systems in developing countries.

The conference also heard that while many of the twenty-two countries with the highest TB burden worldwide have made progress in detecting and treating new cases, continued progress will require coordination from entire health systems, including better integration into primary health care.

More information at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=55041

UK: Government action to fund gaps in health research

A new £5 million research programme which is intended to lead to an increase in service quality and patient safety through better ways of planning and providing health services was announced on 15 October by Public Health Minister Dawn Primarolo, during a visit to Southampton.

The new Health Services Research (HSR) programme will provide funding across the country for a broader range of health

services research than is already covered by the National Institute for Health Research (NIHR) programmes: the Efficacy & Mechanism Evaluation Programme, the Health Technology Assessment Programme, the Service Delivery & Organisation Programme, Programme Grants for Applied Research and the Research for Patient Benefit Programme. These are all specialist subsets in the field of health services research, which means that some projects may be difficult to fund as they fall outside established NIHR funding streams, as well as those covered by the Medical Research Council and the Department of Health.

The HSR programme will fund research mainly through a researcher-led work-stream, whereby grants are provided for both primary and evidence synthesis on topics proposed directly by researchers, on an ongoing basis. The programme may also advertise calls for research proposals on specific topics. Dawn Primarolo said “health services research produces knowledge that can lead to the improvement of health policy, health systems, and health care delivery, ultimately resulting in improvements in population health. This area of research has already made a valuable contribution to the improvement of health and health care in the UK. With this new programme we are taking action to fund important research where there is currently no alternative source of funding.”

The Government recognised the importance of health services research in its national health research strategy ‘Best Research for Best Health’, where one of the strategic goals is to commission research focused on improving health and care. The Cooksey review also highlighted the need for increased funding for research into the implementation of new products and approaches into practice.

Commenting on the launch of the programme Professor Sally C Davies, Director General of Research & Development at the Department of Health said that “all types of study designs appropriate to health services research will be supported, which include both primary research and evidence syntheses. Our early work with stakeholders has highlighted a number of key areas likely to be of interest to this new programme. These include cultural and organisational issues around patient safety, making better use of existing research knowledge through modelling, and the use of existing health

data to improve the planning and delivery of health services and systems.”

The first call for expressions of interest will be taking place in January 2009.

More information and details on how to register at <http://www.hsr.nibr.ac.uk>

UK: Almost one fifth of MPs have experienced mental health problems.

The All-Party Parliamentary Group on Mental Health has found that 86% thought being an MP was stressful. The report criticises the law forcing MPs to give up their seats for life if they are placed into institutional care for six months under the Mental Health Act. No such rules apply to MPs who are physically incapable of working for the same time period.

Joint chairman Sandra Gidley said work on ‘challenging stigma’ was needed. Some ninety-four MPs took part in the survey. One in three said colleagues’ attitudes and the possibility of a hostile media reaction prevented openness about mental health issues. Ms Gidley, a Liberal Democrat MP, said that “greater openness at Westminster about mental health problems would have a significant impact in challenging stigma and discrimination”.

She pointed to the experiences of former Norwegian Prime Minister’ Kjell Magne Bondevik, who publicly disclosed that he needed to take time off work because of depression. She noted that his popularity was unaffected and indeed “he went on to be re-elected and prove that people who have experienced mental health problems can recover and manage a challenging job.”

Paul Farmer, chief executive of the charity Mind, commenting on the survey said that “at a time when the government is appealing to employers to be more understanding about mental health issues as part of its aim to get people off benefits and back into workplace, it seems they should be looking to take action closer to home. Repealing antiquated rules that ban MPs from returning to work after recovering from a mental health problem would send out a clear message to all employers that discrimination should not be tolerated.”

Similarly the charity Rethink’s chief executive, Paul Jenkins, said that the findings were “an affront to democracy. MPs and peers need to be free to bring their personal experiences to their vital demo-

cratic role. Instead they are being gagged by the prejudice, ignorance and fear surrounding mental illness. We look forward to the day when MPs from all political parties with experience of mental illness are able to participate fully in our democracy.”

More information on the survey can be accessed at <http://www.lynnjones.org.uk/survey%20FINAL.pdf>

Channel Islanders could lose some rights to free health care in the UK

Channel Islanders who fall ill or have accidents in the UK could soon be left with huge medical bills if they do not have travel insurance. The necessity to take out comprehensive insurance is likely to be one consequence of the UK’s Department of Health intention to withdraw from the reciprocal health agreement with the Channel Islands of Jersey and Guernsey, as well as other off-shore jurisdictions, including the Isle of Man and Gibraltar.

At the moment, islanders travelling to the UK, and UK residents who visit the Channel Islands are entitled to emergency health care that is free at the point of delivery. Jersey’s health minister Ben Shenton said that the matter was still under negotiation, and insisted that he did not think that any change in the current agreement was imminent.

Under Jersey’s reciprocal agreement, which was established more than forty years ago, the island pays the UK for services it uses in England, and the Department of Health hands over cash to cover the cost of emergency treatment for UK residents visiting Jersey. The taxpayers of both places ultimately pay for the services used, but they are free at the point of delivery for patients.

The Department of Health’s position further strains relations between Jersey and Westminster. In recent months the constitutional status quo has come into sharp focus as a result of the historical child abuse inquiry, and calls for the UK to step in to ensure that the court process is fair to victims and those accused of abuse. Whatever changes will be introduced, the UK has made it clear that Channel Island residents currently studying in the UK will be treated as UK citizens for the purposes of their health care needs.

More information at http://www.gov.je/Health/who_we_are/Channel+IslandsReciprocalHealthAgreement.htm

News in Brief

Summit promotes joint commitment to improve inclusion for millions of Roma

On 16 September in Brussels the European Commission launched the first EU-level summit devoted to improving the situation of Roma communities across the Union. Discrimination against Roma people persists and 77% of Europeans think that being Roma is a disadvantage in Europe. In the Social Agenda of 2 July 2008, the Commission set out a renewed commitment to non-discrimination in general and action to improve the situation of Roma in particular. It concluded that there is a powerful framework of legislative, financial and policy coordination tools available at EU level and that these are increasingly used, but that there is still an implementation gap in the Member States. The Summit forms the next step in this process and aims to support and promote a joint commitment by the Member States, the EU institutions and civil society. The conclusions will feed into discussions at the December 2008 European Council.

More information at http://ec.europa.eu/employment_social/fundamental_rights/roma/index_en.htm

Progress in preventing injuries in the WHO European Region

A new publication by D Sethi, F Racioppi, B Frerick and N Frempong from the WHO European Centre for Environment and Health in Rome, looks at the progress achieved by Member States on injury prevention. It reports on the development of web-based tools comprising a database of country profiles compiled through a questionnaire survey and an inventory of national policies. Good progress is taking place, with the development of national policies for individual types of injury and violence varying from 86% for road safety to about 33% for the prevention of youth and self-inflicted violence. The report notes that the health sector needs to commit to more widespread implementation of effective programmes both in number and coverage and to engage with other stakeholders in a multi-sectoral response to prevent injuries.

The report is available at <http://www.euro.who.int/document/E91710.pdf>

Updated Global Burden of Disease

On 27 October the World Health Organization published a new assessment of the global burden of disease, a study that provides a comprehensive picture of the global and regional state of health. Drawing from extensive data, it features comparisons between deaths, diseases and injuries by region, age, sex and country income for the year 2004. It also provides projections of deaths and burden of disease by cause and region to the year 2030. The study contains details of the top ten causes of death and estimates for over 130 disease and injury causes.

More information at http://www.who.int/healthinfo/global_burden_disease/2004_report_update/en/index.html

Improving cost-effectiveness in the health care sector in Iceland

A new OECD working paper by Hannes Suppanz argues that the high costs of health care provision in Iceland might be addressed by removing impediments to private provision and opening up the health sector to competition. It suggests that introduction of cost sharing where it does not exist (as in hospitals) might be considered, although concerns about equity need to be taken into account. This it is argued would relieve the burden on public finances, as would the introduction of spending ceilings, cost-efficiency analysis and activity-based funding arrangements. The high cost of pharmaceuticals might also be reduced by promoting competition and the use of inexpensive generic drugs.

The working paper is available at [http://www.ois.oecd.org/olis/2008doc.nsf/LinkTo/NT00005C72/\\$FILE/JT03253001.PDF](http://www.ois.oecd.org/olis/2008doc.nsf/LinkTo/NT00005C72/$FILE/JT03253001.PDF)

EU warns of permanent hearing damage from iPods

Listening to personal music players at a high volume over a sustained period can lead to permanent hearing damage, according to an opinion of the EU Scientific Committee on Emerging and Newly Identified Health Risks. The scientific opinion shows 5–10% of those who listen to a personal music player for more than one hour per day each week at high volume for at least five years risk permanent hearing loss. In response, EU Consumer Affairs Commissioner

Meglana Kuneva said that “we need to raise consumer awareness and put this information in the public domain. We need also to look again at the controls in place, in the light of this scientific advice, to make sure they are fully effective and keep pace with new technology.” The Commission will hold a conference in early 2009 in Brussels to evaluate the Scientific Committee’s findings with Member States, industry, consumers and other stakeholders and to discuss the way forward. The seminar will address precautions that users can take, as well as technical solutions to minimise hearing damage and the need for further regulations or revisions of existing safety standards to protect consumers.

More information is available at <http://ec.europa.eu/health/opinions/en/hearing-loss-personal-music-player-mp3>

Report on inequalities in young people’s health

A new report from the Health Behaviour in School-aged Children: WHO Collaborative Cross-National Study presents key findings on patterns of health among young people in forty-one countries and regions across Europe and North America. This report has a special focus on health inequalities and indicates that, while the health and well-being of many young people are cause for celebration, sizeable minorities are experiencing real and worrying problems related to overweight and obesity, self-esteem, life satisfaction, substance misuse and bullying. It concludes that policy makers and professionals should listen closely to the voices of young people and ensure that these drive efforts to put in place the circumstances – social, economic, health and educational – within which young people can thrive and prosper.

The report can be downloaded at http://www.euro.who.int/InformationSources/Publications/Catalogue/20080616_1

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