

# Eurohealth

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Volume 15 Number 2, 2009

## Parallel trade and affordable access to medicines in the EU

Advancing palliative care in the EU

Increasing the use of health impact assessments

The growth of voluntary health insurance in Denmark

Health information technology in the United State • Belarus: primary care developments  
Poland: hospital reform • Italy's new fiscal federalism • Saudi Arabia: allocating funds to pharmaceuticals

# COMMENT

## Parallel trade and affordable access to medicines

In 2007 parallel trade of pharmaceuticals in the EU totalled €4.8bn, accounting for more than 10% of all spending on pharmaceuticals in the Netherlands, the UK, Sweden, Denmark, and Germany. Dermot Glynn writing here in *Eurohealth* reports on work to examine the systemic effects of parallel trade. He finds that adverse effects on safety through inaccurate packaging, counterfeit products and product recalls may have a cost of €0.5 billion per annum; prohibiting both repackaging and re-labelling he suggests would greatly reduce the harm to patients and substantially improve access to safe and affordable medicines. In contrast, while differences in prices may lead to delays in access in some countries, Glynn concludes that any move to introduce a single EU price for any drug would mean that it might become unaffordable in some of the poorer Member States that account for over 100 million of the EU's 480 million citizens.

Elsewhere in this issue, while *Health in All Policies* has been a mantra of policy statements now for some time, Rebecca Salay and Paul Lincoln contend that while the European Commission has a rigorous system of integrated impact assessment, in practice public health implications are not fully considered outside of the health sector. They call for health impact assessments to be made a mandatory core activity of the Commission – otherwise they suggest public health will continue to be a hit and miss, marginal consideration.

Meantime, Jose M Martin-Moreno and colleagues draw our attention to their report for the European Parliament on the state of palliative care in Europe, setting out different options for policy change. They note that great differences in approach and access to palliative care services remain across the EU, but as yet the topic has not commanded great visibility at an EU level. This might, in part, be about overcoming some of the taboos associated with this sensitive subject. Clearly much more needs to be done to raise awareness, disseminate knowledge, and fight for lasting improvements in this field.

Our regular European snapshots feature includes articles on Poland, Belarus and Italy, while Karsten Vrangbæk looks at the growth in voluntary health insurance in Denmark. We also seek to learn from experience elsewhere, here looking at funding for pharmaceuticals in Saudi Arabia and the use of information technology in the United States.

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# The effects of parallel trade on affordable access to medicines

Dermot Glynn

*Summary: A stylised demand curve for patented medicines in the EU was constructed and the price and availability of medicines were predicted by comparing the situation in which prices converge with differentiated prices. Parallel trade causes prices of patented medicines to converge. A single EU price would reduce both the numbers of patients with affordable access to patented medicines and profits by about 25% compared to optimally differentiated prices. The best option from the point of view of health care policy would be to prohibit the repackaging of medicines and require traceability throughout the supply chain.*

*Keywords: Parallel trade, affordable access to medicines, internal market, repackaging*

This paper is based on research commissioned by the EC to help assess the impact of policy options<sup>1,2</sup> to ensure safe medicines through parallel trade; and reduce the risks of counterfeit medicines in the EU. To the best of our knowledge this was the first such work to have been commissioned from the perspective of patients rather than manufacturers or traders. The manufacturers' trade association, the European Federation of Pharmaceutical Industries and Association (EFPIA) had assembled a dossier of complaints which the Commission took seriously.

## Market size and nature

Parallel trade in 2007 was about €4.8bn, a significant increase on the previous year, and accounted for more than 10% of spending on pharmaceuticals in the Netherlands, the UK, Sweden, Denmark, and Germany. According to industry estimates about 140–150 million packages are handled by parallel traders each year, most of which are either repackaged or re-labelled by the parallel trader or his agent.

The proportion of spending on particular drugs represented by parallel imports is often very much higher than 10%, and may exceed 50%, since parallel traders generally

concentrate on the most important patented medicines. The products most subject to parallel trade include Lipitor and Cozaar (cardio), Zyprexa, Risperdal, and Effexor (central nervous system), Casodex, Zoladex, and Arimidex (oncology), Nexium (gastro-metabolism), as well as Plavix (reduction of atherothrombotic events) and Seretide and Symbicort (asthma). These are important medicines for serious conditions and long term prospects for the volumes of parallel trade depend on the extent of price convergence in the Internal Market and on the outcome of some current court cases. Currency fluctuations in the current economic crisis are also affecting the direction of trade.

## The legal and policy framework

Member States have primary responsibility for health care, while Article 95 of the EC Treaty is the basis for EU legislation regarding the establishment and functioning of the Internal Market. The EC Treaty requires that the objective of removing unjustified constraints on the free movement of goods (Article 28) should be set aside

where necessary to protect patient safety and health (Article 30) or intellectual property. Articles 81 (preventing agreements that restrict competition and trade) and 82 (preventing the abuse of dominant position) are also not intended to prevent actions beneficial to consumers. Thus it may be argued that the Treaty makes free movement of goods subordinate to the objective of achieving a high level of patient safety and access to medicines.

The pharmaceuticals directive and the directive frameworks for good manufacturing principles and good distribution principles include only limited detail specifically relevant to parallel trade. The application of the primary legislation to parallel trade has therefore been mainly through decisions by the European Court of Justice (ECJ), decisions which have been made on cases relating to intellectual property and market access rather than the direct interests of patients.\* This means that the ECJ has not so far been presented with detailed evidence about the systemic effects of parallel trade.\*\*

\* However, in a decision of 2006 (T-168/01) the Court of First Instance considered whether a pharmaceutical manufacturer may rely on Article 81 (3) to justify a dual pricing system.

\*\* Analysis of systemic effects would explore the likely economic and social effects of the parallel trade system as a whole, in addition to the effects of specific transactions (so, for example, a systemic analysis would consider the probability that widespread repackaging and re-labelling would lead to a percentage of error, whilst analysis of specific cases would focus on the feasibility of repackaging and re-labelling taking place without adverse result).

## Findings

### *Repackaging and re-labelling*

A significant proportion of the 140–150 million packs of medicine handled by parallel traders each year include out of date package leaflets. No official estimates are available, because no regulatory authority makes systematic checks, but surveys by manufacturers have found that up to 60% include a mistake of some sort. Some of these mistakes concern intellectual property issues rather than mistakes directly linked to patient safety, but taking a conservative view some 20% of parallel traded packs include out of date or otherwise inaccurate information.

Not all package leaflets are read by patients, and not all the inaccuracies would matter to the patients who do read them. Studies have been made of the numbers reading packs, and on the basis of these it is reasonable to assume that about half of the inaccurate leaflets are read. The average harm experienced by patients receiving inaccurate information was taken to be half a quality adjusted life year with some additional economic costs.

Apart from the question of package leaflets, repackaging and re-labelling mean that confusion may be caused by alternate packaging or names for what should be the same medicine; patients may not take medication as intended; and compliance with prescription regimes may be reduced.

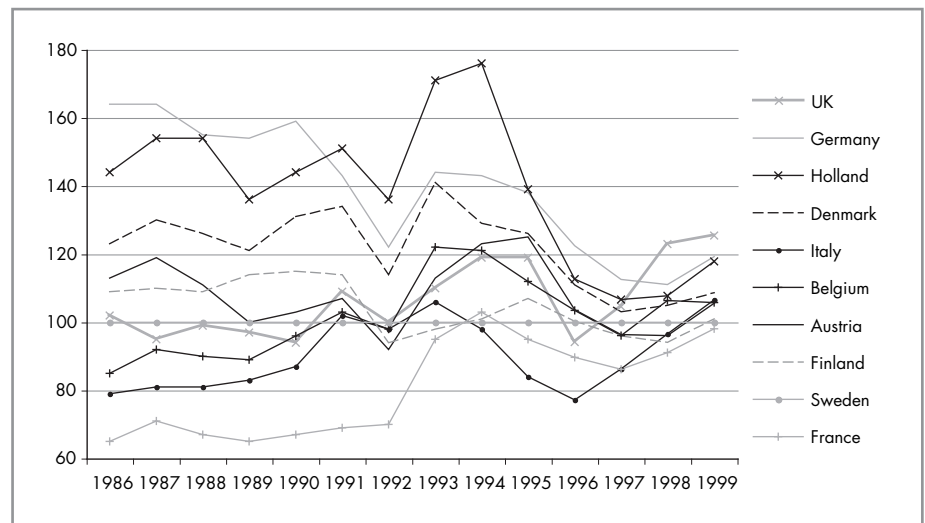
### *Product recalls*

There are a significant number of product recalls (400 in 2006) so that reliability of the systems involved is a significant patient interest.\* Parallel traders sometimes use a separate batch number in addition to the manufacturer's number. The increased number of transactions involved in parallel trade and the parallel traders' wish for confidentiality about the supply chain mean that product recalls initiated for any reason are likely to be less effective.

### *Risk of counterfeits*

The UK Medicines and Healthcare products Regulatory Agency (MHRA) believes that before 2007 fewer than 10,000 packs of counterfeit product reached patients, but incidents in 2007 allowed 30,000 packs to reach patients. There is a move from 'lifestyle' product counterfeiting to inci-

**Figure 1: Price comparisons at the pharmacy purchase level for selected EU Member States, 1986–1999 (Sweden = 100)**



Source: Data are taken from the AIP index from Apoteket AB, providing price comparisons for pharmaceuticals in Sweden and a number of European countries. Comparisons made in January 1999 are based on 150 brands with the highest value sales in Sweden in the previous year

dents involving life-saving products, and indications that parallel traders may have been targeted.

### *Overall effects on safety*

It seems possible that inaccurate repackaging and the increased risks of other sorts reduces the value of the products delivered through parallel by 10% or more, equivalent to roughly €0.5 billion per annum. There are no benefits to patient safety to offset against these losses.

## Effects on affordable access to medicines

### *Continuous supply*

There have been periodic shortages ('stock-outs') of medicines as available supply is shipped abroad from low-price countries or interruptions to supply elsewhere mean that the parallel traded product is not available. EU legislation was introduced (2004 amendment to Article 81 of Directive 2001/83/EC) to require continuous supply, with relevant legislation implemented in Austria, Denmark, Finland, Netherlands, Romania, Sweden, Spain, and the UK. However there have been reports of supply shortages even after implementation of new legislation. The most serious shortages occurred in markets that are significant exporters or importers of parallel traded products.

### *Introduction of new medicines to market*

When a new medicine is approved the patent holder receives a market authorisation. This may be for individual Member States, or for the EU as a whole (centrally authorised products), but in either case regulatory authorities throughout the EU must accept the medicine.

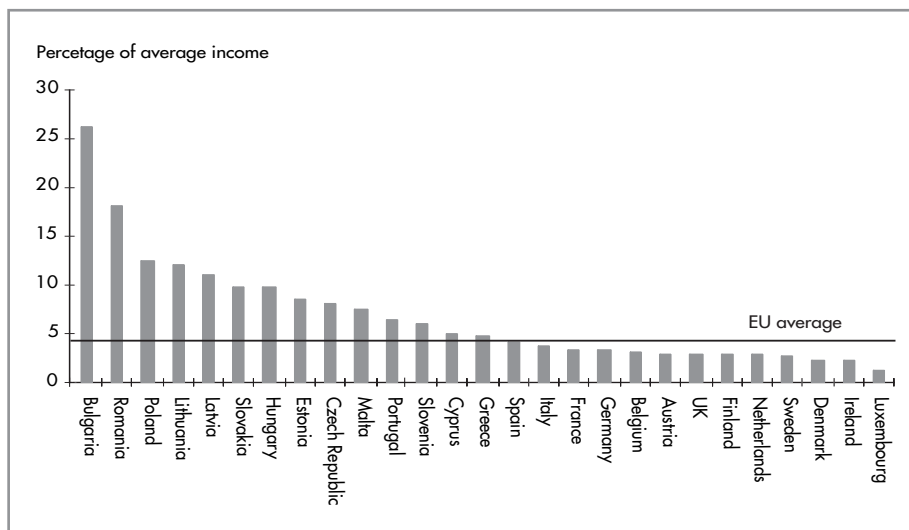
Manufacturers naturally defer agreeing prices in lower-income Member States. This is because such prices would be below average and result both in parallel exports, undermining profitability where incomes are higher, and in the low price being used in reference price comparisons, equally to the economic disadvantage of the patent-holder. Studies have confirmed that patients in lower income Member States have to wait for significant periods after new medicines are marketed elsewhere before they are provided with access, for instance with one study noting that "to the extent that prices are correlated with incomes, permitting parallel trade in the EU would lead to reduced access to new drugs in the low-income EU countries".<sup>3</sup>

### *Price convergence and affordable access*

Any form of arbitrage will lead to price convergence. Figure 1 illustrates how price trends converged between 1986 and 1999. In many markets economists would expect competition to cause prices to tend to converge around those offered by the most efficient (low cost) suppliers. However, this does not apply in the case of patented

\* It was not possible to obtain representative estimates from regulators or companies of the number of packets that reach patients despite recalls or of the reduced effectiveness (if any) of recalls due to manufacturers' error, regulatory intervention or involvement of parallel trade. This is a weakness in present arrangements to monitor the market.

**Figure 2: Percentage of average income needed to pay for a treatment costing €1,000, 2008**



pharmaceuticals where each supplier has an exclusive right to supply its unique product.

Patent holders launching new products must try to set prices at the most profitable levels for the market as a whole. If parallel trade is likely, prices will be about the same in each country, whereas in the absence of parallel trade the profit maximising pricing strategy would normally be to charge different prices in high and low income Member States, reflecting what the health care services or insurers are willing to pay. It follows inevitably that price convergence will add to the prices of patented medicines in Member States with lower incomes, from which parallel exports are

most likely to be made. This is a point of great practical significance since there are substantial differences in income levels between Member States.

At the time of the study the most substantial importers of parallel traded medicines were Germany, the Netherlands, the UK and Sweden (combined population about 170 million and average income per head about €31,000 in 2008). Nine Member States had a Gross Domestic Product (GDP) per head less than half the EU average: Bulgaria, Romania, Lithuania, Latvia, Poland, Slovakia, Hungary, Estonia and the Czech Republic (combined population over 100 million and average income per head about €8,600 in 2008). Figure 2 shows

the proportion of average income that would be needed in each EU Member State to pay for a course of treatment costing €1,000. It clearly indicates that a single EU price would imply that medicines may not be affordable in lower income parts of the EU.

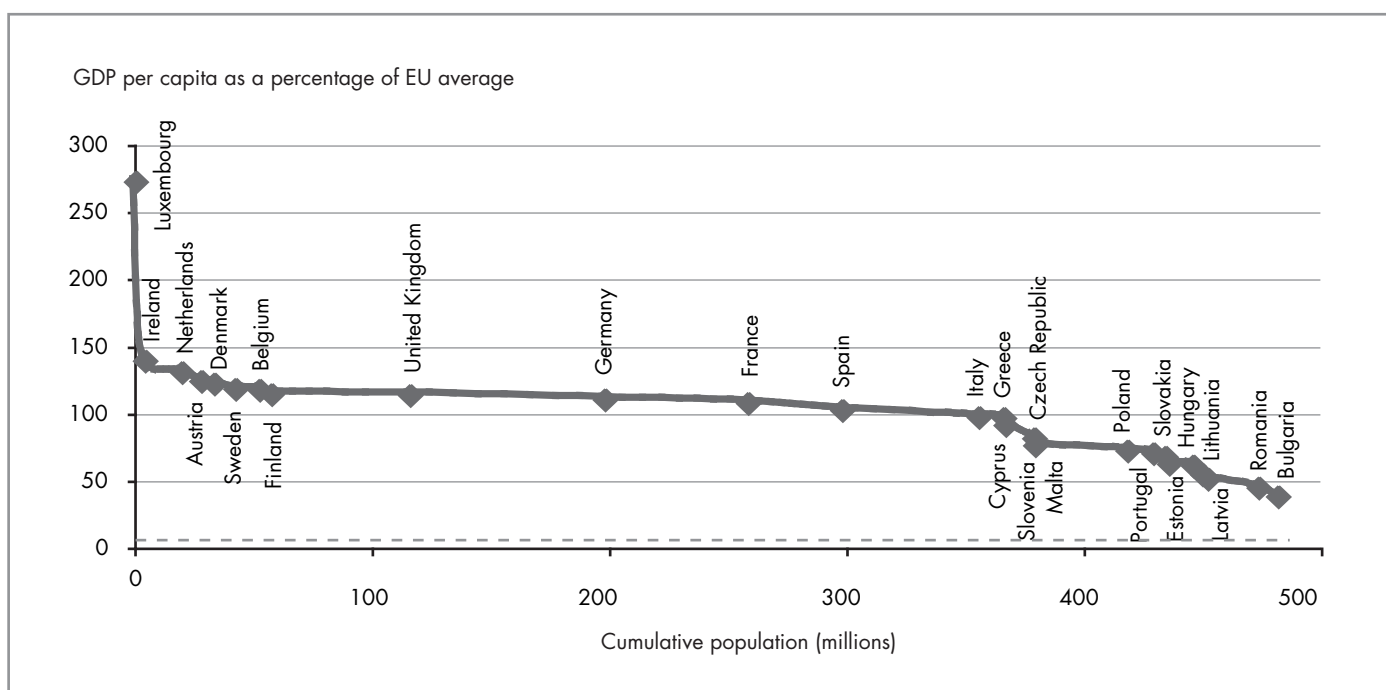
**Quantification of effects**

The previous section reported an estimate that repackaging and other effects of parallel trade represent a disbenefit to patients that is equivalent to about 10% of the value of parallel trade, i.e. about €5 billion in 2007. However, the central issue for EU health care policy is in denying affordable access to patented medicines. If parallel trade were constrained, for example, by prohibiting repackaging and by requiring tamper-proof sealing of packs, then patent holders would be expected to charge different prices according to what each part of the market would bear.

Making use of 2008 population and income level data for each Member State, if the GDP per capita of a country is roughly proportional to the price that country's health service would wish to pay, and that the population of a country indicates the number of potential patients, then it is possible to construct a stylised demand curve for patented medicines (Figure 3).

The solid line shows the demand curve for patented medicines and the dashed grey line represents a roughly constant cost of manufacturing and distribution assumed to be 5% of the EU average price. The area

**Figure 3: Demand curve for patented medicines in the EU, 2008**



between the two lines therefore represents the return of investment in research and development (gross profit) that would result from differentiated prices. An index representing gross profit can be estimated by multiplying the price of medicines by the population for each country, totalling for

all twenty-seven Member States, and subtracting the cost of manufacturing and distribution.

If a uniform price across the European Union were to be adopted, its most profitable level is the point at which gross revenues (sales x price) are maximised (see

Table 1). Using these figures, sales revenues and gross profits would be maximised at a price of €97 with sales of €355,048,324. On these assumptions of an overall EU population of 482 million, over 100 million would not be supplied if a single EU price

**Table 1: Comparison of the effect of differentiated and single prices on potential sales and profits**

Member State ranked by GDP per capita as % of EU average (A)	Population (2008) (B)	Potential sales per country (C = A x B)	Cumulative population (2008) (D)	Cumulative potential sales		
				Differentiated prices	Single prices	
Luxembourg	273	429,200	1,171,716	429,200	1,171,716	
Ireland	140	3,700,000	5,180,000	4,129,200	6,351,716	
Netherlands	131	15,800,000	20,698,000	19,929,200	27,049,716	
Austria	125	8,100,000	10,125,000	28,029,200	37,174,716	
Denmark	123	5,300,000	6,519,000	33,329,200	43,693,716	
Sweden	119	8,900,000	10,591,000	42,229,200	54,284,716	
Belgium	118	10,200,000	12,036,000	52,429,200	66,320,716	
Finland	115	5,100,000	5,865,000	57,529,200	72,185,716	
United Kingdom	114	58,600,000	66,804,000	116,129,200	138,989,716	
Germany	111	82,000,000	91,020,000	198,129,200	230,009,716	
France	108	60,400,000	65,232,000	258,529,200	295,241,716	
Spain	103	39,400,000	40,582,000	297,929,200	335,823,716	
Italy	98	57,600,000	56,448,000	355,529,200	392,271,716	
Greece	97	10,500,000	10,185,000	366,029,200	402,456,716	
Cyprus	92	865,000	795,800	366,894,200	403,252,516	
Slovenia	91	1,985,000	1,806,350	368,879,200	405,058,866	
Czech Republic	82	10,285,000	8,433,700	379,164,200	413,492,566	
Malta	77	390,000	300,300	379,554,200	413,792,866	
Poland	73	38,655,000	28,218,150	418,209,200	442,011,016	
Portugal	71	10,800,000	7,668,000	429,009,200	449,679,016	
Slovakia	68	5,395,000	3,668,600	434,404,200	453,347,616	
Estonia	63	1,440,000	907,200	435,844,200	454,254,816	
Hungary	62	10,070,000	6,243,400	445,914,200	460,498,216	
Lithuania	55	3,700,000	2,035,000	449,614,200	462,533,216	
Latvia	52	2,400,000	1,248,000	452,014,200	463,781,216	
Romania	45	21,700,000	9,765,000	473,714,200	473,546,216	
Bulgaria	39	7,970,000	3,108,300	481,684,200	476,654,516	
<b>Gross profits (maximum total sales -5% of cost at average EU price)</b>					<b>452,821,790</b>	<b>336,746,864</b>

Cumulative sales potential calculations: Differentiated prices = cumulative sum of C; Single prices = A x D

**Table 2: Comparison of single price with differentiated prices**

	Single EU price		Differentiated prices	
Patients supplied	366,029,200	100	481,684,200	132
Gross Profits	€336,746,864	100	€452,821,790	134

were to be adopted. Gross profits would also be substantially lower (see Table 2).

There is a wealthy minority in the low – income Member States who would obtain supplies at the higher price and, for a variety of practical reasons even with the influence of parallel trade, prices would not be identical throughout the EU. This would not, however, change the overall conclusions as presented here. Prohibiting both repackaging and re-labelling would

greatly reduce the harm to patients resulting from present EU policy and substantially improve patients' access to safe and affordable medicines.

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The most recent series providing the data from which Figures 2 and 3 and Tables 1 and 2 below are derived are in Eurostat annual national accounts-auxiliary indicators nama\_aux\_gph select NGDPH 2008 and demography – national data-population demo\_pjan select 2008. The data have been revised very slightly from those from which the Figures and Tables were drawn.

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# Going private? The growth of voluntary health insurance in Denmark

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Karsten Vrangbæk

*Summary: Over the past decade there has been significant growth in the market for supplementary health insurance in Denmark. Two types of voluntary health insurance (VHI) are sold. The first type provides access to private providers. This type of insurance is now held by around one million Danes (18% of the population). The second type provides a lump sum in the event of critical illness for almost 2.2 million Danes. This rapid increase in VHI comes in addition to complementary health insurance, which is held by around two million Danes. The growth in VHI raises important questions on the driving forces and potential consequences for the public health system.*

*Keywords: voluntary health insurance, Denmark, health reform*

Over the past decade there has been significant growth in the market for supplementary health insurance in Denmark. Two types of voluntary health insurance (VHI)

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are sold. The first provides access to private providers and is now held by around one million Danes (18% of the population). The second provides a lump sum in the event of critical illness and covers almost 2.2 million Danes.<sup>1</sup> This rapid increase in VHI comes in addition to complementary health insurance, which is held by around two million Danes. The growth in VHI

raises important questions on the driving forces and potential consequences for the public health system. These questions will be addressed following a brief presentation of some facts on this phenomenon.

#### **The development of the Danish VHI market**

Complementary health insurance has been



a widespread practice in the Danish health system since the 1970s. It has traditionally been used to cover co-payments in the statutory system (mostly for pharmaceuticals and dental care), and for services not fully covered by the state (for example, physiotherapy). The not-for-profit organisation 'Danmark' used to be the sole provider of such complementary insurance. It covered around two million Danes in 2007 (36% of the population).

The widespread use of supplementary VHI is a relatively recent phenomenon. In 2002, there were around 130,000 people with this insurance, a figure that had grown to almost one million by 2008. These insurance plans provide access to private treatment facilities. In addition, there are now 2.2 million Danes with insurance that provides a cash lump sum in the event of critical illness. This type of insurance is typically linked to pension plans and is not the main focus of this article.

The actual utilisation of the VHI insurance policies remains limited so far. This is due to the fact that the uptake of VHI has been mostly by younger, healthier people. Insurance holders are mostly private employees aged between 25 and 60. People with longer educations and higher income are relatively more likely to have insurance than less educated people.<sup>1,2</sup> Supplementary insurance paid out around DKK 220 million in 2002 rising to DKK 754 million (€101 million) by 2007 and an estimated DKK 1 billion in 2008 (€134 million). This figure can be compared with a total public health expenditure for hospitals of DKK 57.7 billion (€7.7 billion) in 2006.

Thus, the general trend is a gradual increase in utilisation as more people become enrolled, the age of insureds increases and private supply expands. Significant events, such as the nursing strike in the public sector in 2008, have accelerated this utilisation trend due to adverse effects on public services. From an industry perspective, VHI has been a rather profitable business in its early years. The ratio of pay out/premium income has however increased from 58% in 2004 to 90% by 2007.<sup>2</sup> This recent increase in pay out has led insurance companies to raise their premium levels for 2009.

The exact composition of these expenditures is unknown, but information from one of the larger insurance companies (Danica Pension) indicate that around 55% goes to surgical procedures, 21% to various medical consultations, 14% to physiotherapy and 6% to psychology visits. The re-

maining 5% goes to unspecified services e.g. chiropractic. Surgical and medical treatments mostly concern more easily treatable conditions and are dominated by orthopaedic surgery, sports medicine, treatments for slipped discs and interventions to deal with obesity. Private treatments typically do not deal with acute conditions, cancer treatment, complex diseases and long term conditions.

### Explaining the growth in VHI

Why are so many VHI policies sold in a system with universal coverage, comprehensive services that are largely free at the point of use and where most users of the system indicate high satisfaction levels?

A change in tax rules providing tax deductions for employers and tax exemptions for employees appears to be part of the explanation. This policy was introduced in 2002 by the newly elected liberal-conservative government with the stated intention of encouraging employers to take a more active interest in the health of their employees. A supplementary motive for the liberal/conservative government was to strengthen private health supply and thus enable a more market based development of the health system in the future.

The change in tax rules came in a period of historically high activity levels in the economy with close to full employment. Competition for employees and the relatively high marginal tax rates on regular income created an environment where non taxable VHI became part of many private employment benefit packages. The fact that the rules required companies to offer insurance to all employees, not just the top echelons, further fuelled the growth. This also meant that VHI changed status from mostly being for a small number of high status employees to cover all levels within the major private sector firms. Tightness in the labour market has also given firms a stronger interest in getting their injured or sick employees back to work as quickly as possible. VHI has been sold as a way to achieve this.

The liberal/conservative political agenda probably also reflects a more general shift in the voting population towards demands for greater flexibility and individuality in public service delivery. There also appears to be a greater acceptance of inequality as long as basic coverage is in place. Such trends can be seen in other parts of the Danish welfare state. Examples include the development of a pension system, which combines public and supplementary pri-

private coverage, and the long standing tradition for private primary schools as a supplement to public schools. Yet importantly, there does not seem to have been a universal loss of support for the welfare state idea, although many small steps are gradually changing the composition and functionality in different sectors.

The expansion of VHI can also be seen in light of discussions about waiting times and quality in the public sector. Recurring media attention indicates that at least some parts of the population have developed an image of relatively poor service and quality in public hospitals. Interestingly this view is not dominant among those individuals that have actually used the health system.<sup>3</sup> Different governments have attempted to address service and quality issues. Free choice of public hospitals was introduced in 1993 and a general waiting time guarantee of two months providing 'expanded free choice' among public and selected private providers in Denmark and abroad was added in 2002. The waiting time limit was further reduced to one month in 2007, although this scheme was temporarily suspended until the summer of 2009.

The quality issue has been addressed by a number of different initiatives including a comprehensive 'Danish Programme for Quality Assessment' combining accreditation and ongoing evaluations based on standards and clinical databases, and the development of 'cancer packages' and programmes for chronic care. A major structural reform in 2007 created larger regions and municipalities in order to reinforce their capacity to improve quality and efficiency through larger catchment areas and specialisation.

Some of the stated results include an increase in activity and productivity levels in Danish hospitals over the past decade.<sup>4,5</sup> Waiting times have generally gone down, although not entirely to the target level of one month for non life threatening diseases. Despite these positive developments there have been ongoing media debates about service and quality. This has probably been a contributing factor to the rise in VHI.

### What are the potential consequences for the public health system?

As specified above, the utilisation of private insurance is still relatively low and focused on particular types of services. Furthermore, the private delivery capacity is still very limited compared to many other European countries. Table 1 for full time/part

**Table 1. Number of doctors and nurses in public and private hospitals 2006**

	Doctors	Nurses
Public hospitals		
Full time	10,653	31,100
Part time	6,101	5,762
Private hospitals		
Full time	35	284
Part time	142	457

Source: Forsikring and Pension 2008

time doctors and nurses in private hospitals provides an illustration, although it should be noted that these figures are from 2006, and the increase in private employment, particularly part time, has since been significant.

In spite of its relatively low starting point, the growth in VHI may still lead to a number of consequences in the coming years as this type of insurance becomes more widely used, and as private health care provision expands to meet demand. The interpretation of possible consequences varies somewhat depending on the focus and political position of the observer. The following sections present a 'positive' and a 'sceptical' perspective.

### The positive perspective

The positive perspective emphasises that VHI helps to develop a private provider market, which increases total capacity in the health system. This is useful in a system where public supply is limited and waiting lists exist. VHI will thus allow a number of patients to be treated outside the public system. These patients will not use public resources, which may instead be used to reduce waiting times in the public sector. Shorter waiting times get people back to work sooner, and thus reduce public expenditure for social services and efficiency loss in the industry.<sup>2</sup>

A positive perspective also argues that VHI and the development of private health providers give Danish health professionals more opportunities and stronger incentives to work extra hours (outside the public system). This leads to a much needed increase in the total number of hours worked in the system. From a patient/citizen perspective, the strengthening of VHI provides more flexibility, and for both employers and patients, provide promise of a more rapid return to work.

Additional arguments for VHI include the possible learning effects between public and private organisations. Private providers may be more prone to experiment with service and/or efficiency enhancing measures in order to attract patients. This may lead to useful insights that may be taken back to public organisations. Another general argument relates to the potential for employers to become more aware of health issues and to devote resources to preventive measures. VHI is then seen as part of an overall package agreement between employers and employees, where employers take an active interest in promoting good health for their employees in order to reduce sick days and productivity loss.

### The sceptical perspective

The sceptical perspective focuses on issues of equity, efficiency and sustainability for the public system. In considering equity, it is hard to deny that some inequity is introduced as VHI is mostly purchased by private sector employers whereas individuals outside the work force, or those employed in the public sector, are largely excluded.<sup>6</sup> This has led some observers to argue that Denmark is developing a two tier system of people with and without VHI. Those with VHI have quicker access to practicing specialists and private hospitals, at least for certain conditions. The acceptance or otherwise of this situation is a matter of personal and ideological attitudes. There are indications that the population in general has become more willing to accept inequities in health care, although it also appears that most Danes continue to support a public system<sup>7</sup> and continue to expect a high standard within this system. An important question is whether this will continue to be the case in the future. One could imagine that growing familiarity with VHI might lead to a situation where VHI holders become less willing to pay

taxes to uphold a general system, while also paying extra for the right to access private suppliers.

Moral hazard may lead to lowering of indication levels for treatment as providers have incentives to treat patients earlier and on more vague indications. There is also a potential risk of ordering more diagnostic tests. It is difficult to document such developments, apart from the broad observation of a very high frequency of back operations in the private sector, and various anecdotal evidence. Private insurance companies obviously have an interest in addressing the issue, but the question is how well they are able to control the medical decisions. Also the risk of appearing too restrictive may not be positive for attracting new customers.

Furthermore, it can be argued that private insurance leads to growth in auxiliary services that are not strictly necessary from a narrow medical perspective (extra diagnostic tests, 'wellness' services, etc.). This may be acceptable if there is a strong demand, but problematic from a more general efficiency perspective.

Sceptics also point out, that the alternative costs of tax exemptions are relatively high. It has been calculated that the state is 'losing' revenue at the level of DKK 470 million (€63 million) in 2007, increasing to DKK 684 million (€93 million) in 2008.<sup>2</sup> The insurance industry argues that this is more than outweighed by the savings on treatment within the public system. This is based on the assessment that all VHI sponsored treatment is necessary, and would have also been conducted in the public sector.

The growth in VHI, along with the 'waiting time guarantee' providing publicly funded access to private providers if waiting times exceed one month, are the major factors for the expansion of private providers in Denmark. A major concern with growing private provision is the fact that qualified personnel are drawn away from the public sector (which paid for their training). Some doctors and nurses work full time in the private sector, while many more work part time in the private sector in addition to holding a regular job in the public sector (see Table 1). Working in both sectors may increase total work output, but there are also risks of negative impact on motivation and performance in the public sector. It is likely that employees holding more than one job will be less flexible and less willing to take on extra duties in

the public sector. On the other hand, such employees might bring in valuable experience from exposure to different organisational forms.

More generally, there is a risk that the overall level of research and educational activities may suffer as private providers focus their attention on production.

Cream skimming is also a potential risk factor with the rise of private provision. At the systemic level, there has been a tendency for private providers to focus on relatively simple elective surgical treatments, while the public sector retains responsibility for the more difficult and less profitable tasks of acute, long term and geriatric care, as well as psychiatry. At the individual patient level, there is a risk that private providers will attempt to select easier cases within a particularly category of patients while the public retains the more complicated cases. Finally the public system serves as a “back up” for complications developed after treatment in private facilities. There is limited systematic information on the importance of such issues.

### Conclusions

As the phenomenon of VHI is still evolving, it is difficult to reach final conclusions on the validity of these various perspectives. To some extent it is possible that both the sceptics and optimists are right and that the expansion of VHI has both positive and negative consequences. Total capacity in the system may increase and the activity level may go up for the benefit of at least some patient groups. Yet, this is likely to come at the expense of greater inequality between those with private insurance and those without, and between the VHI relevant conditions and the rest. Stronger competition for trained professionals and inflationary pressure on wages may be another consequence. Many of the issues cannot be resolved on purely objective grounds, although much more can be done to illuminate the costs and benefits.

### The future of VHI

It seems likely that VHI will continue to play a role in the future, as there is clear demand, while resources will remain limited in the public sector in the face of an ageing population and the introduction of new, costly treatment options. Nonetheless, the degree of growth in the VHI market will depend on a number of factors.

First, the continued availability of tax deductions for those with VHI is probably an important factor, particularly in light of

the fact that insurance prices are starting to go up as the insurers face growing expenditure. Price increases have already been introduced for 2009, although not of a magnitude that is likely to halt demand for VHI unless tax rules are also changed. The government has so far been reluctant to discuss such changes, but government supporters and voices inside the Conservative party have recently indicated an openness to look into this issue as public funds are becoming more constrained.

The second major factor influencing the VHI market will be developments in the public perception of quality and service levels in the public system. Much will depend on the success or failure of government initiatives to both address waiting times and quality issues and subsequently communicate the results. In this regard, the public health sector is facing a difficult task as the media tend to focus on single issues and cases, rather than complex assessments of results.

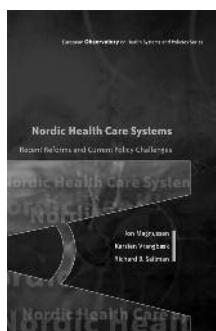
A third factor for the continued development of the VHI market is the general economic climate. An economic decline with a less competitive labour market and companies under pressure to cut costs may lead to a reduction in the use of VHI as a fringe benefit, particularly if tax rules are changed. The global financial crisis in 2009 may have such a detrimental effect on the Danish economy. In any case, it appears that the Danish health system, and to some extent the other Nordic health systems, are gradually adapting to a larger degree of private

financing and provision in their otherwise largely public health systems.

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### FORTHCOMING PUBLICATION



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**John Magnussen,**  
**Karsten Vrangbæk and**  
**Richard B. Saltman**

Open University Press  
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## Nordic Health Care Systems: Recent Reforms and Current Policy Challenges

This book examines recent patterns of health reform in Nordic health care systems, and the balance between stability and change in how these systems have developed.

The following themes are explored:

- Politicians, patients, and professions
- Financing, production, and distribution
- The role of the primary health sector
- The role of public health
- Internal management mechanisms
- Impact of the European Union

The book probes the impact of these topics and then contrasts the development across all four countries. The editors also explore the extent to which a Nordic Health Care Model exists, and the degree to which that model will help to explain the future direction of health policy-making in these four countries. An additional chapter on recent developments in Iceland completes the work.

# Improving efficiency of allocating public funds to pharmaceuticals:

## A pilot study in the Kingdom of Saudi Arabia

*Khaled A Al Hussein, Ali S Al Akeel and Jim Attridge*

*Summary: The optimal management of the allocation of limited public health funds across the growing diverse range of modern medicines is a challenge faced by both high and middle income countries. The context of this study is one in which reform strategies aim to accelerate patient access to the best available medicines, within the context of a well-managed and efficient budgetary regime. Critical in this regard is a concern to better match the usage patterns of medicines with changing patterns of disease prevalence in the local population. A second key aim is to manage the costs of established products more efficiently by the wider usage of less expensive generics in order to release funds to cover the cost of newer innovative products. In this article we report the results of a pilot study in the Kingdom of Saudi Arabia in which a model has been developed for both recording and analysing past data on allocations across different classes of medicines and its use as a predictive tool to consider the potential consequences of choosing alternative priorities for future expenditure. We then explain how using the information from it informed strategic decisions on policy reforms to achieve these objectives.*

*Keywords: Funding medicines, allocation model, Saudi Arabia, pilot study*

### Management of national pharmaceutical expenditures

There is an extensive international literature upon approaches to the effective and efficient management of health expenditures and more specifically effective cost management approaches to the pharmaceutical sector. In developed countries within the Organisation for Economic Cooperation and Development (OECD), in Europe and beyond, a wide range of demand and supply side forms of regulation

or interventions have been adopted.<sup>1-4</sup> Table 1 provides a summary of regulatory or negotiating policy instruments and models adopted across world markets with varying degrees of success.

OECD and Middle Income Countries (MIC) face the same essential challenges

in allocating public health system funds to medicines. Over many years a steady stream of new modern medicines have offered improved outcomes in many disease areas, which at times has driven up expenditure on medicines faster than either health care expenditure generally or

**Table 1: Regulatory and negotiating policy instruments for medicines**

Demand Side	Supply Side
Physician budgets	Government/industry agreements
Drug utilisation review	Profit controls
Prescription audits	Reference pricing (internal/external)
Reimbursement	Price controls
Co-payment:	Develop market for generic drugs
Proportional/deductible	Volume controls
Flat rate	Parallel trade
Generic substitution, prescribing and dispensing	Drug formularies
Over-the-counter (OTC) switch	Pharmacoeconomic studies

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growth in national Gross Domestic Products (GDP). Although the most recent data suggest this era may be coming to an end, two fundamental decision-making challenges remain:<sup>5</sup>

- What proportion of total health care should be spent on medicines in any given national context or timeframe?
- Within the expenditure on pharmaceuticals what criteria or principles should be applied to decide how best to allocate it between different disease areas and classes of medicines?

The first of these questions has been the subject of international benchmarking studies which have identified two general trends. Firstly, as might be expected, average levels of national expenditure increase over the range US\$ 50–400 per capita spend in proportion to increasing GDP per capita (at Purchasing Power Parity, PPP) over the range US\$5,000–40,000, reflecting affordability limits. Less obvious is a trend in which the proportion of total health care expenditure attributable to medicines falls from as high as 30% at the lower end of the GDP range to 10% at the upper end. Considerable variations in national patterns of expenditure make it less clear why this is the case, although *prima facie* it would appear to reflect not so much excessive expenditure on medicines in less affluent countries, but a substantial under-expenditure on other services, notably primary care and uptake of modern technologies in hospital settings.

We report here our experience of a pilot study in the public sector in Saudi Arabia to develop and explore the use of a relatively simple model into which historic annual volume and value data can be entered. This may be of interest to other health care systems currently seeking to establish or upgrade their decision making processes in this area.

### Health care and medicines in Saudi Arabia

The Kingdom of Saudi Arabia is one of the largest countries in the Middle East with a population of twenty-five million of which approximately six million are foreign nationals. It is a relatively 'young' population with 40% under fifteen years of age and only 3.5% over sixty-five. Health care is provided free for all Saudi citizens and expatriates working in the large public sector.<sup>6–8</sup> The Ministry of Health (MoH) is the largest provider of services, covering 62% of all in-patient care; other govern-

mental agencies and the private sector provide the remainder, at 20% and 17% respectively. The MoH is also responsible for administering a regional system of preventative and primary care centre services; the latter acting as the 'gate-keeper' for access to the hospital sector. Since the 1970s a series of five year plans have greatly improved both the quality and national coverage of services. Widening free access to services to all social classes and geographical regions, whilst upgrading the technological basis of the medical infrastructure continue to be the core objectives. Currently there are ambitious plans to build up to two thousand new primary care centres and to increase the hospital bed stock with a network of fifty strategically located five-bed hospitals to meet the demand of a growing population.

### Funding and provision of prescription medicines

Medicines are funded by the MoH largely on a 'global budget' basis for the hospital sector. The balance of hospital expenditure on medicines, at 25–30% of total expenditure, is relatively high in the OECD/MIC range outlined above. It lies in a similar range to the new EU member states of Eastern Europe. The cornerstone of policy is the principles outlined in the WHO Guidelines for Drug Policy. The prime criteria are to ensure:

- fair and equitable access to medicines for all sections of the community,
- efficient allocation of health care funds and other resources, and
- that the pattern of expenditure on medicines is constantly reviewed and updated to meet the changing patterns of diseases and health needs.

In a situation of growing demand for modern medicines, good data and analysis to identify potential areas for cost savings in respect of older products, thus creating 'headroom' for expenditure on new products, is a key feature of the system.

### An expenditure model

A model has been developed to analyse actual expenditures on medicines using the internationally accepted Anatomical Therapeutic Classification (ATC) system. In this pilot phase the model has been populated with MoH statistics for the years 2004 and 2005. Individual medical products are identified by their registered trade names, pharmaceutical forms, dose levels and pack sizes and data taken from the annual

national health statistics data base.<sup>9</sup>

The model covers 77 ATC classes, which are subdivided into three sub-groups;

- G1 Products for life threatening diseases,
- G2 Products for essential medicines for important diseases,
- G3 Products for less essential diseases.

The data base consists of a universe of 613 products, for which the following metrics have been included:

- Pack sizes prescribed and dispensed
- Number of units purchased
- Price per unit
- The date at which the product was first introduced into the market.

The use of the G1–G3 classification has international precedents. For example, the French Haute Autorité de Santé (HAS) price and reimbursement system uses this conceptual distinction, both in classifying new products according to their degree of innovative added value and as a basis for determining percentage patient co-payment levels.<sup>10</sup> We recognise that this way of classifying disease states and treatment classes involves value judgements and difficult choices for border line cases and therefore should be treated with some caution.

We have used the dates of product introduction into the market to classify products according to 'age' into the following four categories:

- Y1 Products introduced between 1999–2004 (0–5 years old),
- Y2 Products introduced between 1993–1998 (5–10 years old),
- Y3 Products introduced between 1987–1992 (11–15 years),
- Y4 Products introduced prior to 1987 (15+ years).

This segmentation of expenditure based upon product age groups, Y1–Y4, offers a fairly crude way of distinguishing the most recent innovative products from those that are long-established. In broad terms groups Y1 and Y2, products up to ten years old would, more or less equate to products which were patented, on the assumption that of the normal twenty year patent life the first ten years is consumed by the research and development (R&D) process, leaving only about ten further years for the marketing phase. Beyond ten years in a

competitive market there will be increasing levels of brand generic competition, which will both erode prices down to much lower levels and fragment the market for any given molecule, between the originators brand and competing generics.

In Saudi Arabia, in line with many other markets, the generic industry sector is becoming an established feature of supply side competition, where there are a steady flow of new product entrants, which are both brand generics and minor product variants, such as new formulations, dosage forms and combination products.

To summarise, this model provides a base case analysis of expenditures which can be interrogated using three key product characteristics; the ATC level 3 or 4 class to which it belongs, the severity of the disease for which it is used (G1, G2, G3) and its age (Y1, Y2, Y3, Y4) and at all levels of aggregation from individual product, to ATC level 3 and 4 classes, to higher levels of aggregation for specific disease states and total expenditure levels.

The model has a facility to undertake simulations of the impact upon annual expenditure of the following alternative strategies, using the following parameters:

- Selective reimbursement of ATC classes or product sub groups
- Variable levels of patient co-payment
- Price changes at the individual market, product class or ATC disease sector level
- Unit/volume changes.

### The base case analysis

The results of the base case analysis for MoH Hospital expenditure for the year 2005 focus attention upon three dimensions:

- (a) Expenditure by disease/therapeutic area category
- (b) Expenditure by therapeutic class and age of products
- (c) Relative unit prices between therapeutic classes and age categories.

#### Expenditure by therapeutic category

Figure 1 shows the spread of expenditure across the three categories of disease, G1, G2, G3, used in the model. The Figure shows, as we would expect, that the majority of the expenditure (>70%) is spent on the more serious life threatening diseases. However, it is notable that there

Figure 1: Analysis of hospital expenditure in 2005 by severity of disease state (US\$m)

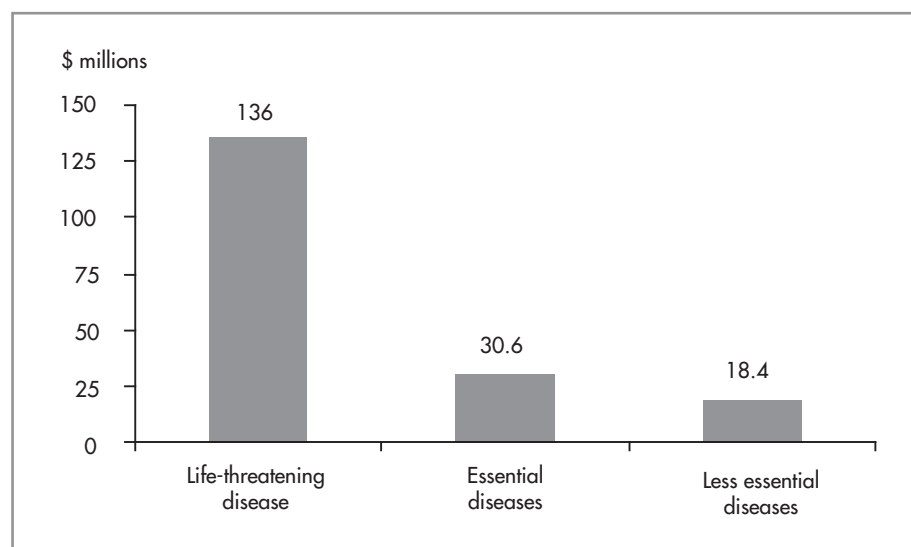
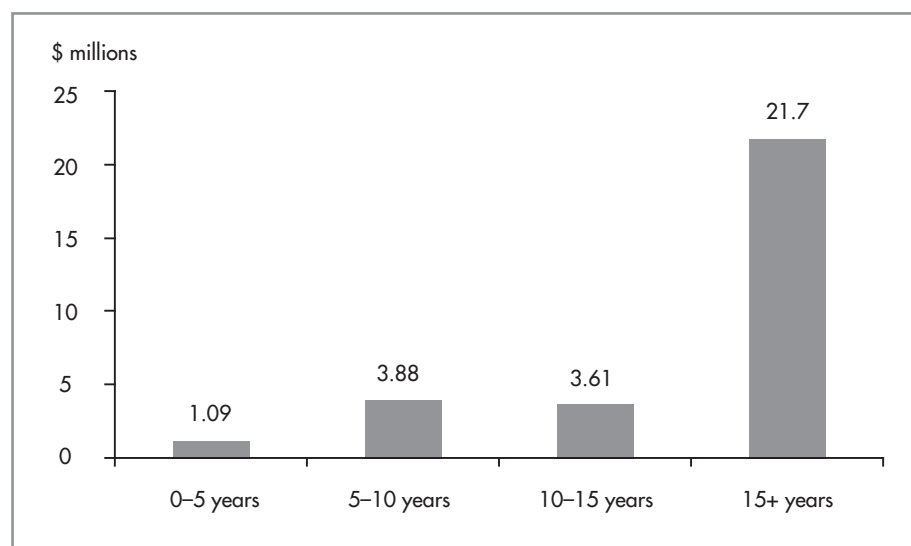


Figure 2: MoH volume consumption (standard units) in 2005 by drug age



are substantial levels of expenditure on the less essential medicines. Also a more detailed analysis of this G3 category at the ATC therapeutic class level shows that the two largest components are vitamins and cough/cold remedies. In category, G2, there are a wider range of therapeutic areas and product classes represented, of which anti-infectives and analgesics are major components.

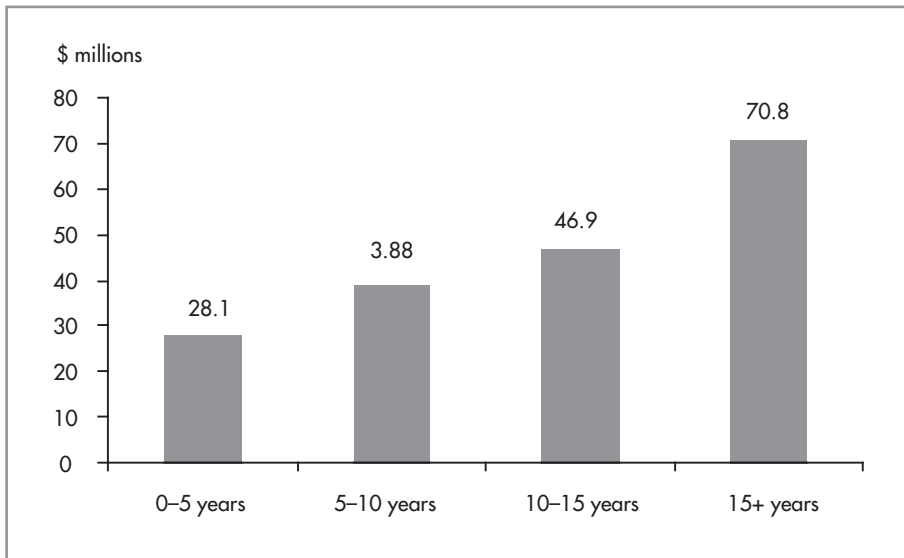
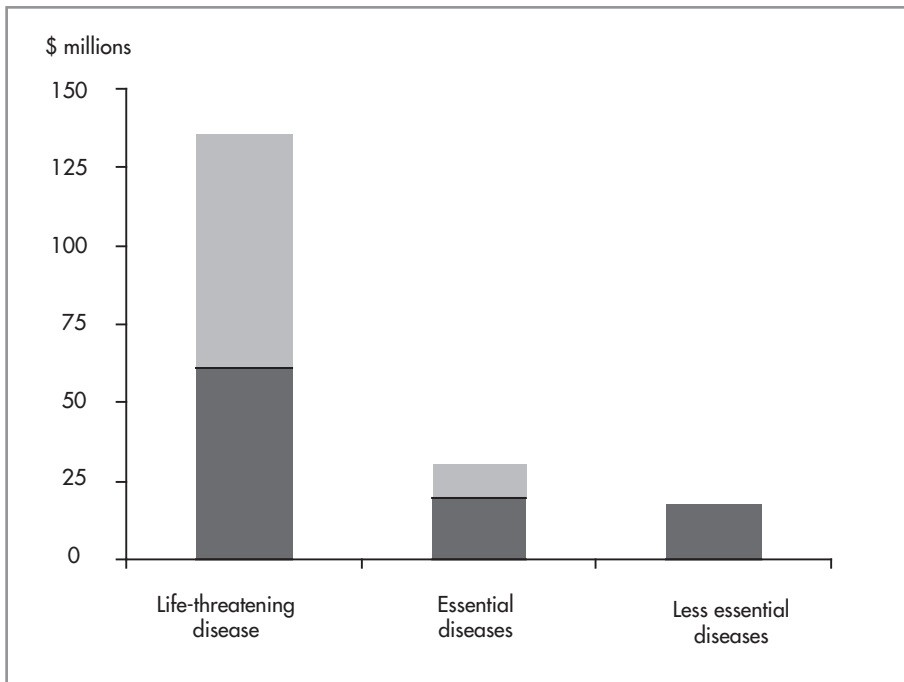
#### MoH expenditure by product age

The volume consumption as a function of age is summarised in Figure 2, which clearly shows that expenditure is dominated (70.2%) by products that have been in the market for more than fifteen years and that products which entered the market in the most recent five years accounted for only 3.6% of the total. Surprisingly there is little evidence of incremental increase in the percentages on the intermedi-

ary 5-10 year and 10-15 year categories, which are also low.

Figure 3 shows the same analysis in value terms with a total expenditure for the year 2005 of \$185m. On the basis that inevitably newer products, particularly the newest market entrants, are likely to be substantially more expensive than the older categories this shows the expected, less pronounced gradation in the increase in expenditure as the product classes age i.e. 15% for 0-5 years; 21% for 5-10 years; 25% for 10-15 years; and 33% for products 15+ years. A more detailed analysis of the products in the 0-5 year old category showed that of the 15%, 9.4% were originator brands of innovative products and 5.7% were other brands or generics sold by local or international generic companies.

This base case analysis suggests that even

**Figure 3: MoH value expenditure by drug age categories****Figure 4: Expenditure on acute and chronic therapies as a function of disease category**

though for 2005 expenditure was well focussed upon serious life threatening diseases, most of the medicines being used had been in the market for at least ten years (84% by units; 64% by value).

We have also examined the ratio between expenditure on chronic as opposed to acute disease states and as a function of the diseases categories G1–G3, as shown in Figure 4. Overall, as one might expect, the share attributed to acute conditions falls from \$75m (55%) for life threatening diseases to \$10.6m (35%) for essential diseases and to a negligible level for less essential diseases. However, the share held by chronic

conditions, at \$61m (45%) of the life threatening diseases, appears to be high in a hospital setting and would perhaps merit further investigation at lower ATC class levels

We have also analysed average unit prices, based upon the age segments, Y1–Y4. The prices of medicines in the less than five years old group, the newest products, at an average of US\$25.7 were considerably more expensive than those in the oldest category, at an average of US\$3.26 (15 year+). However the intermediate categories 5–10 years old at US\$9.99 were actually lower than the 10–15 year category

at US\$13.0. This result suggests that in this latter category there are some anomalies and a lack of competition in some classes.

### Simulation Analyses

This model has considerable potential for examining a wide range of options to address questions as to what might be the impact of alternative new funding approaches or provision policies for different disease states and product types. These could include market price structures, selected price increases or decreases, limits on indications and patient categories and patient co-payment schemes. In this initial phase we have focussed upon examining alternative reimbursement strategies. We have evaluated the possible cost saving potential of introducing some form of graduated patient co-payment scheme, in which medicines for life threatening diseases, G1, would continue to be 100% reimbursed, serious diseases, while G2 would require a small co-payment and category G3 would have substantial co-payments. This analysis suggested there might be some scope within the expenditures for G3 products to achieve savings of around 17–27% per annum.

### Discussion

We have reviewed Saudi Arabian policies on the reimbursement, purchasing and deployment of prescription medicines in the publicly funded hospital sector. The aim has been to ensure that investment in medicines reflects changing patterns of disease incidence and prevalence in the relevant population and to develop a strategy for improving access to innovative medicines at reasonable prices, whilst also making the best use of less expensive older generic ones.

Saudi Arabian policies have focused upon a selected combination of these measures in the past, most notably international price comparison (external reference pricing against a basket of thirty other countries.) and internal reference pricing on a product class basis. In more recent times a policy of selective price reductions has been adopted on a class by class or individual product basis, with a particular concern for sales growth and budget impact criteria. Another important principle has been to discriminate based upon pack value, whereby price reductions may be applied to all packs which have a price above a given fixed value. Pricing and admission of products to reimbursement has recently begun to focus upon health technology assessments of relative added value within

competitive existing products.

The following represent the main findings from our analysis of Saudi Ministry of Health purchases for hospitals in 2005.

- (1) Of the total hospital expenditure of \$185m, the majority, \$135m (73%), is allocated for treating serious life-threatening conditions which are normally treated in a hospital setting.
- (2) Of the total expenditure, \$118m (64%) was spent on products that had been in the market for more than ten years, which would be predominantly patent expired products and brand generic copies.
- (3) Spending on the Less Essential Diseases category constituted only 10% of total expenditure, but notably this category contained significant levels of expenditure on products normally associated with the retail or 'Over the Counter' (OTC) sectors, such as vitamins, topical creams and cough and cold remedies.
- (4) Expenditure on chronic conditions, such as asthma, hypertension and hypercholesterolemia, which can be precursors to acute episodes that require hospitalisation, do not appear to be consistent with broader national epidemiological data on the disease burden and treatment patterns for these conditions.
- (5) As only 9.4% of total expenditure is currently attributable to newer innovative products *prima facie* scope may exist to improve outcomes through a higher allocation of funds in this area. This is particularly critical for treating life threatening diseases which are still treated in large part with 'older/off patent' drugs; the exception being for cytostatic and psychotropic products, where innovative products are more widely used.
- (6) Older off-patent drugs are priced relatively highly compared to recently introduced versions of the same drugs, suggesting that lower purchase prices could be achieved.

### International Comparisons

It is difficult to find comparable data to assess how the situation in Saudi Arabia compares with other countries. In Table 2 we show a limited set of comparative market shares of products up to five years old for selected European countries, which further differentiates between innovative

originator products and brand generic, generic or copy products.

We recognise that national environments vary greatly in terms of the health care funding and provision systems and the priority given to different disease areas.<sup>1,4</sup> Furthermore these countries are all undergoing dynamic change in regulation of access, prices and reimbursement and supply side competitive structure. There is considerable variation in uptake rates for innovative products at one end of product life cycles and the extent to which effective generic competition occurs at patent expiry at the other.

Thus, a country such as the UK has a long tradition of being slow to embrace new products and over recent years has developed a highly competitive off patent generic market. Hence in Table 2 the 0–5 year share of originator products is relatively low at 9.7%, whereas the share of new generic entrants over this period at 9% is high compared to other countries. In contrast, in France, Italy and Spain shares held by originator products in the first five years are much higher, reflecting more rapid diffusion of innovative products, but underdeveloped generic markets. This latter situation is now changing rapidly.<sup>11</sup>

Even within the newer EU middle income states of Central and Eastern Europe (CEE) there is considerable diversity in the situation. Hungary having a liberally regulated market shows a relatively high uptake of new products, contrasting sharply with Poland, where over this time frame there were strong regulatory barriers to reimbursing innovative new products and many delays in the administrative procedures resulting in an abnormally low figure.

Similarly we need to be cautious in interpreting the results for Saudi Arabia. The data cover the hospital market which is under the direction of the MoH, whereas the EU data cover both the retail and hospital sectors. The analysis of expenditure on chronic versus acute therapies suggests that maybe in the Saudi Arabian context, hospitals play a more significant role in distributing chronic therapies on an ambulatory basis that would normally be distributed through primary care and retail pharmacies in EU countries. Despite these limitations we would make the following observations on Table 2:

- (i) By EU country standards the Saudi market appears to be less dynamic, in that for products less than five years old the share of the market appears to be relatively low

both for innovative originator and other brand and generic entrant products.

(ii) The lower innovative product uptake may be because the Saudi product sample is skewed towards the acute hospital sector and hence the impact of major new classes of primary care product categories, such as statins or atypical antidepressants which have shown high growth during these years, will have been less prominent than in the EU.

(iii) It may also be that formal price controls limit the incentive for new generic companies to enter the market and compete solely on the basis of price. An effect widely observed in southern European markets.<sup>4, 11</sup>

(iv) The low uptake of innovative new products, at a level very similar to that in the UK, may reflect the same combination of 'therapeutic conservatism' by clinicians combined with budgetary constraints.

### Conclusions and further development of this type of model

In the context of Saudi Arabia we see considerable potential to extend the use of this model by:

- (i) Extending data collection in future years to build up a better understanding of 'cause and effect' relationships between policy changes and market outcomes.
- (ii) Prospective studies of the likely impact of new technological advances in medicines, notably biologic products.
- (iii) As part of the new primary care network development the model could aid decisions as to which products are supplied via ambulatory care services at hospitals and which should be delivered and funded through primary care services.
- (iv) At a lower level of aggregation, versions of the model could be developed for individual general and specialist hospitals. Expert formulary committees could input assessments of the clinical and cost-effectiveness of new products and examine the budgetary consequences of alternative strategies for patient access.
- (v) Evaluate the benefits and costs care in selectively adopting patient co-payment contributions to medicines.

More generally many MICs are now upgrading their management systems for pharmaceuticals in response to the growing importance of health care expenditure as a proportion of total public expenditure.



**Table 2: International comparison of value share (%) of total medicines market by product type and age category.**

Country	Share (%) of originator brands 0–5yr old	Share (%) of all other brand generics 0–5yr old	Share (%) of products over 5 yr old	Comment
SAUDI ARABIA*	9.4	5.7	84.9	
MAJOR EU**				
Spain	18.5	7.5	74.0	High uptake of new products – weak generic competition
Italy	13.2	6.4	80.4	As above
France	13.5	7.8	78.7	
Germany	10.6	12.6	76.8	High growth in generics
UK	9.70	9.00	81.3	Low innovation uptake -mature generics market
NORTH EU				
Norway	19.1	8.4	72.5	
Belgium	18.8	6.6	74.9	
Denmark	18.1	10.8	71.1	
Netherlands	14.5	1.5	84.0	
Sweden	12.9	6.4	80.7	
Finland	10.6	6.4	83.0	
CENTRAL/EASTERN EUROPE				
Hungary	13.1	9.0	77.9	
Czech Republic	11.8	14.9	73.3	
Poland	5.3	15.8	78.9	Very limited access to innovative products

Source: EU data from EFPIA

\* Saudi Arabian data is the MoH (hospital sector) for 2005

\*\* EU country data includes both hospital and primary care retail distribution data for 2003

Historically decision-making has been driven by medical need tempered by short-term perceptions of affordability. From both of these perspectives the quality of decision-making has been severely limited by a lack of epidemiological and cost data to understand trends in both need and cost patterns, as a basis for formulating medium-term strategies. In consequence, decision-making processes for medicines often rely heavily upon arbitrary annual budget increases and ad hoc, short-term cost containment interventions on prices or access to reimbursement to deal with frequent over-expenditures. In order to move forward toward systems based upon medium-term strategic plans, rather than a succession of short-term tactical responses, progress is needed on three fronts:

(a) A major increase in investment in epidemiological data and cost data collection, taking advantage of modern information technology and communication technologies.

(b) The development of planning models which can accommodate this data at various levels of aggregation.

(c) More sophisticated ‘trade-off’ models which improve the overall efficiency of allocating limited funds.

This pilot study has achieved a substantial step forward in Saudi Arabia in bringing together improved data collection systems under (a) in a decision-making model under (b). Clearly the further widespread adoption of this model and population of it with longer trend data sets will provide a

sound platform for initiatives under (c) involving appropriate forms of health technology assessment (HTA).

Currently many MICs appear to be embarking upon ambitious reforms adopting the more advanced concepts of HTA under (c), without paying adequate attention to putting in place the necessary systems and infrastructures at levels (a) and (b). We would therefore commend the development of this type of model in Mic involved in this transitional process, as part of the progression to achieving a better service for patients by improving the balance between the funds available for innovative new products and the optimal use of the cheapest available generic versions of older ones.

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# Belarus: developments in primary care

Valentin Rusovich and Erica Richardson

In order to maintain the provision and access to health care services following independence, Belarus has pursued a policy of incremental health care reform. Consequently the Belarusian health care system bears many of the same features as the Soviet Semashko system which the republic inherited in August 1991. However, the primary care sector in Belarus is one area of the system which has seen more change in the last decade. In common with health systems across Europe, primary care services have been expanded in response to rising health care costs and the need to develop better ways of caring for people with long term conditions.<sup>1</sup> Evidence from around the world suggests that primary care services are more technically efficient than hospital in-patient services and health systems that have a greater primary care orientation have better aggregate health outcomes as well as better access and equity.<sup>2</sup>

Shifting the focus from secondary to primary care involves a broad package of measures, such as enhancing the prestige of primary health care, shifting resources away from secondary to primary care and strengthening the gatekeeper role of primary health care practitioners.<sup>3</sup> However, reforms designed to increase the primary care orientation of established health care systems can be very challenging to implement in practice as their success is contextually dependent.<sup>2</sup>

## Primary care reforms in Belarus

Primary care in Belarus has been in transition since the late 1990s as the country has

experimented with different models of organising services. The successful piloting of per capita resource allocation in Vitebsk oblast (region) led to the nationwide roll out of new financing mechanisms for primary health care from 2000 and the implementation of per capita financing for services from 2004.<sup>1</sup> Reforms in health care financing have aimed to improve efficiency in the system by moving away from input-based financing mechanisms to reduce excess capacity in the hospital sector thereby releasing extra resources for primary care services. The *Concept on the Development of Health Care in the Republic of Belarus 2003–2007* was envisaged as a document which would guide the health care system to a new model in which primary care would become the main priority and resources would be allocated to it accordingly.<sup>1</sup> The aim was to improve the technical efficiency of the health system as a whole and reverse worrying demographic trends in the country related to the rapid ageing of the population and the burden of premature mortality. As a result there has been significant investment in order to improve both the quality and accessibility of primary care services in rural areas, namely a significant expansion in the number of primary care facilities and capital investment to improve the state of repair of 113 rural health care facilities.<sup>4</sup> This capital investment has been accompanied by a significant investment in the retraining of primary care doctors working in rural areas as general practitioners.

## Organisation of primary care services

As a result of these reforms, there is now a dual primary health care system in Belarus: a system of general practitioners in rural areas and on the outskirts of some cities and the maintenance of the traditional Semashko polyclinic system in urban areas. All primary care facilities are state owned and financed and controlled by Regional Health Care Departments. In remote rural areas primary care services are provided

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through FAPs (feldsher-midwife [akusher posts] staffed by mid-level medical professionals. The FAPs are attached to the rural outpatient clinics located in the larger settlements and are staffed by primary care doctors and a team of nurses. A proportion of the remote rural outpatient clinics have between ten and twenty beds that are mainly used for the care of older people and people with chronic illnesses. Of the rural outpatient clinics, 70% are staffed by general practitioners (retrained primary care internists or paediatricians); the remainder still have separate doctors for adults and children.<sup>1</sup> While the introduction of general practice in rural areas has been deemed a success, there are no plans to extend general practice into urban areas.

In the five regional cities and the capital, Minsk, primary care is provided through two parallel networks of polyclinics (as in the Semashko system): child polyclinics and adult polyclinics with women's consultation units. The main categories of narrow specialists for outpatient consultations (surgeons, ear, nose and throat (ENT) specialists, ophthalmologists, neurologists, endocrinologists, cardiologists, and gynaecologists in adult polyclinics) are available at these polyclinics and patients can self-refer to the relevant specialist without a referral from a primary care internist or primary care paediatrician. The urban polyclinics also have diagnostic facilities: laboratory, X-ray, ultrasound and endoscopy.<sup>1</sup> There are separate parallel networks of specialists and diagnostic facilities for adults and children which leads to the duplication of diagnostic facilities at hospitals which also have both adult and paediatric specialists.

### Future reform challenges

Many of the challenges faced in Belarus reflect similar difficulties faced in other countries in trying to reorientate their systems in favour of primary care. However, reformers are potentially in a much stronger position to effect change in Belarus relative to other countries of the former Soviet Union because population health is a genuine political concern and the health care system receives significant public sector funding. According to WHO estimates, in 2005 total health expenditure was 6.6% of Gross Domestic Product (GDP), of which 5% was public sector expenditure on health. By contrast, WHO estimated that total health expenditure in the Russian Federation was 5.2% of GDP in 2005, of which 3.2% was public sector expenditure.<sup>5</sup>

Future primary care reform challenges centre on attracting and retaining the best staff; raising prestige; and improving the gatekeeping function of doctors working in primary care. There are ongoing problems in rural areas in attracting and retaining health care personnel. The shortage of primary care doctors in Belarus, despite extremely high rates of physicians per capita nationally, is one of the most acute problems in the health care system. In many respects, the introduction of general practice to rural regions was a response to the realities of the situation – primary health care doctors in understaffed practices were working alone treating both adults and children, irrespective of their training as either paediatricians or internists treating adults.

One measure to address this shortage has been the reintroduction of compulsory placements in primary care settings for all new graduate doctors from 2007. Salaries for doctors working in primary care have also been boosted by 40%, but working conditions are still very challenging. The main expansion in primary care in Belarus has been in the workload of primary care doctors, particularly the need to fulfil a large number of routine annual check-ups, that in many cases has to be conducted by four to five narrow specialists (ENT, neurologist, surgeon, ophthalmologist). These check-ups involve extensive paper work and cover large segments of the population (e.g. all school children twice a year, chronically ill patients, women of reproductive age). Primary care doctors also are responsible for carrying out annual fluorography screening for tuberculosis, opportunistic screening (particularly for cancers) and all sick leave authorisations. All these practices contribute to the extremely high number of out-patient contacts in Belarus, which increased to 13.6 per person per year in 2007.<sup>5</sup>

There has been little success thus far in raising the prestige of primary health care in order to attract more young doctors. Indeed, compulsory placements in primary care could serve to reinforce the idea that working in primary care is not something to be embraced as an active career choice. The low prestige of general practice and primary care services is also one reason why the traditional polyclinic system with community specialists has been maintained in the cities. However the polyclinics in the big cities are also understaffed and face the constant drain of primary care doctors to the specialist and hospital sectors, and in

many cases out of the medical profession.

Patients prefer the traditional polyclinics and would rather consult a specialist than an internist or general practitioner [6]. Patients prefer to self-refer to specialists when they are ill, as is their constitutional right, and the weak gate keeping role of primary care doctors mean that there is a considerable over-utilisation of inpatient care. The fact that such rights are enshrined in the constitution makes it especially challenging to change the status quo in urban areas; in rural areas, it is only the geographical distance from specialist services which reinforces the gate keeping role of primary care doctors. Nevertheless, the ongoing development of a new two-year national health strategy provides the Belarusian government with a good opportunity to define a clear vision for the future of primary care in Belarus.

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# Poland: will legal restructuring affect the (real) economy of hospitals?

Adam Kozierekiewicz

In Poland, major restructuring of health care facilities started in the early 1990s, when a law on health care units was introduced. By virtue of this law, health care institutions have been separated into two legal structures: public but autonomous 'SPZOZs' and non-public NZOZs.

Prior to the introduction of this legislation public health care units had been operating as, 'budgetary units', fully owned and dependent on their public 'mother administration'. However, this form of operation had been considered ineffective, with burgeoning bureaucracy and debts, whilst delivering poor patient services, leading to the decision to make all public health care units autonomous units (SPZOZs).

Since 1995 the new public health care units were established at different public administrative levels (municipal, county, regional or central) and the non-public units by other private sector bodies, including foundations.

## Instability and insolvency protection

Structures have been changing gradually.<sup>1</sup> Formally, one key difference between the old budgetary units and the new SPZOZs is that the latter are registered in a dedicated chapter of the national legal register and have a similar legal status to companies and foundations. However, unlike other legal entities on this register, SPZOZs are protected from bankruptcy. They are autonomous in management but should financial difficulties arise, liability rests

with the public authorities. This guarantee was intentionally introduced in the 1990s, as Parliament wanted to prevent the sudden collapse of health care facilities considered important for the maintenance of public health.

In subsequent years of operation, it became obvious that, while this mechanism protected these health care facilities, it hampered their business partners, such as medical and fuel suppliers. Moreover, managers of the SPZOZs, aware of their special position, often spent more than their units' revenues permitted for, increasing the level of debt. Despite governmental efforts to clear and restructure hospital debts, many SPZOZs have continued to build up deficits. In the period since 1998, the state spent more than €3 billion (12 billion Złoty (PLN)) on debt bailouts. In 2008 alone cumulative debt amounted to €1.5 billion, compared to a total health budget of approximately €14 billion (50 billion PLN).

Without appropriate incentives to control costs, the SPZOZs threaten to seriously destabilise the finances of local administrations. In this respect, it appears to be absolutely necessary to undertake further action. It is worth noting, however, that the distribution of debt is uneven; 80% of the accounts payable by SPZOZs were generated by 10% of the units. Of 1,730 units examined by the Ministry of Health, 828 did not have any outstanding debts (47.9% of all SPZOZs surveyed).

## Privatisation

Since the 1990s privatisation has been undertaken, to a large extent, in the ambulatory care sector, and today the majority of ambulatory health care providers have been converted into NZOZs. It was commonly perceived that private ownership of ambulatory care results in better care, more flexibility and more dedication of providers to maintain good relationships with their patients. Privatisation has not limited ac-

cess to public services, as private providers have been fully integrated into the public health care system and largely operate on the same principles. Moreover, privatisation of ambulatory care has not been linked with any significant sale of property: local administrations continue to own properties, renting space to companies staffed by former SPZOZ employees.

The beginning of the new millennium marked the first attempt to 'restructure' hospitals by changing their legal structure. Unlike ambulatory health care, the majority of the population has remained suspicious of the privatisation of hospitals. The process of privatisation in general, let alone hospital privatisation, has had little support.

Nonetheless by the end of 2006, there were approximately 150 hospitals run as NZOZs, including fifty established by companies owned by local governments. These latter entities were established, in most cases, as a result of 'closing down' the public facility (SPZOZ) and creating NZOZs established by a company and owned partially or fully by local government.

From the legal perspective, these new entities were 'non-public', established by limited liability companies. However, since the shares are mostly owned by local authorities, it is difficult to talk of privatisation in this context and the term 'non-public health care institution' does not really apply.

All hospitals owned by companies run by local governments are contracted by the National Health Fund and their scope of services is similar to the previous SPZOZs. This seemingly obvious statement is important because, in the eyes of the public (and indeed that of some political forces), a change in the legal status to 'non-public' is synonymous with 'payment for services'. This is, of course, untrue. Only a handful

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of the fifty restructured hospitals encountered difficulties after the change and most experienced an improvement in their financial and management situations.

Following the initial success of restructuring, the government was inspired to push for a universal change of status in hospitals from SPZOZ to NZOZ. In 2008 the government formulated a programme, initially proposed as a law, which required each SPZOZ to transform itself into a company owned by the local community.

Governmental plans had scheduled this to be completed by the end of 2010. However, the obligatory nature of the process and tight timeframes were major reasons for political opposition to the proposal. Accompanied by populist rhetoric, calling for “state responsibility for citizens’ health”, this opposition was strong enough to force the President to veto the law.

In these circumstances the government undertook steps to encourage hospitals to change by using financial incentives, including debt bailouts and special credit lines for investments. According to very conservative estimates, at least seventy hospitals (of 650), will respond positively to this offer. Many more are however likely to wait for even more generous offers from future governments.

The reform of health care facilities in Poland has hardly begun. We face further challenges and are likely to see more extensive liberalisation of markets in health care. Opposition to this reform, coupled with the traditional budgetary attitude of health care decision makers, remains strong, and this will exclude and isolate many units. Another round of changes is expected in the next few years, when the government will be even more pressed by financial crises within the sector.

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# Italy's new fiscal federalism

## George France

In May 2009, Italy's Parliament approved Law 42 which sets down the broad elements of the new fiscal federalism which the national government intends to introduce over the medium term. “Fiscal federalism” is concerned with the working of the arrangements used to govern the financial relations of different levels of government.<sup>1</sup> Under the new fiscal federalism, sub-central governments will enjoy a substantial increase in financial autonomy with the aim of securing a closer match between their spending powers and their tax revenues. This will consist, in the main, of the national government ceding pre-specified guaranteed shares of the revenues raised within the territory of a region from national value added tax and national income tax. Law 42 also changes how the State's contribution to each region's spending needs in the health care sector is to be calculated.

### Funding and expenditure mismatch

As devolution has proceeded over the years in Italy, a mismatch has emerged as sub-central governments acquired independence in administration and organisation at a faster rate than they did the authority to raise the financial resources to finance these. For example, on average own-revenue sources have provided 38% of total regional revenues, ranging from 56% for the richer northern regions to 26% for the poorer southern regions.<sup>2</sup> This ‘skewness’ between spending and revenue powers has contributed to the creation of a problem of accountability and a record of intergovernmental strife. The process of devolution is most advanced in the public health care sector; 70% of the total regional budget goes on health care and the regions manage 90% of total public expenditure on health care. The sector has been characterised by chronic deficits, with the regions regularly spending more than the annual funding

allocation they receive from the State.

This accountability problem was aggravated by a constitutional amendment in 2001 whereby the regions were required to guarantee to all residents a health care entitlement (specified in the form of positive and negative lists of services). The aim here is to protect the ‘national interest’ in health (defined in terms of universal, comprehensive and financially accessible care), which it is feared is threatened by the centrifugal forces set in motion by devolution. This entitlement is defined centrally in consultation with the regions, but it is the State which has to ensure that all the regions have the financial means necessary to deliver it.

The problem is that the regions, in the knowledge that the State is obliged to guarantee them funding for the entitlement, have had an incentive to spend more than may be strictly necessary or at least to be less than fully zealous in trying to live within their annual funding allocations: spendthrifts may have been rewarded at the expense of the more frugal.

All this has spurred the central government, faced with the constraint of meeting its obligations in respect of European Monetary Union regarding aggregate levels of public expenditure and public debt, to apply measures deliberately aimed at curtailing the autonomy of those regions revealed to be serial deficit spenders. For example, the central government has begun to require that regions with budgetary difficulties introduce new and/or increase patient co-payments and regional taxes. This is causing anxiety about geographical equity.

Moreover, since such central intervention means in effect backtracking on the devolution design, at least for the regions involved, it could have political costs for the national government. The intention of Parliament now is that, being granted expanded tax revenue sources, the regions will be more inclined to live within their means and be more accountable for their actions to both their regional electorate and the national government.

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### Standard cost approach

The way the cost of delivering the health care entitlement is calculated has also made it difficult for the State to refuse *tout court* to finance regional deficits. Up until now, the annual aggregate contribution by the central administration to aggregate public health care spending has been officially set as a percentage of Gross Domestic Product (GDP) and divided among the regions on the basis of the weighted population.

Under the new fiscal federalism the States contribution to regional health care costs will be calculated principally using standard costs. This could help to reduce the chronic regional deficits until now covered in part by supplementary State funding granted *ex post*.

Data for 2007 give a difference of €6 billion between planned expenditure and the effective cost of financing the entitlement, an overshoot of 8%.<sup>3</sup> There are large differences between individual regions in this regard; it is calculated that seven regions accounted for over 80% of total overspend in the period 2000–2005.<sup>4</sup> This overshoot, according to the Court of Accounts, the national body responsible for auditing the public accounts, represents the sum of underestimated spending needs and the costs of operating inefficiency.

One estimate of what might be called the ‘inefficiency burden’ is €2.2 billion.<sup>3</sup> This measure is obtained by comparing what all twenty-one regions actually spent in delivering the health care entitlement with what they would have spent had their costs been similar to those of the four regions with the best record of efficiency and quality of care, but with quite different organisational and administrative arrangements. Another study, based on the costs of two regions, widely claimed in government circles to have the ‘best performance’, calculates the aggregate ‘inefficiency burden’ to be €4.3 billion.<sup>5</sup> With the reform, the State’s contribution to the regions would be capped using the standard costs of delivering the entitlement.

The principal source of data for estimating standard financial needs is the *Sistema Informativo Sanitario* (SIS – Health Care Information System), which collects data on services and costs at facility level from all the regions using a common methodology nation-wide. The SIS is being revised on the basis of the results of the so-called ‘Progetto Mattone’ (loosely translated as the Brick-upon-Brick Project), a major collaborative effort between the Ministry of

Health and the regions. The aim is to generate for all the regions comparable data which emphasises efficiency, quality and appropriateness for all the regions. However, the SIS still has a long way to go before it will furnish reliable comprehensive data, including that on services contained in the national entitlement.

The standard cost approach required by the new law will have to be used with caution. Standard cost is not minimum cost – contrary to what seems to be assumed with the inefficiency burden estimates cited above; rather it is the cost of *efficiently* providing the entitlement.

While many studies report important interregional differences in efficiency, current variability between regions in the costs to deliver the entitlement to their citizens cannot be explained solely in terms of efficiency. For example, both the regions used to calculate the inefficiency burden of €4.3 billion cited above have younger populations and are richer and so tend to make less use of health services in absolute terms and, when they need care, to go more often to the private health sector.<sup>6</sup> The two regions also happen to be relatively efficient. In addition, a recent investigation of the performance of regional health systems highlights important differences among regions in their governance capability and this seems to have a direct impact on the cost and quality of services provided.<sup>7</sup>

These are all reasons why the Ministry of Health will have to work long and hard at convincing and assisting the regions to provide reliable and methodologically uniform data on the costs and activities of their staff and facilities and those of private contractors which take maximum account of quality and appropriateness. Perhaps one of the most serious obstacles to calculating standard costs is the fact that quite a number of the regions furnish data which fail to

meet SIS criteria, a situation likely to persist for quite some time. However, Law 42 on the new fiscal federalism does go in the right direction when it moves standard costs to centre stage.

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### Slovenia Health System Review



June 2009

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Health Systems in Transition (HiT) profiles are country-based reports that provide a detailed description of a health system and of policy initiatives in progress or under development. HiTs examine different approaches to the organisation, financing and delivery of health services and the role of the main actors in health systems; describe the institutional framework, process, content and implementation of health and health care policies; and highlight challenges and areas that require more in-depth analysis.

# Increasing the use of health impact assessments:

## Is the environment a model?

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Rebecca Salay and Paul Lincoln

*Summary: Increased rates of chronic illnesses will overwhelm health systems and negatively impact economic growth if current trends are not reversed. Health impact assessment (HIA) helps policymakers gauge the impact of decisions on health, ensure coordinated cross-government action and meet the goal of health in all policies. HIAs are under-utilised at the European Commission and are not a mandatory requirement for Member States in the same way as environmental impact assessments. This paper, which is part of a longer report by the National Heart Forum, analyses the position of health and environmental impact assessments and sets out an agenda for policy development to ensure that health impacts are assessed as regularly and thoroughly as environmental impacts.*

*Keywords: health impact assessment, environmental policy, Europe*

The increase in avoidable chronic diseases such as heart disease, stroke, diabetes, obesity and cancer is having a serious impact on quality of life across Europe. With forecasts showing skyrocketing obesity levels in the coming decades, along with increases in linked avoidable chronic diseases among younger generations, the cost of treating these diseases is likely to overwhelm health systems and negatively impact on economic growth if current trends are not reversed.

The Foresight report on *Tackling Obesities*, published in October 2007 in the United Kingdom, mapped the complex drivers of the obesity epidemic and demonstrated the health and economic impact if the rising rates of obesity are not reversed.<sup>1</sup> The report also highlighted similarities between the challenges of obesity and climate change: both require systemic cultural change, across government sectors and throughout society. In fact some of the proposed actions to address obesity, such as increasing physical activity by encour-

aging active travel, may also help to address climate change by reducing carbon emissions.

Sustainable economic development and long-term economic growth are only possible if both environmental and health impacts are considered in all government policies. Impact assessments are an important tool to help make this goal a reality, but in practice health impact assessments (HIA) tend to be under-utilised, particularly in comparison to environmental impact assessments, and their results often overlooked. This is in part due to the fact that the European Commission has established formal requirements for Member States to carry out environmental impact assessments and strategic environmental assessments, while no similar requirement exists for health impact assessments. Increasing the usage of health impact assessments at the European Commission and Member State level is one important strategy to incorporate health into all policies and reduce the growing rates of chronic disease.

**Including health in all policies is a necessity to improve health and well-being**  
*Tackling Obesities* illustrated what the public health community already knows,

namely that many of the factors impacting on health and well-being stem from sectors external to health, such as planning and transport, food, the environment and fiscal policy. In order to improve health and well-being, and stem the rising tide of chronic illnesses, health impacts must be considered in all policies, by all government departments.

HIA is a tool to determine the health effects of a policy, programme or project, and the distribution of those effects within the population.<sup>2</sup> It can help policy makers gauge the impact of decisions on health, ensure coordinated cross-government action, and meet the goal of health in all policies. Council Conclusions on Health in All Policies issued at the close of the Finnish presidency (June–December 2006) cited Article 152 and called on the European Commission (EC), Member States and the European Parliament “to ensure the visibility and value of health in the development of EU legislation and policies by...health impact assessments”.<sup>3</sup> The 2007 EU Health Strategy also called for the use of HIA to strengthen the integration of health in all policies, which is one of the strategy’s four fundamental principles.<sup>4</sup> The WHO Commission on the Social

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Determinants of Health report, Closing the Gap in a Generation, also recommends that regular health equity impact assessments be institutionalised in national and international policymaking.<sup>5</sup>

### Health impacts not fully considered by the EC

The EC has a rigorous system of integrated impact assessment, but in practice public health implications are not fully considered outside the health sector. The result is many EU policies have negative unintended impacts on health. Integrated impact assessments cover such a large number of issues that health, considered as a part of overall “social impacts,” is often overlooked while other top-line issues, more easily expressed in economic terms, are emphasised. An internal review by the UK’s National Heart Forum (NHF) found that in 2005 and 2006 73 out of 137 impact assessments carried out by the Commission did not mention the word ‘health,’ either in regard to health systems or public health.

While there is still a long way to go to fully address the challenge of climate change, the environmental movement has successfully mainstreamed environmental concerns into government decisions and environmental impact assessments are carried out on a more regular basis than HIA. This difference comes despite similar language in the EU Treaty regarding the EU’s obligations toward protecting human health and the environment.

Although Member States have the ultimate responsibility for health, Article 152 of the Amsterdam Treaty explicitly states “a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.” The Treaty also states that Community policy should “contribute to the preservation, protection and improvement of the quality of the environment.” That obligation is strengthened by the Directive on Environmental Impact Assessments<sup>6</sup> (EIAs) and the Strategic Environmental Assessment (SEA) Directive,<sup>7</sup> which establish a legal obligation for Member States to carry out environmental impact assessments. Currently there is no legal obligation to carry out an HIA either at Member State or EU level.

The NHF’s research found several other impediments to HIAs being regularly carried out at the European Commission. Each Directorate General (DG) has the discretion to decide which of their

proposals requires an impact assessment and how it will be designed and organised. These decisions are seldom challenged by other DGs. For example, if DG Agriculture decides there is no need for a health impact assessment on the Common Agricultural Policy (CAP), then that decision is likely to stand with no input from other DGs or stakeholders.

It is also unclear how much core competence the European Commission, Parliament and Council have in this area, both in terms of carrying out HIAs and knowing what questions to ask when reviewing impact assessments. Anecdotal evidence indicates that DG Health and Consumers may not have the capacity to contribute when asked to assist another DG in impact assessment. DG Health and Consumers needs to have staff with the time and the expertise to understand, for example, the impact of agricultural or transport policy on health. Without it those issues may go unaddressed, despite the fact they directly impact on risk factors for chronic disease.

### Agriculture and transport policies impact on health

Agriculture and transport are just two examples of sectors which impact on the health of people throughout the European Union, but where health impacts are not fully considered. Agricultural policy affects the type and price of food available for consumers, and the CAP provides an opportunity to target investment to improve nutrition. Currently, relatively small amounts of CAP funding subsidise fruit and vegetable production, while dairy subsidies promote production and consumption of products high in saturated fats. The Swedish Public Health Institute has looked at the health implications of the CAP, but the EC has never commissioned an HIA on the CAP. If they did, one might find that investment in fruit and vegetable production should be increased, with subsidies used to make them more affordable, or that incentives should encourage production of low-fat rather than full-fat milk.

Transport policy is another area which directly impacts on health. Shifting transport priorities to favour walking and cycling would increase physical activity levels, reduce congestion and air pollution, and help address climate change. In September 2007 the EC published a Green Paper on urban mobility. Promotion of walking and cycling is discussed in the context of sustainability, but health benefits must be fully assessed and weighed against other costs

and benefits before the final action plan is drawn up.

### Proposals to increase the use of HIA

What are the steps policymakers need to take to improve the current process of impact assessment and include health in all policies? Firstly enabling legislation must be passed to create a legal obligation for HIA which mirrors that for SEA and EIA. The directives for EIA and SEA give legal force to the treaty obligation to protect the environment, and could serve as a model to create a legal obligation to carry out an HIA either at the Member State or EC level. Outside Europe, Thailand has set a strong example in enshrining HIA into law in 2007. Citizens have the right to demand that an HIA be conducted, and to participate in the process, while the 2007 Thai constitution also includes strong provisions on HIA.

Secondly, Article 152 should be strengthened to require HIAs on all major proposals. Conducting an HIA on every Commission policy would be prohibitive in terms of cost and staff resources, but significant policies should be required to fully address health either in a separate HIA or within the integrated impact assessment. A potential model operates in England, where policy makers must answer three screening questions relating to impacts on health services, health determinants, and lifestyle related risk factors, to establish whether a full HIA is required.

Thirdly, the EU Health Strategy should require HIA on major proposals and specify the need for public health-focused impact assessments. Finally, DGs should be provided with sufficient resources, including staff training, to allow them to appropriately carry out impact assessments and to contribute expertise to impact assessments in other DGs. The European Parliament and Council should also develop staff expertise in HIA and ensure they are undertaken.

The World Health Organization and others have recognised that including health in SEAs can be an effective strategy to address health impacts without a separate HIA. Protection of human health is included in the SEA directive but Member States have the flexibility to broaden the scope to include health promotion. In England the Department of Health is developing guidance to include a broad interpretation of human health in SEAs and ensure health impacts are addressed early in the planning process. Again, this



could serve as a model for Member States. Many Member States are acting on their own to institutionalise HIAs, but development differs across Europe and leadership is needed at the highest level. Public health advocates should work with future presidencies to continue the emphasis on health in all policies. In the absence of political leadership, the National Heart Forum believes that one strategy is to *find the right partnership to take on a legal challenge* to clarify the EU's obligation about conducting HIAs.

Health, sustainable development and economic growth are inextricably linked. Without a focus on health and sustainability that is integrated throughout all government departments, increasing rates of avoidable chronic illnesses will overwhelm health systems throughout the EU and limit economic growth. In particular reform of the CAP, which consumes nearly half of the EU budget, should not move forward without a comprehensive understanding of its impact on health. The EU's contribution to public health will only be

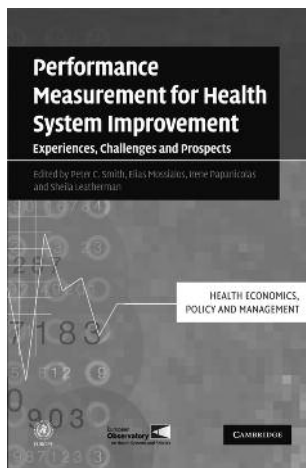
fully realised if HIAs are made a mandatory core activity of the Commission – otherwise public health will continue to be a hit and miss, marginal consideration.

*This article is based on a text which appeared in the Lancet (2008;372:860–61). For the full National Heart Forum report on health impact assessment, please visit [http://www.heartforum.org.uk/Publications\\_NHFreports.aspx](http://www.heartforum.org.uk/Publications_NHFreports.aspx)*

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## Performance Measurement for Health System Improvement: Experiences, challenges and prospects



Edited by Peter C. Smith, Elias Mossialos, Irene Papanicolas, Sheila Leatherman

In a world where there is increasing demand for the performance of health providers to be measured, there is a need for a more strategic vision of the role that performance measurement can play in securing health system improvement. Performance Measurement for Health System Improvement articulates such a vision and it marshals the evidence of how to go about this in practice.

Leading authorities in the field aim to present technical material in an accessible way and illustrate with examples from all over the world. Presenting opportunities and challenges associated with performance measurement it examines the various levels at which health system performance is undertaken, the technical instruments and tools available, and the implications using these may have for those charged with the governance of the health system. Many chapters also highlight government's crucial role in guiding performance measurement policy and the numerous political considerations that must be examined alongside technical measurement issues.

#### Contents:

*Introduction; Population Health; Patient-Reported Outcome Measures and Performance Measurement; Measuring Clinical Quality and Appropriateness; Measuring Financial Protection in Health; Health System Responsiveness; Measuring Equity of Access to Health Care; Health System Productivity and Efficiency; Risk Adjustment for Performance Measurement; Clinical Surveillance and Patient Safety; Attribution and Causality in Health-Care Performance Measurement; Using Composite Indicators to Measure Performance in Health Care; Primary Care; Chronic Care; Mental Health Services; Long-term Care Quality Monitoring using the inteRAI Common Clinical Assessment Language; Targets and Performance Measurement; Public Performance Reporting on Quality Information; Developing Information Technology Capacity for Performance Measurement; Incentives for Health-care Performance Improvement; Performance Measurement and Professional Improvement; International Health System Comparisons: from Measurement Challenge to Management Tool; Conclusions.*

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# Transforming research into action: A European Parliament report on palliative care

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Jose M Martin-Moreno, Meggan Harris, Lydia Gorgojo, David Clark,  
Charles Normand and Carlos Centeno

*Summary: The authors of a European Parliament report on palliative care summarise the process of the five-month investigation, as well as the real and potential results of the study. Engaging a large number of national and international stakeholders, including ministries of health, national palliative care associations and the European Association for Palliative Care (EAPC), we were able to draw on a well of previous research and diverse experiences before formulating operative policy options for the EU and its Member States. While the report itself fomented some self-examination in the countries studied, its full exploitation by palliative care advocates is still pending.*

*Key words: palliative care, Europe, European Parliament, health systems, health policy and management*

The European Parliament has recently published an external report, *Palliative Care in the European Union*.<sup>1</sup> As the main researchers in this endeavour, we examine the unique nature of the palliative care field, including the important role of multi-disciplinary teams, psycho-social care, volunteers, palliative care training for general practitioners (GPs) and other specialists, and the challenges faced by patients with terminal illnesses. Delving into the individual palliative care structures among European countries, we found a pronounced heterogeneity in the way in which national health systems care for their dying, as well as the quality and access of the care provided, not only between countries, but also within them. The report concludes with a wide variety of policy options which are intended to present ideas, stir debate and stimulate creative proposals among decision-makers in their efforts to improve the

care offered to patients at the end of their lives.

The study was, in part, conceived as a follow up to the *Recommendation Rec (2003) 24 of the Committee of Ministers to Member States on the organisation of palliative care*. That initiative, the most ambitious to date, made recommendations for palliative care development in the fifteen countries then making up the European Union. The next four years brought the expansion of the EU to its current twenty-seven countries, as well as advances in the palliative care field across the continent. These dynamic changes spurred the European Parliament Committee on Environment, Public Health and Food Safety to issue a closed invitation to tender in October 2007 for a new external study on palliative care in Europe, to be managed by the Economic and Scientific Policy Department.

The following December, one of us (Jose M Martin-Moreno, a medical doctor and public health specialist) was commissioned to lead the investigation. He assembled a multi-disciplinary team which included specialists in palliative medicine with extensive experience in comparative palliative care studies and an expert in health system economics. We also had the support and active participation of the European Association For Palliative Care (EAPC) through its president, Dr Lukas Radbruch, and other expert members. The EAPC proved to be a crucial partner in the initiative, as information was freely and collegially exchanged with the mutual objective of contributing at a policy level to the improvement of patient care.

## Study objectives

The proposal to the European Parliament fitted closely to its stated wishes, with an increased focus on the elements characterising the palliative care field (see Box 1) and a brief description of the situation in the twenty-seven EU countries. A standard template was used in the country profiles to facilitate comparison, and an original and complex ranking system was formulated with information from the EAPC in order to measure the relative progress and vitality of each country's palliative care structures.

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**Box 1. Areas of assessment**

- Availability and access, including place of care, paediatric palliative care and availability of opioids
- Integrated health care networks
- Human resources, including GPs, nurses, palliative care and paediatric palliative care specialists, psychologists, social workers and volunteers
- Quality assurance
- Emotional and psychological support
- Legal and policy provisions
- Financial planning models
- Best practices

**Methodology**

Due to the short time frame for the study (five months), the limited space requested by the European Parliament (fifty pages) and the broad scope and impact of the study, conciseness and efficiency were as important as up-to-date accuracy. With this in mind, the research team took three steps that simultaneously maximised efficiency and enriched the final text.

First, a comprehensive search of scientific and grey literature was surveyed. Synthesising and analysing this information, we were able to depict a relatively accurate picture of the situation in European countries, as well as describing some of the key areas of assessment. A few of the principal sources used in this endeavour, especially for the country profiles, were the *EAPC Atlas of Palliative Care in Europe*,<sup>2</sup> *Helping People at the End of their Lives*<sup>3</sup> and *Transitions in End of Life Care*.<sup>4</sup> This research also helped identify national policies which have already been proven successful in improving quality of life for European patients; these positive national experiences are the backbone of the policy options at the end of the report.

In order to update the secondary data gathered, we directly contacted all ministries of health and palliative care organisations throughout the EU to obtain primary data on the organisation of palliative care in their countries. After two rounds of contact letters and emails, nearly forty responses were received from twenty-six European countries, allowing us to update our findings with current figures and developments. These reflected the vitality of the palliative care field and also highlighted the need for regular comparative studies to document

the achievements. Although the EAPC Atlas was published with data from 2006, our contacts with national stakeholders showed that much progress and many changes had occurred in the following two years.

Interestingly, the responses received from health authorities in many countries with little palliative care development were quite candid, acknowledging that palliative care had received little attention in their health system but also recognising its importance. This circumstance suggests the pro-active effect that this type of report can stir, stimulating national policy-makers to consider bringing a palliative care agenda to the table. The involvement also provided the opportunity for health authorities to explain the strengths and weaknesses of their national model, as well as allowing for palliative care associations to express their ideas, frustrations and successes.

Finally, a number of European specialists were invited to make special contributions to the final text, detailing their area of expertise and the pending challenges to tackle. They included Franca Benini (paediatric palliative care), Marilène Filbert (GP training), Phillip Larkin (nurse training), Inmaculada Martín-Sierra (social work), Marina Martínez (psychologist training), David Oliviere (volunteers), Lukas Radbruch (quality assurance and best practices), Stein Kaasa (research) and Luzia Travado (psychological support). Channeling these contributions into a broader public health-based approach, we aimed to synergise solid research evidence with operational health system policies.

**Findings**

The wide participation in the formulation of this document ensured that the conclusions truly reflected the diversity, but also the inequalities, of the European reality. Palliative care structures vary widely, as different cultures deal with death in different ways. England is the cradle of the 'hospice', while France initially developed services in hospitals. Other countries, such as Ireland and Hungary, concentrate their resources on providing home-care teams, whereas Belgium and the Netherlands are increasingly investing in day centres and nursing homes. Grassroots movements have been responsible for palliative care development in Poland, while government intervention was the key in the Netherlands. Inequalities within countries vary as well; rural/urban divisions, regional socio-economic status and decentralised governance seemed to be the most important

factors, although economic resources should not be discounted.

The needs of patients with terminal illnesses, however, are strikingly similar: high quality multi-disciplinary care with clear pathways and lines of communication between the care team, the patients, their loved ones and other related professionals; treatment options which allow them to stay in their homes as much as possible, reducing suffering and respecting their wishes; and a social network which actively includes patients and their families in a supportive community.

Europe could play an important role in some of these key areas: currently, there are neither accepted standards nor evidence-based solutions to measure the quality of a programme. Official certification for professionals is not available in most countries. It would be ideal if palliative care were recognised on the same terms as other social and health care structures, thereby ensuring funding and investments in organisation. European support for these objectives would be welcome, both by patients and professionals in the young palliative care field. Furthermore, it is our hope that by directly engaging high-level stakeholders in the formulation of the report, we have opened a new door to the self-examination of palliative care services within the different national health systems.

**Policy options**

With this in mind, and knowing that the European Parliament was not looking for a prescriptive solution, but for a range of operational alternatives, we presented three policy options based on solid data and experience collected and documented during our investigation. The first was a conservative, horizontal approach, which in theory could be accomplished by simply acknowledging palliative care as a medical field. A second strategy was a recommendation to Member States on further actions to take; this has been an effective tool in the past to promote development in targeted areas while respecting national sovereignty. A third course of action was to intervene directly with European legislation. These tactics were detailed fully in the report and are summarised in Table 1.

**Discussion**

The proposals were presented to the European Parliament; however, many of the ideas are relevant for national policy-makers as well. We believe that the report itself constitutes a potentially effective tool for

**Table 1. Policy options to advance palliative care in the European Union**

Strategy	Course of action	Advantages	Disadvantages
Conservative and horizontal approach	<ul style="list-style-type: none"> <li>• Ensure that palliative care is recognised as a medical field</li> <li>• Bolster general measures to improve health care delivery, such as reducing waiting times and declaring a Patient's Bill of Rights</li> </ul>	<p>Minimise bureaucracy and increase flexibility in innovation and treatment decisions</p>	<p>Given the lack of development in many countries, this approach may not be enough to guarantee quality or access.</p>
Recommendations to Member States	<p>Some possible recommendations:</p> <ul style="list-style-type: none"> <li>• Formulate national plan on palliative care</li> <li>• Increase investments in training and research</li> <li>• Improve accessibility and proper use of opioids</li> <li>• Promote integrated health care networks</li> <li>• Facilitate specialist accreditation</li> <li>• Identify and promulgate best practices</li> <li>• Forge partnerships within and between countries</li> </ul>	<p>This could be an excellent tool for advocacy in many Member States while respecting some countries' wishes for no new legislation.</p> <p>It could also pave the way for recognised guidelines in Europe.</p>	<p>Because it is important to ensure some degree of harmonisation in such an important field, this plan may fall short.</p>
New European legislation or directives	<p>Possible areas of legislation:</p> <ul style="list-style-type: none"> <li>• Guarantee equal rights for all patients</li> <li>• Ensure availability of opioids</li> <li>• EU action plan and monitoring system</li> <li>• Declare palliative care to be a human right</li> <li>• Create a dialogue with Member States to discuss priorities and identify challenges</li> <li>• Establish a European platform to stimulate research</li> <li>• Establish an interface between research and policy</li> <li>• Create a European Reference Centre or European Institute of Palliative Care</li> <li>• Promote cross-border cooperation and patient mobility</li> </ul>	<p>Direct European Parliamentary involvement would work to make palliative care a priority on the European agenda and would bring about an enormous advance where palliative care is currently not very developed.</p> <p>Investments, especially in research and training, would provide welcome stimulus to the field.</p>	<p>Harmonisation efforts could be problematic for countries whose palliative care programmes are already developed.</p> <p>Additionally, European competence in national health systems has yet to be solidly established, which would make some of the proposals very difficult to achieve.</p>

lobbying efforts, and we continue to support its dissemination. In May 2008, the results were presented at the 11th Congress of the European Association for Palliative Care in Vienna, where the team leader reiterated his encouragement for its use in the national and European context. For governments with limited experience in palliative care policy, section two of the report, detailing the basic elements of a successful programme, is a useful summary and builds the foundations of knowledge to begin debating on what policies would work best in their country context. Section three provides a concise quantitative and qualitative comparison on service provision in Member States. It provides an idea of what is possible within limited resources. Section four, covering best practices, has a benchmarking function and aims to both recognise merit and stimulate interest in successful initiatives. Finally, the conclusions and policy options set out a flexible and adaptable plan of action to move forward.

Unlike other issues which have received more rapid attention from the European Parliament following the publication of an independent report, palliative care has yet to be added to the agenda. Particularly now, as the world financial economy teeters and the EU and Member States struggle to find a coherent response, it will be challenging to return palliative care policy to the European and national stages. However, the ageing of the population means that this issue will gain relevance rather than lose it in the coming years. Local activism has been the principal engine of palliative care development in most European countries since its beginnings in the late 1960s in England, and it must continue to be so for the sake of patients and their loved ones. Real development in Europe will not be the fruit of this report, but rather the result of how it is utilised, in combination with other advocacy tools, to raise awareness, disseminate knowledge, and fight for lasting change.

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# Health information technology in the United States: Can planning lead to reality?

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Natasha Desai, Brendan Krause and Marin Gemmill-Toyama

*Summary: The United States has started to implement electronic health technologies due to the increasingly complex nature of health care. This paper aims to review the organisation of health information technology in the US through the analysis of standards and privacy protocols at the federal level and programme implementation at the regional level. Recommendations for policy planning are given in the conclusion, as well as insight into the need to merge the health information technology agenda with quality improvement goals so as to align incentives for providers, patients and payers.*

*Keywords: health information technology, quality, health systems, USA*

The increasing burden of disease, particularly chronic diseases, along with more sophisticated medical treatment has dramatically increased the complexity of health care delivery. Fragmented systems of care delivery, teams and layers of clinicians and complex treatment protocols require administrative oversight and integration that health information technology (HIT) can provide.

While many high-income countries like Denmark, England, Norway and Sweden have made great strides in implementing HIT systems, health care administration in the United States remains predominately paper-based. If the utility gained from increased health technology is to benefit individuals and society, barriers to implementation of HIT and health information exchange must be overcome in ways that allow health care organisations to move forward with quality improvement agendas that use HIT as a tool for work practice improvement.

A federal-state framework for HIT implementation that addresses the commonly cited barriers of engagement, privacy, security, and fiscal sustainability is widely seen as essential for HIT diffusion in the US. In recent years, significant attempts to advance the HIT agenda have occurred at both state and federal level. This article highlights some of the current efforts to develop this framework and discusses the likely next steps.

## Federal organisation of HIT

The recent passage of the American Recovery and Reinvestment Act of 2009 provides \$19 billion in federal spending to move the HIT implementation agenda forward. While the United States has a relatively decentralised governance system, with policies usually formulated at the state-level, a national framework is necessary in order to preserve privacy and security and to ensure interoperability between local and regional systems.

As a step toward a national framework, the American Health Information Community (AHIC) was formed in 2005 with the goal of providing recommendations to the Secretary of the Department of Health and Human Services (HHS) on how to accelerate HIT.<sup>1</sup> AHIC came up with a list of priorities and standards gaps for a national IT strategy. However, this federal body

work group failed to engage the private sector (manufacturers of health technology software) and consumers of HIT such as physician practices. Subsequently, AHIC was reinvented as a public private partnership, being succeeded by AHIC Successor and eventually in 2008, the National eHealth Collaborative (NeHC). With funding of \$13 million over a two-year period, NeHC coordinates with the Certification Commission for Healthcare Information Technology (CCHIT), which is formally recognised as the HIT accrediting body by HHS and the Health Information Technology Standards Panel (HITSP), which is made up of voluntary standards experts to develop interoperability standards.<sup>2</sup>

Without mandated interoperability standards, physicians and other providers may be hesitant to buy HIT software for fear that they might need to replace it in the near future to meet developing standards. Thus, the purpose of CCHIT is to certify health IT products, including electronic health records, so that providers can be aware that 'CCHIT Certified' products meet basic requirements for functionality, interoperability, security and privacy. So far, CCHIT has certified 160 health information programmes.<sup>3</sup> However, it is possible that CCHIT's fee for vendor accreditation is too high and deters smaller

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companies from obtaining certification. Regardless, the fact that CCHIT products guarantee a certain level of interoperability should decrease barriers to implementation of electronic health records.

In terms of privacy and security, the existing privacy laws in the US have not been amended to include provisions for electronic transmission and storage of medical data. The US Privacy and Security Solutions for Interoperable Health Information Exchange project, which was launched in 2005 by the Agency for Healthcare Research and Quality (AHRQ) and the National Coordinator for Health Information Technology, aimed to determine the necessary level of protection for health information. The project concluded that there was a patchwork of practices, policies and state laws that protected health data and several conflicting laws regarding security existed.

The primary federal law covering privacy and security is the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Importantly, Regional Health Information Organisations (RHIOs) have emerged as local initiatives to facilitate health information exchanges (HIEs) but HIPAA laws do not extend to RHIOs, prompting concern about data security at the local level.

The implementation of HIPAA laws also varies considerably from state to state because there is a provision that permits states with more protective laws to continue with their existing laws.<sup>4</sup> For example, some states require consent for nondisclosure in all situations while other states only require consent in some situations, creating variability that could result in difficulties in cross border care, especially in emergencies.<sup>4</sup> While some feel that more stringent federal privacy rules are key in the national IT strategy, others strongly feel that adding more stipulations would only provide barriers to health information exchange, slowing implementation.<sup>5</sup>

### Why would there be a state role in HIT?

Inter-state integration is a key HIT challenge for US policymakers, not just in terms of HIE, but for health system design and reform generally. It is important to note that these state barriers are not just legal, but are historic and cultural, partially because it was the states that originally worked together to create the federal governance structure. This history plays out in modern policy making by leaving states with substantial responsibilities for regulat-

ing the health care marketplace.

Rather than viewing individual state regulation and policy as a barrier, there is a strong case to be made for a major state role in the development of the US HIT infrastructure. States regulate and license providers, clinics, hospitals and health plans. States protect important consumer rights, including privacy. States purchase health care for large numbers of public employees and they also finance and manage health care services through programs such as Medicaid and the State Children's Health Insurance Programme. These roles have given states strong competencies in delivery system management and design. However, for a national HIT infrastructure that enables the electronic exchange of important clinical and epidemiological data to succeed, state policies will have to be aligned.

### What have states done so far?

Recognising the important role for states and the significant planning tasks before both state and federal policymakers, several federal-state partnerships have emerged. Ranging from grants and technical assistance for individual projects to consensus building bodies comprised of stakeholders from government, as well as the private sector, these partnerships offer a potential way forward from policy to practice.

#### *AHRQ state and regional demonstration grants*

In 2004 and 2005, the AHRQ gave demonstration grants to six states: Colorado, Delaware, Indiana, Rhode Island, Tennessee and Utah. These 'State and Regional Demonstrations of Health Information Exchange' provided five years of funding for projects that demonstrated state or regional interoperability and data sharing for quality improvement. Grantee states are using different governance and business models that will enable exchange of clinical data and that can demonstrate a sustainability model. Grantee states must also determine the role that the Medicaid programme (for state residents who are poor or living with disabilities) will play in the HIE model. AHRQ shares the states' findings through a technical assistance centre called the National Resource Centre for Health IT.<sup>6</sup>

#### *Health Information Privacy and Security Collaboration*

Concerned that state-level privacy and security laws for individual patient data could in themselves provide a barrier to

HIE, yet must continue to protect consumer interests, the Office of the National Coordinator for Health Information Technology and AHRQ created the Health Information Security and Privacy Collaboration (HISPC). HISPC offered competitive federal funding to forty states and the two territories of Guam and Puerto Rico that established multi-stakeholder commissions to analyse state privacy and security laws and business practices that could interfere with HIE.

In particular, HISPC teams looked for state policies that went beyond the privacy standard established by the federal HIPAA. The eighteen month contracts were managed by RTI International, a non-profit management consultancy, working in partnership with the National Governors Association Centre for Best Practices, the non-profit technical assistance arm of the State Governors' Membership Association.<sup>7</sup>

#### *State Alliance for e-Health*

In January 2007, the Office of the National Coordinator awarded a contract to the National Governors Association Centre for Best Practices to create a consensus-building entity known as the State Alliance for e-Health (State Alliance). The purpose of the State Alliance is to provide a national platform on which to discuss and analyse state health policies that could lead to HIE. Co-chaired by two governors, the State Alliance is comprised of state legislators, attorneys general, insurance commissioners, local government administrators and private sector representatives.<sup>8</sup> The Alliance, also composed of task forces, issues recommendations for HIT adoption and implementation.

### Where to go next?

After years of investment in state planning and collaboration, it is reasonable to ask what precisely has been learned and how these findings can be taken forward. While not yet a concrete plan of action, recommendations contained in the 2008 report from the Public Programmes Implementation Task Force of the State Alliance for e-Health provides some insight into the consensus growing among policymakers. The taskforce recommendations focused on five main points:

- Setting state e-Health goals;
- Educating providers and consumers;
- Encouraging group and collaborative purchasing of HIT services;

- Providing incentives for adoption; and
- Requiring adoption and use of HIT.

Specific recommendations include creating a state-level coordinating body for HIT with authority for individual state agencies; creating provider mentoring and continuing education programmes to help practices to change patterns; negotiating group discounts to lower HIT start-up costs; and altering reimbursement schemes to incentivise phased-in HIT adoption. In general, the specific recommendations for each category present a roadmap in which voluntary standards and incentive structures lead to uniform, and at times mandatory, standards for HIT and HIE. Determining precisely which responsibilities and standards should be left with state policy-makers, as well as those which must lie with the federal government, will prove an essential component of the US framework for HIT.<sup>9</sup>

### Conclusion

The complexity of health care delivery in the US presents not only the strongest case for HIT deployment but also the biggest challenge to achieving true health information exchange. Federal, state and local initiatives demonstrate that there is much enthusiasm for the promise of HIT, but the existing patchwork of laws and practices highlights the need for more central guidance and coordination, particularly in clarifying privacy and security issues and ensuring interoperability. The \$19 billion stimulus bill may be an important factor in achieving these goals, particularly through the funding that it provides via Medicare payments for physicians to adopt HIT. While the legislation provides yearly incentive payments to physicians, including \$15,000 for the first year of implementation and \$12,000 for the second year; a study done by Miller et al. in 2005 found that for small group practices the cost for HIT implementation would be upwards of \$44,000 per provider in upfront costs, not including revenue lost due to training or loss of productivity.<sup>10</sup>

While impressive in their commitment and forward in their thinking, to date most US planning efforts for HIT implementation have focused on the technological interventions or the standards that define their makeup rather than the problem that the technologies are intended to solve. This is a path that many other nations have followed with varying degrees of success. While such planning is certainly necessary, it may not be sufficient to spur the desired

level of diffusion of HIT or to gain the potential benefits from its use.

Directly merging the HIT agenda with specific quality improvement goals could represent the ideal next generation of HIT planning. Linkage of HIT adoption initiatives with initiatives that target chronic care could be the first step in applying a more dynamic approach. Targeting the highest-cost and most prevalent diseases with the aim of improving care coordination and adherence to a clinical standard could provide the structure of a national system that is lacking, while leaving room for innovation and regulation.

While the US health care system is fragmented, defining priority areas and adopting consensus treatment protocols for patients over the course of an episode of care would create clear lines for intervention, by providers, by payers, and patients alike. These links might then be reinforced through Information Communication Technology (ICT) which would facilitate the coordination of that care. The ICT would also make it easier for the provider to care for the patient according to the protocols that are agreed upon to improve quality for a specific condition, rather than according to new workflow processes determined by the software package. Moreover, state and federal government could continue to work together to lead and convene the stakeholders they have successfully gathered. In short, fixing a problem that everyone acknowledges with a solution that provides value to all stakeholders seems the best way forward, not only in the HIT world, but in the real world as well.

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# Mythbusters

## *Myth: In health care, more is always better*

Picture this: two fifty year-old men are experiencing chest pain and abnormal heart rhythms. One of the men is admitted for care at a local community hospital in a small town. The other is admitted at a teaching hospital in one of the nation's largest cities. It's natural to assume that the city-dweller will fare better, since his hospital spends more money and therefore has greater resources and provides more specialised care. In the same way, it's instinctive to think that the small-town patient will suffer worse outcomes, since his hospital has less money with fewer resources and poorer access to specialised care.

According to the research, however, when it comes to invasive procedures, and even diagnostic testing, "less is more . . . and better".<sup>1</sup> In fact, compared to patients in regions that spend less, patients in high-spending regions are no more satisfied with their care, and actually experience a greater risk of harm and possibly even death.<sup>2-4</sup>

### **Where you live begets the care you receive**

In many cases, it's difficult to determine whether patients receive appropriate care. What is known is that there is great variation in the amount of health care people receive that depends largely on where they live.<sup>5-12</sup> For more than fifteen years the Dartmouth Atlas Project, led by John E Wennberg and Elliott S Fisher, has tracked "glaring variations" in the distribution and use of health care resources in the United States.<sup>2</sup> Based on US Medicare data, the studies consistently show that more resources – specifically, frequent

**Table: Select Dartmouth Atlas studies comparing regional differences in spending and the content, quality and outcomes of care<sup>13</sup>**

	High-spending regions compared to low-spending regions*
Content and quality of care <sup>3,5,14</sup>	Less adherence to process-based measures of quality Little difference in rates of major elective surgery More hospital stays, physician visits, specialist referrals, imaging, and minor tests and procedures
Health outcomes <sup>4,15,16</sup>	Higher mortality over a five-year period following heart attack, hip fracture and colorectal cancer diagnosis Higher survival in regions that practiced medical versus invasive cardiac management of heart attack patients No difference in functional status
Physician perceptions of quality <sup>17</sup>	More likely to report poor communication among physicians More likely to report inadequate continuity of care Greater difficulty obtaining inpatient admissions or high-quality specialist referrals
Patient reported quality of care <sup>18</sup>	Worse access to care and greater wait times No difference in satisfaction

\* High and low spending regions are defined as the US hospital referral regions in the highest and lowest quintiles of per capita Medicare spending.<sup>3</sup>

specialist visits, diagnostics, and specialist and hospital care – don't necessarily lead to better care (see Table).

In one study involving nearly one million patients dispersed over 306 regions in the US (based on where people go for hospital care), Fisher and colleagues found that patients in high-spending regions received 60% more care than those in the

lower-spending areas. However, they did not experience lower mortality rates, better functional status or higher satisfaction.<sup>4</sup> In fact, patients in the lower-spending regions actually received certain preventive services (influenza vaccination, Pap smear and mammography) more often than patients in the highest-spending areas.<sup>3</sup>

It's not just an American phenomenon. In Ontario, the Institute for Clinical Evaluative Sciences has documented large regional variations in the provision of health care for a range of services. Specifically, patients with conditions such as cardiac disease,<sup>8</sup> stroke,<sup>9</sup> arthritis,<sup>10</sup> asthma,<sup>11</sup> and diabetes<sup>12</sup> are getting vary-

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

*The full series is available at [www.chsrf.ca/mythbusters/index\\_e.php](http://www.chsrf.ca/mythbusters/index_e.php)  
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ing degrees of care, despite the availability of evidence-based clinical guidelines in these areas.

Canadian research also highlights that in some cases, ready access to care can be a bad thing for patients. A Vancouver-based study that assessed the effectiveness of a range of elective surgeries found that cataract surgery was often ordered in the absence of significant visual impairment and that it left 27% of patients reporting no change or even deterioration in their visual function.<sup>19</sup> A built hospital bed is a filled one

Other predictors can also drive the use and, more specifically, the overuse of services. These include patient demand, a medical culture in which physicians often do more tests and interventions than are really necessary, and the fee-for-service structures that reward physicians for providing more and more care.<sup>20</sup> One particularly strong predictor that factors into the equation is the availability of health care resources such as hospital beds and specialists.<sup>5</sup> As the 1960s health services researcher, Milton Roemer put it, “A built hospital bed is a filled hospital bed.”<sup>5</sup> In practice, ‘Roemer’s Law’ can indicate inefficient systems that offer ineffective and inappropriate care for patients.

### Conclusion

Although Canadians may feel better when they live in close proximity and have quick access to health care resources, the research suggests they may be experiencing a false sense of security. So is there such a thing as too much medicine? Almost certainly there is, according to a 2002 issue of the *British Medical Journal*.<sup>21</sup> And as everyday life becomes increasingly medicalised, with a new pill or procedure constantly in development, the problem is growing.<sup>21</sup> At the same time, some patients benefit from invasive, high-tech care, but better evaluation of health care performance is needed to identify these cases. Doing so would help in matching resources to population need, with a view to clinical and financial efficiency and overall improvements in quality of care.

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## Assessing relative efficacy of antidepressants

*“The question isn't whether they work or how well they work, but which of them works best, and how might we choose to use them”*

Let's be honest. There are times when the eyes glaze over and the brain goes into a dreamlike trance when statistics and probabilities are thrown around, especially when devoid of any apparent link to reality. Statistics does that to most people, apart, that is, from some statisticians and a small number of pointy-headed academics.

The rest of us feel a need to be grounded, to have some grasp, however tenuous, of what the numbers mean, and how they affect us or other people. It's why we get upset with media headlines about a doubled risk of some incredibly rare event.

Even so, there are times when something comes along that makes us stop and think, and to struggle with the arcane world of statistics and meta-analysis. A recent meta-analysis on antidepressants published in *The Lancet*<sup>1</sup> is one such, perhaps because it might be something of a watershed, not because of the statistics, but the thinking behind it.

### What is efficacy?

Let's start with something comparatively easy. What does efficacy mean? Now there are lots of different definitions, but let's keep this simple. To most of us simple people, there are three questions we want answered, and we don't really care what they are called. Bandolier thinks these three questions worth asking about the 'efficacy' of any intervention are:

*Does it work?* In most, but not all, cases, this implies doing better with the intervention than with an inactive intervention like placebo. Statistics can be useful here, things like relative risk, and p values.

*How well does it work?* After all, it's not much good if something works a very, very, little bit. Ideally we want the intervention to work really well. Here we might want an NNT (number needed to treat).

*How well does it work compared with other interventions we have for this condition?* Here we

might compare NNTs for efficacy outcomes (in league tables on some occasions), but realise quite quickly that there are other issues to consider, like adverse events, and whether patients will accept it, and the cost, and so on. At various times ratios of NNT to NNH (number needed to harm) has been suggested, but in truth there hasn't seemed to be any approach with general applicability. Here we begin to move from efficacy (does it work) to effectiveness (how well does it work in practice).

That is where the multiple-treatment meta-analysis comes in, and can be helpful. Bandolier thinks there is a way of making the approach easier, and do-able on the back of an envelope, but first, a brief description on what was going on.

### Background

Drug treatment of depression involves frequent switching to find a drug that works well for that particular patient, because of the usual problems of lack of efficacy or adverse events. Bandolier covered a terrific randomized controlled trial (RCT) that looked at just this issue (*Bandolier* 95-4), in which only 44% of patients started on a drug were on it at the end. The trial showed that having three SSRIs (selective serotonin reuptake inhibitors) was much better than one. An accompanying editorial made the point that while the three SSRIs were equal on average in clinical trials, they were not equal for every individual patient.

Inevitably, we need more than one antidepressant. The question isn't whether they work or how well they work, but which of them works best, and how might we choose to use them in a sequential treatment cascade to get the best results for patients, both individually, and for the whole population with depression. The multiple treatments meta-analysis set out to ask whether any of twelve new generation antidepressants were noticeably better than the others.

### Methods

The data set was 117 randomised trials comparing one antidepressant with another; placebo-only controls were not used. Trials lasted six to twelve weeks. Doses of drugs were set as low, medium, or

*Bandolier is an online journal about evidence-based healthcare, written by Oxford scientists. Articles can be accessed at [www.medicines.ox.ac.uk/bandolier](http://www.medicines.ox.ac.uk/bandolier)*

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high, depending on pre-set criteria.

Two outcomes were used. The first, and efficacy outcome, was at least 50% reduction in a recognised depression score, or clinical global impression of much or very much improved, at eight weeks. The second, acceptability, outcome was all-cause with-

drawals at eight weeks. Some sophisticated statistics were then done, both on pairwise analyses and then on all the data comparing direct and indirect comparisons, and did sensitivity analyses on doses within the therapeutic range, and on methodological issues.

**Results**

Results were expressed as the probability of any of the twelve drugs being among the top four for both efficacy and acceptability. Figure 1 shows the cumulative probability for both criteria as a percentage – with higher percentages obviously better.

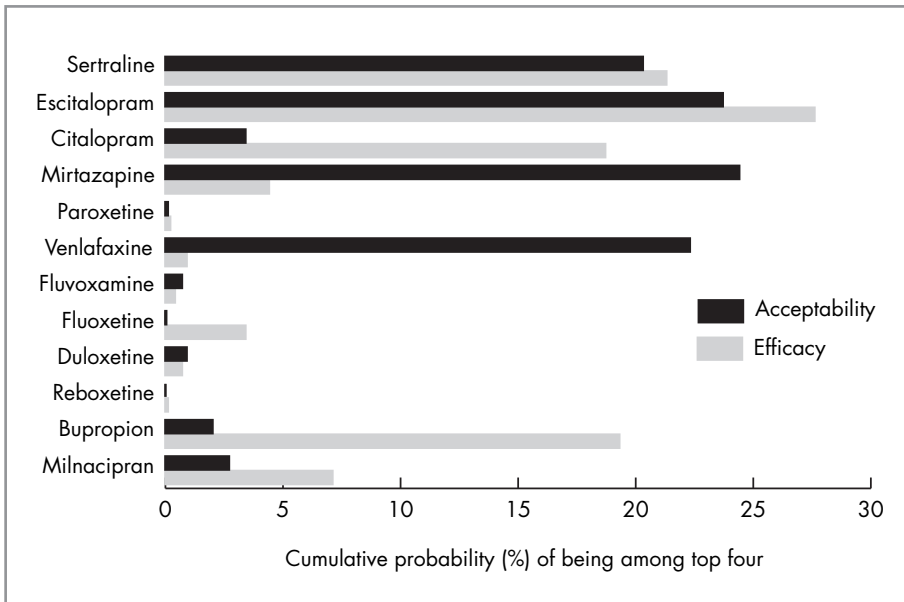
Some drugs (sertraline, escitalopram) do well on both counts, while others (citalopram, mirtazapine, venlafaxine) do well in one but not the other. Some (paroxetine, reboxetine) have a low probability of being in the top four on either criterion. Issues of dose and method made no difference to the overall results in sensitivity analyses, and direct and indirect analyses gave different results no more than may be expected by chance.

**Comment**

This is excellent. Knowing that several antidepressants perform generally better than others is useful, and we may conclude that those at the top of the ladder might come earlier in any care pathway of treatment strategy, but that doesn't mean that the others are without effect.

Bandolier has tried a slightly different approach using the data from the paper. Figure 2 shows the numbers of patients with

**Figure 1: Probability of being among top four drugs for efficacy (at least 50% reduction in depression score) and acceptability (all cause withdrawal) at mean of eight weeks of treatment**



**Figure 2: Simplified assessment of efficacy and acceptability using simple percentages for efficacy (at least 50% reduction in depression score) and acceptability (all cause withdrawal) at mean of eight weeks of treatment, together with some information on cost**

CIPRIANA DECONSTRUCTED							
		Substantial improvement ≥50% reduction from baseline (higher percentage better)			All cause withdrawal (lower percentage better)		
		Events	Total	%	Events	Total	%
Consider using one of these drugs first	Sertraline	1528	2453	62	515	2317	22
	Escitalopram	1617	2736	59	542	2859	19
	Citalopram	1096	1928	57	384	2088	18
	Mirtazapine	862	1398	62	312	1251	25
Probably useful when first four shown not to be helpful	Paroxetine	1936	3427	56	973	3621	27
	Venlafaxine	1696	2827	60	727	2855	25
	Fluvoxamine	407	779	52	195	779	25
	Fluoxetine	2857	5196	55	1427	5145	28
Probably not worth considering at all	Duloxetine	690	1368	50	326	1217	27
	Reboxetine	326	683	48	211	683	31
*not licensed for depression in the UK	* Bupropion	928	1623	57	474	1708	28
	* Milnacipran	271	569	48	197	569	35
Costs key:		<£5 per month		Efficacy and acceptability key:		Indicates most effective or acceptable	
(shade of box behind drug name)		£5–10 per month				Indicates intermediate efficacy or acceptability	
		£15–25 per month				Indicates least effective or acceptable	
		>£25 per month					

efficacy and acceptability criteria, the total number, and the percentage with each outcome. These were then simply divided into those with the best (white background) and worse (shaded light grey) performance for each outcome, with the others shaded mid grey. There is broad agreement with the statistical approach. Drugs doing best with efficacy generally also did well for acceptability, while those doing worse for efficacy generally did worse on acceptability.

In addition, simple cost information is provided, based on approximate cost for a month of treatment in the UK, using British National Formulary costs for medium doses. Generally, those drugs doing better on efficacy and acceptability had lower costs.

The implication is again that in creating care pathways it would be better to use the drugs at the top of the table first. Note that two of the twelve drugs (bupropion, milnacipran) do not have a UK license for depression at the time of writing.

### Objections

Not everyone likes the meta-analysis, and MeReC<sup>2</sup> took issue with it on a number of points. It is useful to question them.

(1) Most studies were done by pharmaceutical companies. That of course is true, and large independent trials are perhaps to be desired. But the fact is that, in the world in which we live, most trials have commercial interests. The development of rigorous criteria for design, reporting, conduct, and monitoring of trials has been instituted to prevent commercial and other biases affecting results. Ask the question from another angle: where is the convincing evidence that these trials are wrong? They have been accepted by regulatory agencies like the FDA (US Food and Drug Administration) and EMEA as being adequate, on the basis of much greater detail than is presented in published papers.

(2) Discrepancies existed between indirect and direct comparisons. This is directly answered in the paper, where six out of 133 comparisons were different, exactly the expected number by chance alone. Put the other way, 127 out of 133 direct and indirect comparisons gave the same result.

(3) Studies were poor quality. The description of treatment allocation was unclear in most trials (105/117 trials), as it is in 90% of trials. There are two Cochrane reviews just published on escitalopram and sertraline.<sup>3,4</sup> These show that all trials were described as both randomised and double

blind, the areas most likely associated with bias. As the meta-analysis itself discusses, this is usually an issue of reporting in journals with tight word limits rather than an issue of conduct. The problem with using treatment allocation concealment as the main or only criterion means that unclear is the best you can get.

(4) Mean sample size was small. The mean sample size was 110 participants per group (range 9–357). Bandolier is also concerned about small studies, and prefers omitting trials of small size. But one of the reasons we do meta-analyses is to overcome the problem of size. A quick look at Figure 2 shows that for most of the drugs there were impressively large numbers, and in total about 26,000 patients were involved. None of the drugs favoured had fewer than 1,000 patients treated.

(5) The mean duration was only six weeks, and trials were all six to twelve weeks in duration. It is useful to question trial duration when the use of an intervention is longer. Firstly, any shorter trials have been omitted. In the absence of substantial evidence from longer trials, this is the best we have. In what amounted to a real world primary care experiment, only 44% of patients were still taking the treatment to which they had been randomised by nine months. Others either switched to another antidepressant or stopped treatment because of adverse effects or lack of efficacy. There is an argument that six to twelve weeks is the window in which issues of lack of efficacy, adverse events, and switching take place, making it the ideal period trial duration on which to base decisions.

(6) The clinical significance of the dichotomous measure of efficacy is unclear. This is a very old-fashioned argument. Using mean data is hopeless for all sorts of reasons, some of which are rehearsed below. Similar dichotomous outcomes are now becoming widely used in other areas, and are proving very useful. This is no more than a trivial objection; though that does not mean that better dichotomous outcomes won't be developed.

(7) No adjustments were made for multiple statistical testing, another useful point. On the other hand, the simplistic approach outlined in Figure 2 produces much the same result.

### Further comment

This approach has application way beyond just depression. This has every prospect of being a useful methodological simplifica-

tion and advance that could be used much more widely. The use of a dichotomous measure of benefit, set at a high level, is in accord with developing thinking in a number of fields. Combining this with a measure of how many people can take the drug hits directly at effectiveness – because there's no benefit at all when people can't take it.

Changes in average scores usually reflect the experience of very few patients. Moreover, it is common to use last observation carried forward, meaning that people who discontinue can still contribute to efficacy measures, even when there can be none because they have stopped taking it.

There is one other comment. The authors suggest that their results make sertraline the base case – raising the base well above placebo. They raise the question whether sertraline should be the new placebo, or at least the common comparator for all future depression trials.

And finally, the main point in all of this is that of getting “the best for the most with the least”. What the meta-analysis provides is the raw material for the next step, namely creating and testing a care pathway or pathways for depression that provides good results for the largest number of sufferers in the shortest time and at the lowest cost.

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Eurohealth aims to provide information on new publications that may be of interest to readers. Contact Azusa Sato at [a.sato@lse.ac.uk](mailto:a.sato@lse.ac.uk) if you wish to submit a publication for potential inclusion in a future issue.

## Theory versus practice: discussing the governance of health technology assessment systems

Paul Healy and Meir Pugatch



London: Stockholm Network, 2009

63 pages

Freely available online at:

[http://www.stockholm-network.org/downloads/publications/Theory\\_versus\\_Practice.pdf](http://www.stockholm-network.org/downloads/publications/Theory_versus_Practice.pdf)

This report gives an overview of governance in the field of Health Technology Assessment (HTA) systems. It takes the cases of four countries – Australia, Canada, Germany and the United Kingdom - to analyse some of the key elements within HTA systems, and finds that whilst these systems have much in common, there are still considerable differences among them, ultimately leading to different outcomes and outputs.

Aside from describing and analysing each agency and rationale for HTA, the report's main aim is to categorise each system under five separate ideas: their relationship with health care decision makers ('policymaking'); the competence of HTA bodies to provide recommendations of technologies

('competence'); the degree of openness and inclusion from various stakeholders ('accessibility'); output and performance ('functionality'); and public perception ('perception'). Having done this, the report then recommends that HTA bodies need flexibility to appreciate local and individual concerns. Further, the authors argue for a more transparent system whereby decision making processes are there for all to see. Once HTA decisions have been made, their integration into national health systems are crucial and must take into account policy actions and budgetary consequences in a wider context. Finally, the report urges both the public and policymakers to keep a critical eye on the system to realise its full potential.

*Contents:* Glossary of acronyms; Executive summary; Introduction; HTA process; HTA systems; Australia; Canada; Germany; United Kingdom; Conclusions and policy considerations; Bibliography

## Child day care centre or home care for children aged 12–40 months of age – what is best for the child?

Edited by Sara Holmgren



Ostersund: Swedish National Institute of Public Health, 2009

ISBN: 978-91-7257-617-9

40 pages

Freely available online at:

<http://www.fhi.se/PageFiles/6290/R2009-09-Child-day-care-center-or-home-care.pdf>

In Sweden it is common that both parents work, full- or part-time. Most children whose parents work are enrolled in day care centres. Statistics from the Swedish National Agency for Education show that in 2008, 46% of all twelve to twenty-three month old children, as well as 85.8 % and 88.8% of those aged twenty-four to thirty-five months and thirty-six to forty-eight months respectively were enrolled in day care centres. In 2008, the Swedish government introduced a child-raising allowance to enable parents to stay at home with their children beyond the standard period of paid parental leave.

With this as a background, the Swedish National Institute of Public Health conducted a literature review in order to examine what is the best for the child in the preschool years between twelve and forty months of age. Child outcomes from day care centres versus home care experiences were captured using measures of cognitive and socioemotional development. International studies were included if quality of day care centres were

comparable to those found in Sweden.

The review found four studies that met quality requirements. In two of these studies, day care children demonstrated higher cognitive and language skills at age thirty-six months. Long-term effects of day care centres were demonstrated in both verbal and mathematical ability in eight-year old children. In the other two studies, no such effects were detected. No firm conclusions could be drawn on the effect of day care centres on socio-emotional development.

Overall the review concludes that day care centres enhance cognitive development. From a public health perspective, it argues that children at risk, and especially children from poor families, benefit from enrolment in day care centres. It notes an association between child poverty and poor developmental outcomes that can be reduced through investment in high quality day care centres.

*Contents:* Foreword; Summary; Introduction; Background; Objectives; Methods; Results; Discussion; Conclusions; Appendices

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## Swedish Presidency of the EU

<http://www.se2009.eu>

Sweden takes over the presidency of the EU in July 2009. In respect of the social policy, health and consumer affairs' web pages on the site, users can browse upcoming events and conferences, as well as download policy documents related to labour market inclusion, non-discrimination, health and dignified ageing, alcohol-related harm and patient rights to health care in the EU. The site can be accessed in English, Swedish and French.

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## National Institute for Health Research School for Social Care Research (NIHRSSCR)

<http://www.lse.ac.uk/collections/NIHRSSCR>

The NIHR School is a partnership between five leading academic centres for social care research in England, all of whom have a mission to improve care services and practice. The web site outlines objectives, research areas and visions, as well as activities and ongoing consultations. The news and 'in the media' sections include links to recent press releases and interviews. Contact details of staff and listings of the advisory board can also be found online.

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## Alzheimer Europe

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

Alzheimer Europe is a non profit organisation that aims to improve the care and treatment of Alzheimer patients through collaborations with member associations in Europe. The web site provides an overview of the disease and the role of national associations. This includes information on the prevalence of dementia, tips for carers, as well as data on rare forms of dementia and legal rights in different countries. Reports are also available for download and purchase. Past and future Alzheimer Europe conference news is presented and an exclusive members' only area exists. The site is available in ten European languages.

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## Health and Environment Alliance (HEAL)

<http://www.env-health.org>

HEAL is an alliance of non-governmental organisations, professional bodies representative of doctors and nurses, academic institutions and other not-for-profit organisations. Its mission is to protect the environment as a means of promoting the health of all people living in Europe, as well as to ensure the participation of citizens in environmental and health-related policy making at the European level. The website outlines challenges, policy implications and priorities, especially in light of climate change. A video link to You Tube is also provided, in addition to downloadable publications, newsletters, subscription services and posters of past campaigns. The site is hosted in English only.

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## Determine

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

Determine is an EU consortium for action on policies and interventions to promote health equity within and between European countries. The website provides an outline of EU and national policies, databases, a directory of 'good practice' and links to upcoming events. Although pages are available in English only, some documentation is also available in twelve European languages.

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## European Social Network (ESN)

<http://www.esn-eu.org/home/index.htm>

ESN, a not-for-profit charitable company established in 1998, coordinates an independent network of local public social services in Europe. It brings together directors of social work and social care services working at the local level, in order to bridge the gap between European policy-making and local social care practice and management. The English language website contains publications, policy reports and e-newsletters that are available for download. There is also a special section dedicated to social care in central and eastern Europe.

# News

## NEWS FROM THE INSTITUTIONS

### World Health Assembly held amid concerns about flu pandemic

The 62nd World Health Assembly took place in Geneva from 18 to 22 May. In her address to the Assembly, WHO Director-General, Dr Margaret Chan noted that the world was facing multiple crises, including the current financial crisis and global economic downturn. In addition to this, it also faced the prospect of the first influenza pandemic of this century. In view of the influenza situation WHO Member States earlier agreed to shorten the Assembly from nine to five days.

Dr Chan said that the world today was more vulnerable to the adverse effects of an influenza pandemic than it was in 1968, when the last pandemic began. The increase in air travel meant that any city with an international airport was at risk of an imported case. Global economic interdependence amplified the potential for economic disruption. Under these circumstances, it was vital to see that no part of the world suffered disproportionately. "We have to care about equity. We have to care about fair play," she said.

Dr Chan noted that 85% of the burden of chronic diseases was concentrated in low-income and middle-income countries, which meant that the developing world had by far the largest pool of people at risk for severe and fatal H1N1 infections. She urged the international community to look at everything that could be done to collectively protect developing countries from bearing the brunt of an influenza pandemic.

The Director-General said she had reached out to manufacturers of antiviral drugs and vaccines, to Member States, donor countries and UN agencies, civil society organisations, nongovernmental organisations, and foundations to stress the need to extend prepara-

tion and mitigation measures to the developing world. The United Nations Secretary-General had joined her in these efforts.

Dr Chan also said that concerns about a pandemic should not overshadow, or interrupt other vital health programmes. She said that an effective public health response to threats depended on strong health systems that were inclusive, and offered universal coverage down to the community level. Adequate numbers of trained, motivated and compensated staff, as well as fair access to affordable medical products and other interventions were all required for an effective public health response to the current situation.

The Assembly closed with the adoption of resolutions. In addition to measures in respect of influenza these included endorsing strict quality standards for the provision of anti-tuberculosis (TB) drugs and efforts to limit their misuse and agreement to strengthen measures to make access universal to multi and extensively drug resistant (M/XDR) TB diagnosis and quality treatment. Research for new TB diagnostics, medicines and vaccines is also prioritised under the resolution through support for extra financing. At the same time, WHO will also work with Member States to develop national TB response plans that will prevent more people from getting drug-resistant tuberculosis, and diagnose and treat those that do.

After intense debate, Member States also adopted a final plan of action on public health, innovation and intellectual property which includes an agreed list of stakeholders who will be involved in the process, as well as a time frame and progress indicators by which to monitor progress. The plan of action aims, among other things, to foster innovation and improve access to medicines for diseases that disproportionately affect the poor.

In respect of the social determi-

nants of health a resolution urged WHO Member States to show political commitment, "as a national concern", towards the main principles as set out in the WHO report on the social determinants of health; to encourage dialogue among different sectors of government with a view to "integrating a consideration of health into relevant public policies and enhancing intersectoral action"; and to "consider developing and strengthening universal comprehensive social protection policies" to ensure that everyone has access to goods and services essential to health and well-being.

The Assembly also adopted a resolution on the renewed commitment to primary health care, with a particular emphasis on the need to ensure that health systems are adequately financed to ensure comprehensive health services are available to everyone in the context of the current international financial crisis. It urged Member States to develop "national equitable, efficient and sustainable financing mechanisms" which allow for universal access to primary health care; to "to promote active participation by all people" through the empowering of communities, especially women, in the processes of developing and implementing policies; to develop and strengthen health information and surveillance systems in order to "facilitate evidence-based policies and programmes and their evaluation" and to ensure an appropriate mix of skills among primary health care staff, to ensure an effective response to people health care needs.

Other resolutions include a work plan to scale up WHO's technical assistance to countries to assess and address the implications of climate change for health and health systems, and a call for Member States to formulate national policies, regulations and standards, as part of comprehensive national health systems to promote appropriate, safe and effective use of traditional medicine.

Press releases and other suggested information for future inclusion can be emailed to the editor David McDaid [d.mcdaid@lse.ac.uk](mailto:d.mcdaid@lse.ac.uk)

The Director General's speech to the Assembly can be accessed at [http://www.who.int/dg/speeches/2009/62nd\\_assembly\\_address\\_20090518/en/index.html](http://www.who.int/dg/speeches/2009/62nd_assembly_address_20090518/en/index.html)

Further information on proceedings available at [http://apps.who.int/gb/e/e\\_wba62.html](http://apps.who.int/gb/e/e_wba62.html)

### Fighting Cancer: new European partnership

On 24 June the European Commission created the European Partnership for Action against Cancer. It will focus on actions that can be taken at EU level to more effectively prevent and control cancer across Europe. In Europe, one in three people will develop cancer in their lifetime. This translates to 3.2 million people being diagnosed with the disease every year. Cancer is not equally distributed in Europe and the chances of surviving cancer differ greatly between countries. By bringing together all relevant organisations working on cancer, the intention is to identify gaps, address needs and learn from each other.

This represents the latest in a series of Commission actions related to cancer. Most recently the Commission published European guidelines for quality assurance in breast and cervical cancer screening and diagnosis adopted a Report on the Implementation of the Council Recommendation on cancer screening in December 2008.

The new European Partnership will be launched officially in Brussels in autumn 2009. It aims to support countries in their efforts to tackle cancer by providing a framework for identifying and sharing information, capacity and expertise in cancer prevention and control. It will engage a wide range of stakeholders, including non governmental organisations, researchers, patients groups, industry and national authorities across the EU in a collective effort and with a common commitment to addressing cancer. This approach will also help to avoid fragmented and/or duplicate efforts.

#### Health promotion and early detection of cancer

One third of all cancers are preventable, and prevention offers the most cost-effective, long-term strategy for reducing the burden of cancer. The Partnership also aims to put in place healthy lifestyle interventions and improved early detection of cancer, by achieving 100% population

coverage for screening for breast, cervical and colorectal cancer, which can dramatically reduce the impact of the disease and the loss of lives.

#### Identification and dissemination of good practice in cancer-related health care

By focusing on best practice, the Partnership hopes to encourage a multi-disciplinary and comprehensive approach to cancer-related healthcare, which will ensure a better quality of life for cancer patients. This will help to reduce inequalities in cancer deaths related to health care between different Member States; the Partnership is aiming for a 70% reduction by 2020.

#### Priorities for cancer research

The Partnership will work towards developing a more coordinated approach to cancer-related research across the EU, with a particular focus on identifying and tackling discrepancies and obstacles in cancer-related research. By doing so, at least one third of all European research efforts should be coordinated by the end of the Partnership.

#### Health information and data

It is important to continuously collect and analyse information and data on cancer in order to ensure effective public health interventions. To this end, the Partnership will examine current obstacles in the collection of this necessary information and look for solutions – by 2013, comprehensive data for all Member States should be available for the first time.

More information on the new European Partnership at <http://tinyurl.com/mzk9sx>

### WHO report highlights health sector's carbon footprint

Cutting carbon dioxide (CO<sub>2</sub>) emissions in the health sector must form part of a comprehensive package of measures to mitigate the impact of climate change at the December climate conference in Copenhagen according to the World Health Organization (WHO).

A discussion draft report prepared by the WHO and the non-governmental organisation Health Care Without Harm, says hospitals have a major role to play and can reduce their environmental impact by using alternative energy sources, designing 'greener' buildings, and being more efficient in their use of water, transport and food. By 'shopping green', the health sector can make its own operations more ef-

ficient and can help leverage broader change throughout the economy, according to the report.

The authors also called on the United Nations Climate Change Conference to specifically promote climate change mitigation in the health sector. It is suggested that prioritising primary health care and pursuing disease prevention strategies, in order to lower dependence on resource-intensive therapies, can simultaneously reduce the burden of disease and the health sector's fossil fuel consumption.

Several examples of good practice are highlighted. It notes that the National Health Service in England has taken a lead in this area and proposed a range of measures including offering fewer meat and dairy products on its menus. It calculates that it spends £20 billion a year on goods and services, which translates into a carbon footprint of 11 million tonnes, 60% of the NHS's total carbon footprint.

Addenbrooke's Hospital in Cambridge, England, has reduced the number of cars on the campus by 16%, with staff car use down 22%. The health authorities have commissioned a bus to the hospital, offered discounted bus passes and introduced interest-free loans for bicycles as well as a car share scheme. At the Pilgrim Hospital, Lincolnshire, England, a biomass boiler will come into operation next year as part of a plan to cut its CO<sub>2</sub> emissions by 50%. The boiler will run on locally harvested and renewable woodchips and will be supplemented by a Combined Heat and Power (CHP) plant which will generate electricity for hospital operations.

In Torun City Hospital in Poland improved insulation, room temperature control and modern heaters have helped produce energy savings of 30% in renovated buildings and 54% in new buildings. At Constance Hospital in Baden-Württemberg, Germany, CO<sub>2</sub> emissions have been cut by over 25%. The hospital installed solar panels and CHP technology that has 75% efficiency (versus 35% efficiency for conventional generators). In addition, buildings and windows throughout the hospital have been equipped with thermal insulation.

The report lists seven elements for a climate-friendly hospital:

*Energy efficiency:* reduce hospital energy consumption and costs through efficiency and conservation measures;

*Green building design:* build hospitals that



are responsive to local climate conditions and optimised for reduced energy and resource demands;

*Alternative energy generation:* produce and/or consume clean, renewable energy onsite to ensure reliable and resilient operation;

*Transportation:* use alternative fuels for hospital vehicle fleets; encourage walking and cycling to the facility; promote staff, patient and community use of public transport; site health care buildings to minimise the need for staff and patient transportation;

*Food:* provide sustainably grown local food for staff and patients;

*Waste:* reduce, re-use, recycle, compost; employ alternatives to waste incineration;

*Water:* conserve water; avoid bottled water when safe alternatives exist.

Dr Pendo Maro, joint senior climate change and energy advisor at Health Care Without Harm and the Health and Environment Alliance said Europe's health sectors have a key role to play in Copenhagen, "With the world's governments set to establish a new agreement for addressing climate change in Copenhagen this December, it is essential that Europe's health sector speaks out and puts pressure on the EU and our governments to advocate for a strong stance that addresses the most serious environmental health issue that the world faces today."

The report can be accessed at <http://www.noharm.org/details.cfm?ID=2199&type=document>

### European Commission and Russia agree to strengthen dialogue in public health

On 28 May in Moscow, European Health Commissioner Androulla Vassiliou and Minister of Health and Social Development of the Russian Federation Ms Tatyana Golikova signed Terms of Reference for establishing a dialogue in public health.

This dialogue goes beyond the current health provisions in the EU–Russia Partnership and Cooperation Agreement. For example, it includes the monitoring and control of the spread of HIV/AIDS, tuberculosis, and other infectious diseases, the promotion of healthy lifestyles to reduce avoidable premature mortality and strengthening surveillance the cooperation on the development of common food safety standards.

Following the signature of these Terms of Reference, Commissioner Vassiliou said that "concerted health promotion efforts and an effective collaboration across borders are essential to the future of our health systems. Health challenges, common to Member States and Russia, can be better addressed when tackled by joint actions and international initiatives. This dialogue on public health will contribute to the current EU–Russia Partnership as well as to future bilateral relations and to global health initiatives."

Commissioner Vassiliou and Minister Golikova also discussed possibilities for immediate joint actions related to influenza A H1N1, youth health, as well as diet and nutrition. The health dialogue is part of a wider process of improving EU–Russian contacts, which was agreed at the EC–Russia summit in 2005.

### European Commission steps up action on Alzheimer's disease and other neurodegenerative conditions

There are currently over seven million people with Alzheimer's disease (70% of all dementia cases) and related disorders, including vascular dementia, in Europe and it is predicted that this number will double in the next twenty years. In 2005, the total direct and informal care costs of Alzheimer's disease and other dementias were estimated at €130 billion in the EU27 (€21,000 per patient); 56% of these costs were for informal family care.

The European Commission's 2007 EU health strategy 'Together for Health' identified the need to better understand neurodegenerative diseases such as Alzheimer's in the context of ageing. In the latest move on 22 July 2009, the European Commission adopted concrete proposals to tackle Alzheimer's disease, dementias and other neurodegenerative conditions.

EU Health Commissioner Androulla Vassiliou said that "losing mental capacity to dementia is not just a normal part of getting older. As the European population ages, we must work together to better understand and prevent these conditions. We must show our solidarity to people with dementia by sharing best practice in caring for them and respecting their rights and dignity."

EU Science and Research Commissioner Janez Potočnik said that "we want to help research play a bigger role in tackling such societal challenges as Alzheimer's and re-

lated disorders. The Commission already has a track record of supporting European research projects with the best scientists in this area. But we will see a major step ahead if Member States now start coordinating their national programmes around a common agenda".

The Commission proposes four main areas of action: acting early to diagnose dementia and to reduce the risk of dementia in the first place; improving research coordination between EU countries; sharing best practice; and providing a forum to reflect on rights, autonomy and dignity of patients.

Alzheimer's disease and related disorders have been identified by EU Member States as an area where the first Joint Programming of research activities should be launched. Joint Programming addresses EU countries willing to engage in the development of a common Strategic Research Agenda which will allow their participation on a variable geometry basis. Twenty countries have already shown their willingness to pool resources and to conduct research in an area where a common initiative would offer major added value compared with the current, fragmented research efforts in Europe.

The Commission Communication on a European Initiative on Alzheimer's disease and other dementias is available at [http://ec.europa.eu/health/ph\\_information/dissemination/diseases/alzheimer\\_en.htm](http://ec.europa.eu/health/ph_information/dissemination/diseases/alzheimer_en.htm)

### Antitrust: shortcomings in pharmaceutical sector require further action

Market entry of generic drugs is delayed and there is a decline in the number of novel medicines reaching the market, according to the European Commission's final report on competition in the pharmaceutical sector.

The inquiry began in January 2008 to examine the reasons why fewer new medicines were brought to market and why generic entry seemed to be delayed in some cases. The goal was to find ways that help the market work better. Tensions have been high between the industry and the Commission following a dramatic series of unannounced raids on the offices of top pharmaceutical companies in January and November 2008. A preliminary report published in November 2008 alleged that anti-competitive practices in the sector were hampering innovation and blocking the entry of cheap generics onto the

European market.

More than seventy submissions were received from stakeholders. Consumer associations, health insurers and the generics industry welcomed the results, arguing that they confirm their concerns. The originator industry and their advisors supported the call for the creation of a Community Patent and a specialised litigation system, whilst arguing that generic delay and the decline in innovation had been caused by regulatory shortcomings.

The final sector inquiry report represents a shift in tone. It suggests that company practices are among the causes, but does not exclude other factors such as shortcomings in the regulatory framework. As a follow up, the Commission intends to intensify its scrutiny of the pharmaceutical sector under EC antitrust law, including continued monitoring of settlements between originator and generic drug companies. The first antitrust investigations are already under way. The report also calls on Member States to introduce legislation to facilitate the uptake of generic drugs and notes near universal support amongst stakeholders for a Community Patent and specialised patent litigation system in Europe.

#### *Main findings and policy conclusions*

The inquiry has contributed significantly to the debate on European policy for pharmaceuticals, in particular for generic medicines. On the basis of a sample of medicines that faced loss of exclusivity in the period 2000–2007 in seventeen Member States, the inquiry found that citizens waited more than seven months after patent expiry for cheaper generic medicines, costing them 20% in extra spending.

Generic delays matter as generic products are on average 40% cheaper two years after market entry compared to the originator drugs. Competition by generic products thus results in substantially lower prices for consumers. The inquiry showed that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible.

The inquiry also confirms a decline of novel medicines reaching the market and points to certain company practices that might contribute to this phenomenon. Further market monitoring is ongoing to identify all the factors that contribute to this decline in innovation.

Reacting to the findings, the Commission

will apply increased scrutiny under EC Treaty antitrust law to the sector and bring specific cases where appropriate. The use of specific instruments by originator companies in order to delay generic entry will be subject to competition scrutiny if used in an anti-competitive way, which may constitute an infringement under Article 81 or 82 of the EC Treaty. Defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts will remain under scrutiny.

To reduce the risk that settlements between originator and generic companies are concluded at the expense of consumers, the Commission will carry out further focused monitoring of settlements that limit or delay the market entry of generic drugs. In the case of clear indications that a submission by a stakeholder intervening before a marketing authorisation body was primarily made to delay the market entry of a competitor, injured parties and stakeholders are invited to bring relevant evidence of practices to the attention of the relevant competition authorities.

On regulatory issues the inquiry found that there is an urgent need for the establishment of a Community patent and a unified specialised patent litigation system in Europe to reduce administrative burdens and uncertainty for companies. A full 30% of patent court cases are conducted in parallel in several Member States, and in 11% of cases in national courts reach conflicting judgements.

Recent initiatives of the European Patent Office (EPO) to ensure a high quality standard of patents granted and to accelerate procedures are welcome. This includes measures taken in March 2009 to limit the possibilities and time periods during which voluntary divisional patent applications can be filed.

As a result of the inquiry the Commission is also urging Member States to ensure that third party submissions do not occur and in any event do not lead to delays for generic approvals. It also urges them to significantly accelerate approval procedures for generic medicines, take action if misleading information campaigns questioning the quality of generic medicines are detected in their territory, and streamline trials that test the added value of novel medicines.

To assist Member States in delivering speedy generic uptake and improved price

competition, the report contains an overview of national measures and their effects on generic uptake (volume, prices, number of entrants) and encourages Member States that want to benefit from generic savings to consider such measures. In this light the Commission will also examine existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).

#### *Reaction*

Speaking on the publication of the report Competition Commissioner Neelie Kroes said that “we must have more competition and less red tape in pharmaceuticals. The sector is too important to the health and finances of Europe’s citizens and governments to accept anything less than the best. The inquiry has told us what is wrong with the sector, and now it is time to act. When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices. The first antitrust investigations are already under way, and regulatory adjustments are expected to follow dealing with a range of problems in the sector.”

Arthur J Higgins, Chief Executive Officer Bayer Healthcare and president of the European Federation of Pharmaceutical Industries and Associations, welcomed the report and focused on streamlining intellectual property infrastructure saying that “we have stated consistently that complex and divergent regulatory barriers are the primary cause of market entry delay for both generic and innovative medicines. We are pleased that the final report recognises this reality.”

“We welcome many of the policy recommendations, such as a more streamlined patent system that reduces costs and increases legal and commercial certainty. We commit to working constructively with the internal market commissioner, member states, and the European Patent Office to push reforms forward under the Swedish Presidency. What is important is that the Commission uses this report to address the issue of competition in the off-patent market. This is an area that can generate savings which could be reinvested to fund innovative medicines.”

Greg Perry, Director General of the European Generic Medicines Association also welcomed the “importance given by the European Commission to the need of

high quality patents and raising the bar for patent applications. The existence of certain dubious secondary patents has indeed created a block against competition and undermined confidence in real innovation.” He reiterated the need for urgent reform in the pharmaceutical sector, calling for Europe’s legislative framework to be tightened in the areas of patent law, pharmaceutical legislation, price and reimbursement rules and competition law.

Monique Goyens, director-general of European consumer organisation BEUC, said the sector inquiry shows the pharmaceutical industry is not working properly and that “vicious tactics” are used to delay or prevent the entry of more affordable and innovative medicines into the market. “Millions of euros are spent in promotional activities, in legal disputes and settlement agreements instead of in the development of new medicines to meet patients’ needs,” Goyens said. She called for concrete actions at EU and member state level to address unethical practices.

*The final report and other documentation are available at <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html>*

### Health Council conclusions

At a meeting of the EU Health Ministers at the Council of the European Union in Luxembourg on 8 and 9 June EU health ministers have adopted a recommendation on patient safety, including prevention and control of health-care related infections. The objective of the proposals is to support national-level implementation of prevention strategies and programmes and control of undesirable events and infections related to health-care providers. Member States have been asked to develop common definitions and terminology on patient safety which can be shared, and also to establish a set of reliable and comparable indicators, to identify safety problems, to evaluate the effectiveness of interventions aimed at improving safety and to facilitate mutual learning in this area.

The Council also adopted a recommendation on an action in the field of rare diseases which aims to provide a coordinated EU approach to ensure effective recognition, prevention, diagnosis, treatment, care and research in the field of rare diseases in Europe.

The Health Ministers also held a public debate on the issue of cross-border health-care in an attempt to provide a platform

for ministers from Member States to discuss their existing concerns about the directive. Despite an overall consensus about the need for cooperation in the field of health care, ministers still had worries about the need for prior authorisation, the legal basis for the proposals and the issue of long-term care. The first round of negotiations may have concluded but there remains a lot of work to be done in order to reach agreement on these proposals.

### Pharmaceutical package

On the basis of three progress reports from the Presidency, the Council held an exchange of views on the legislative proposals forming the ‘Pharmaceutical package’. With regard to preventing falsified medicinal products from entering the legal supply chain, ministers broadly welcomed the proposal, highlighting the importance of the draft directive for the safety of medicinal products.

The discussions in the responsible Council working group have shown that delegations consider the Commission proposal to be a good basis for improving the existing directive on medicinal products for human use as regards protection against falsified medicinal products. However, individual elements of the proposal need further discussion. This concerns particular definitions, for example, of ‘falsified medicinal products’, the scope of the proposal and the safety features.

Concerning ‘pharmacovigilance’, i.e. the strengthening of the EU system for safety monitoring of medicinal products, ministers warmly welcomed the Commission proposals for a regulation and a directive, and highlighted their contribution to the protection of patients. Initial discussions in the responsible Council working group show however, that continued examination of the proposals is necessary, in particular with regard to the composition, role and mandate of the proposed Pharmacovigilance Committee and its interaction with other preparatory bodies of the European Medicines Agency (EMA).

As regards the proposed regulation and directive concerning provision of information by marketing authorisation holders, many ministers expressed concerns that had already been raised in the working group. While agreeing that there is a need to improve the information to the general public on prescription-only medicinal products, many delegations fear that the suggested system will be overly burdensome for competent authorities

without leading to significant improvements in the quality of the information provided to patients. In addition, many delegations hold that the distinction between ‘information’ and ‘advertising’ is not sufficiently clear and therefore fear that the proposals will not provide sufficient guarantees that the prohibition of advertising of prescription-only medicinal products to the general public will not be circumvented.

All five proposals are based on Article 95 of the Treaty (internal market); qualified majority required for a Council decision; co-decision procedure. The first-reading opinion of the European Parliament is expected at the earliest in the autumn of 2009.

*More information at <http://tinyurl.com/mvrgqfo>*

## NEWS FROM THE EUROPEAN COURT OF JUSTICE

### ECJ: Can a risk to health turn a food supplement into a medicinal product?

On 30 April 2009, the ECJ issued a judgment relating to the classification of borderline products (C-27/08, BIOS Naturprodukte GmbH v Saarland) which further clarifies and harmonises the classification criteria for borderline products in the EU.

The plaintiff, BIOS Naturprodukte GmbH, a company marketing several food supplements in Germany, placed the product in question on the German market as a food supplement. German authorities prohibited BIOS from continuing to offer the product on the ground that it was a medicinal product which had not received prior marketing authorisation. Scientific research had shown that the recommended daily dose of the product was unable to produce therapeutic effects but on the other hand posed a certain risk to health since it could have the effect of aiding inflammatory processes.

The company challenged the authorities’ decision but their appeal was rejected. When the case came before the German Federal Administrative Court Bundesverwaltungsgericht, the court proceedings were stayed and a ruling was requested from the ECJ on whether Article 1 (2) of Directive 2001/83 must be interpreted to the effect that a product intended for human consumption and described as a food

supplement is a medicinal product by function if it contains substances which pose a risk to health in a low dose, without being capable of producing therapeutic effects, but which have therapeutic effects in high doses.

The ECJ stressed that national authorities must decide upon the classification of such borderline products on a case-by-case basis, taking into account all the characteristics of the product, in particular its composition, its pharmacological, immunological or metabolic properties. The mere fact that the use of a product presents a 'risk to health' is not an indication that the product has pharmacological effects and, thus, must be classified as a medicinal product. The ECJ concluded that a product which includes in its composition a substance that has physiological effects when used in a particular dosage, is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings.

*More information on the judgement at <http://tinyurl.com/kmyloj>*

## COUNTRY NEWS

### Russia: President surprised at level of alcoholism

As reported by the Moscow Times on 2 July, President Dmitry Medvedev has expressed surprise at how much alcohol Russians drink and ordered the government to develop a programme to discourage drinking. "The alcohol consumption we have is colossal." According to a transcript on the Kremlin's website, Medvedev told Health and Social Development Minister Tatyana Golikova at recent meeting, that he was "astonished to learn that we now drink more than we did in the 1990s, although those were very tough times."

He told Golikova to devise an anti-alcohol strategy. "We need to prepare a corresponding programme and take appropriate measures." His statement comes soon after a report in *The Lancet* said alcohol-related diseases caused about half of all deaths of Russians between the ages of 15 and 54 in the 1990s.

Prime Minister Vladimir Putin also highlighted the problem at a meeting with the

World Health Organization Director General in June and promised to promote a healthier lifestyle. Also lending his support for action, former Soviet leader Mikhail Gorbachev, who initiated a 1986 anti-alcohol campaign that led to a boom in illegal production of low-quality alcohol, said that "we are destroying ourselves, and then we will look for those who destroyed our country, for those who made us drink."

*More at <http://www.moscowtimes.ru/article/1010/42/379218.htm> (subscribers only)*

### Czech Republic: User fees generate substantial revenues

During its first year of implementation, user fees in the Czech Republic brought ten billion Czech Crowns worth of savings and income to the health care system (five billion was collected in user fees and another five billion represents accumulated savings within the system). Health insurance companies used these resources to finance modern and up-to-date treatments. In addition, these financial resources enabled access to previously inaccessible and expensive treatment for the seriously ill, brought effective and modern treatment into specialised centres, increased the number of surgeries, reduced waiting times and increased resources for emergency services. User fees improved general access to health care facilities, freed up overfilled waiting rooms, and therefore increased the comfort of patients. Emergency services were no longer misused, opening up care to those who truly required their services.

The expectations of the Czech Minister of Health have been fulfilled: user fees serve for the better use of public health resources and redirect money towards those with highest need, and help to reduce unnecessary physician visits. The number of emergency visits dropped by 36%, ambulatory specialist visits by 15% and ambulatory specialist visits in inpatient facilities by 19%. In addition, the number of prescriptions fell by 28% and expenditures on drugs costing up to 150 Czech Crowns decreased by 19%.

Minister of Health, Daniela Filipiová, spoke of the benefits of user fees for patients stating that "user fees have made it possible to limit wastage in the health care system, save resources for cheap drugs and use them for treating severely ill patients. In specialised centres (where patients with cancer, multiple sclerosis and

other serious diseases are treated), 40% more patients were treated than in 2007. Coverage of drug expenditures in the specialised centres increase by 47%, and the number of hip and knee replacements paid for by the General Health Insurance Company increased by 35%. At the same time user fees serve as an effective anti-crisis measure."

The impact of user fees on limiting excess emergency and ambulatory specialist visits, and inpatient days appears stable and permanent. Moreover, in the area of drug consumption, the effect of reduced expenditures on cheap drugs such as aspirin is on-going and has enabled health insurance companies to improve access to modern and effective treatment in specialised centres. "Due to behavioural changes by all, the billion crown savings can be used for previously inaccessible or prohibitively expensive treatment for the seriously ill" said Marek Šnajdr, the first deputy of the ministry of health. He continued, "user fees are closely connected with a protection limit which protects mainly chronic patients and patients suffering from more than one disease. Treatment expenditures have been reduced for 18,700 insurees. Whilst user fees are not popular, they have increased the confidence of our citizens, ensuring that when they, or their relatives, become seriously ill, they will have access to timely, modern and effective treatment."

*More information in Czech at <http://tinyurl.com/mfq5v8>*

### Spain: Pharmacy associations fined by Spanish Competition Authority

On 24 March 2009, in Decision 649/08, the Spanish Competition Authority imposed a €1 million fine on four pharmacy associations – Spanish Federation of Pharmacists (FEFE), Confederation of Pharmacies of Andalucía (CEOFA), Professional Association of Pharmacies of Málaga (PROFARMA) and the Professional Association of Pharmacies of Sevilla (APROFASE) – because they had induced their members to refrain from acquiring certain generic medicines from the pharmaceutical company Laboratorios Davur.

Davur had published advertisements in different specialised magazines in 2007 stating that the price of its generic medicines was lower than the price established in the Ministerial Order that sets the reference price of generic medicines subject to medical prescription. The four phar-

macy associations had made certain announcements in specialised magazines and had circulated certain communications amongst their members regarding the lowering of the prices by Davur. In general terms, the associations indicated that the voluntary lowering of the price of Davur's generic medicines would lower the reference prices for the coming year.

The publications and communications between the associations and their members also reminded pharmacists that, pursuant to Spanish legislation, pharmacies are not obliged to sell the cheapest medicines on the market. Instead, they are obliged to sell the lowest-price medicines according to Annex 5 of the Ministerial Order, which sets the reference price of generic medicines subject to medical prescription, or in case it is the same price, they have to sell the generic medicine (which would exclude Davur's medicines). It was noted that different pharmacies had decided to give up buying generic medicines from Davur and had informed them that they ceased commercial relationships, as pharmacists work with a percentage on the final sale price.

The Spanish Competition Authority concluded that the four pharmacy associations had carried out a collective recommendation prohibited by Article 1 of the Spanish Competition Act (Law 15/2007). The collective recommendation was made to coordinate the behaviour of all the pharmacies so that they would cease acquiring the generic medicines marketed by Davur.

### **Ireland: Health Minister seeks delivery of cost effective colorectal cancer screening programme**

On 17 June the Minister for Health and Children, Mary Harney, announced that she has asked the Health Information and Quality Authority (HIQA) to identify innovative ways of introducing a national programme of colorectal cancer screening in Ireland. The introduction of this screening programme is now a priority.

Welcoming publication of two related reports – the National Cancer Screening Service's (NCSS) Expert Report on Colorectal Screening and the Health Technology Assessment (HTA) carried out by HIQA, the Minister said "I want to introduce a national programme of colorectal cancer screening as soon as possible. Colorectal cancer kills over 900 people in Ireland every year. The expert reports confirm that a properly organised screen-

ing programme would have huge public health benefits and I want to find innovative ways of putting that in place".

In Ireland colorectal cancer is the second most frequently diagnosed cancer in men, after prostate cancer and the second most frequently diagnosed cancer in women, after breast cancer. The new cases of colorectal cancer in Ireland – around 2,000 per year – rank among the highest in western Europe for both men and women, and the death rate is higher for men in Ireland than elsewhere in Europe.

The purpose of the HTA was to evaluate the cost-effectiveness of various options for a population-based colorectal cancer screening programme in Ireland and also to estimate the resource requirements and health outcomes that would result in the first decade following the implementation of such a programme.

Dr Patricia Harrington, Acting Director of HTA with HIQA said "the results of the HTA clearly show that lives can be saved through the introduction of this screening programme and the associated higher detection rate of colorectal cancer at an early stage. The recommended programme would be highly cost-effective, when compared with a policy of no screening. Specifically, a programme based on faecal immunochemical testing (FIT) every two years for people aged 55 to 74 years was found to be the optimal strategy and it would provide the greatest health gain, while remaining highly cost-effective." Dr Harrington also stated that "the Authority's advice to the Minister in recommending a screening programme based on FIT every two years would result in a 14.7% reduction in the incidence and 36% reduction in mortality from colorectal cancer."

The Minister has asked HIQA to report to her by the end of September. In the time limited study, HIQA will explore different ways of delivering a high quality colorectal screening programme within existing resources, based on the range of advice contained in the two expert reports.

Minister Harney said that she was "pleased that HIQA has agreed to use its skills and expertise to set out how the Irish health care system can deliver this important programme within existing resources". The Minister also welcomed the commitment of the Irish Cancer Society to play a very supportive role in the design of an appropriate, high-quality screening programme.

*The NCSS expert report is available at <http://www.rte.ie/news/2009/0617/NCSScancer.pdf>*

*The HIQA report is available at [http://www.hiqa.ie/news\\_releases/090617\\_HTA\\_colorectal\\_cancer\\_screening\\_programme.asp](http://www.hiqa.ie/news_releases/090617_HTA_colorectal_cancer_screening_programme.asp)*

### **Scotland: Launch of mental health improvement programme**

Scotland's mental health improvement plan was launched on 7 May indicating that an understanding of the importance of protecting a person's own mental health could be key to reducing the number of people with mental health problems. Public Health Minister, Shona Robison, said that good mental health can bring a healthier lifestyle, better physical health, better relationships with family and friends and greater productivity in the workplace.

Plans for mental health improvement include national marketing campaigns raising awareness of how adults and young people can promote their own wellbeing, aided by self-help resources and practical support. There will also be awareness raising and help for older people to spot the early signs of dementia and get earlier diagnosis and training for health and social workers on how best to promote mental wellbeing in children and young people.

There is also a focus on the links between physical and mental health – help to stop smoking, be more active and eat healthier, as well as on promotion of wellbeing in the workplace – focusing on the prevention of common mental health problems, retaining people in work when they experience mental health problems and helping those out of work, due to mental illness, back into work

Additional objectives are for research to build a clear picture of all the key factors that lead to suicides, creation of a secure, confidential suicide register for Scotland and to improve knowledge and understanding of self-harm and guidance for services to aid treatment and prevention

Ms Robison said "we want to create a more successful Scotland with a thriving society that offers everyone the opportunity to reach their full potential. Promoting good mental wellbeing, reducing the occurrence of mental health problems and improving the quality of life of those experiencing mental health problems is vital to doing just that. Our immediate aim is to help everyone to understand how their own and other's mental health can be

improved and create a step-change in how we, as a society, look after our mental health.”

*The report entitled ‘Towards a Mentally Flourishing Scotland: Policy and Action Plan 2009–2011’ is available at <http://www.scotland.gov.uk/Publications/2009/05/06154655/5>*

### **England: publication of consultation document on reform of long-term care**

July saw the publication by the Department of Health in England of the long awaited consultation paper on the future funding of long-term care. *Shaping the Future of Care Together* sets out a vision for a new care and support system, it highlights the challenges faced by the current care system and the need for radical reform, to develop a national care service that is fair, simple and affordable for everyone.

Under the current funding system the government only provides social care to those on low incomes, leaving others to pay for care with no support from the state until they have only £23,000 left. The issue is of particular importance given projections that by 2026 there will be 1.7 million more adults in England in need of care and support.

Three options have been proposed. Under the first option, *Partnership*, which the government recommends should be the foundation of the new system, the government would pay for around a quarter to a third of the cost of a person’s care and support (or more if they have a low income). This would leave an individual paying an average £20,000–£22,500 under a basic partnership scheme, though some would pay far more.

The second option, *Insurance*, would build on this model, with the government making it easier for people to take out insurance to cover their remaining costs. The final option, *Comprehensive*, would mean that everyone received free care in return for paying into a state insurance scheme. The paper warns that its favoured partnership option “does not fully protect people against the risk of having to pay high costs towards their care and support” and that a small number of people could still be forced to sell their homes to pay for care.

If the second option were implemented, the government has said that it could work with the private insurance industry, or set up a state-backed insurance system. With

the government paying around a quarter or a third of costs, it is envisaged that the currently prohibitively high premiums could be reduced. This option is presented as that most likely to appeal to those keen to protect their estate and pass it on to dependants. However, there is a risk that few people would join a voluntary scheme. Andy Burnham estimated a take-up rate of around 20% and suggested that cover would cost between £20,000 and £25,000.

Under the third option, everyone over the age of 65 would be required to make a contribution, either set at one level or means-tested. This could prove cheaper than the voluntary insurance scheme given its mandatory nature, but would mean that some people who never required care still had to contribute. The paper suggests that people could make a contribution as a lump sum from savings, defer their state pension and use that money to pay into the scheme, pay in instalments throughout their retirement or defer the whole payment until they died. The cover would cost between £17,000 and £20,000, according to Health Minister, Andy Burnham, reflecting the larger risk pool than that generated by option two. The paper rules out a tax-funded system, which Andy Burnham said would put an unfair burden on the shrinking proportion of working age people, who would need to pay high contributions to pay for those in need of care.

All parties agree that the scale of the challenge is considerable. A 65-year-old can expect to need care costing on average £30,000 during their retirement. However this figure conceals great variation in need and cost. 20% of people will need care costing less than £1,000 during retirement but another 20% will need more than £50,000-worth of care. Some people could face a bill of more than £100,000.

Introducing the paper to Parliament, Mr Burnham said these were “radical and serious proposals” that required a broad, cross-party consensus. However, Shadow Minister for Health, Andrew Lansley, said ministers had “dithered for months” about the paper and said the long-awaited publication failed to clarify where the funding for the state’s contribution to care would come from. He said “we do not need a nationalisation of social care service” and accused the government of taking local government out of the equation. Liberal Democrat health spokesman Norman Lamb said the paper came “twelve years

too late”. He warned that, given the proximity of a general election that there was a real risk of any reform being postponed.

Other reactions to the Green Paper have been mixed, recognising that many tough decisions lay ahead. Stephen Haddrill, the ABI’s director general, said that “the current funding situation is not sustainable, and given that the government has made clear that no extra money is available, the private sector has an essential part to play in meeting the growing need for care. The insurance industry stands ready to work alongside the Government to provide a realistic and sustainable solution.”

But Ian Owen, chairman of Partnership, the only private sector member of the Department of Health’s stakeholder panel which advised on the paper and one of only two providers of immediate needs annuities, described it as a “major disappointment.”

Owen said that “the fact that no new funding is being offered means that the £6 billion care funding gap identified in the Wanless report on funding long term care is no closer to being bridged. Indeed, with our ageing population, the gap will only grow over time.” He said that the public’s attitude required a “complete overhaul” and that existing insurance-based products had a “crucial role” to play in encouraging people to make provision for their retirement.

A spokesman for the insurer Aviva said that “our experience is that it is a challenge to persuade people to think about the possibility of needing care. As a result we feel it could be extremely difficult to encourage people to pre-fund for long term care and would caution the Government against over reliance on this form of funding.” Aviva is suggesting that changes are made to the way in which pensions, savings and property are used to fund long-term care.

The consultation runs until 13 November. Respondents are invited to complete/participate in a variety of ways. This includes a series of thirty-six stakeholder events held between July and October, four in each NHS region. These will be supported by public consultation activities in town centres where events are being held.

*The Green Paper is available at [http://www.dh.gov.uk/en/PublicationsandStatistics/Publications/PublicationsPolicyAndGuidance/DH\\_102338](http://www.dh.gov.uk/en/PublicationsandStatistics/Publications/PublicationsPolicyAndGuidance/DH_102338)*

# News in Brief

## European Commission promotes cycling as healthy way to travel

The European Commission promoted cycling as a healthy and safe way to travel in cities at the 15th Velo-City conference, organised by the Brussels Region. Vice-President Kallas, Commissioner for Administrative Affairs helped to sign the Brussels Charter committing various cities to promote the use of bicycles. To promote safe cycling, the EU already helps to fund the development of cycle infrastructure, for example through the EU's Structural and Cohesion Funds. For the period 2007–2013, an estimated budget of more than €600 million will be used to invest in cycle infrastructure in eligible regions across the EU.

More information on Velo-City 2009 at <http://www.velo-city2009.com/index-en.html>

## INPES 'Prevention Days' 2009 a success

Almost 1300 people took part in the 'Prevention Days' event, organised by the French National Institute for Disease Prevention and Health Education (INPES) in Paris. A total of 150 experts, including thirty-five representatives from other countries, took part in nine themed workshops over two days. The establishment in June by the French National Assembly of Regional Health Agencies (ARS) was also noted as a key step in defining the importance of health education. "It makes the therapeutic education of patients an integral part of management and care," said French Minister for Health and Sport Roselyne Bachelot-Narquin, opening the event.

More information (French only) at <http://www.inpes.sante.fr/>

## Towards better information sharing on diabetes

The Best Information through Regional Outcomes (BIRO) Project has published the outcomes of the initiative in a new report which looks at attempts to build a common European infrastructure for standardised information exchange on diabetes care. The results from the project mean that the BIRO system is ready to be rolled out to a network of clinical units, regions and Member States. Its development

further progress towards the creation of a European Diabetes Register.

More information at <http://eubiroad.eu/home.htm>

## Active and dignified ageing

In Luxembourg in June the EU Employment, Social Policy, Health and Consumer Affairs Council adopted a series of recommendations which seek to establish the conditions "for the active life and dignified ageing of women and men". Among the recommendations for measures to be implemented at the national level are the creation of active ageing policies for older workers; efforts to support employers in their efforts to recruit and retain older workers in employment; and measures to address the needs of older people, including older women living alone, in order to reduce their isolation and to promote their independence, equality, participation and security.

More information at [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lsa/108375.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/108375.pdf)

## Sweden: Protecting the mental health of young people

The Swedish Association of Local Authorities and Regions (SALAR) has published a position paper on mental health, children and young people which is now available in English. The paper consists of sixteen standpoints and argues that joint efforts must be made by all of the social stakeholders concerned to promote the health of children and young people, deal with mental illness and alleviate the consequences of mental health problems.

The paper can be downloaded at <http://tinyurl.com/l5mn93>

## NICE guidance on managing long-term sickness absence and incapacity for work

The National Institute for Health and Clinical Excellence (NICE) in England has published guidance on managing long-term sickness absence and incapacity for work. Three of the recommendations aim to help employers and employees work together to ensure the right support is available to help someone on sickness absence return to work as soon as they are able. They

include a recommendation for identifying someone who is suitably trained and impartial to undertake initial enquiries with an employee who is experiencing long-term sickness absence or recurring short- or long-term sickness absence, and if necessary, to then arrange for a more detailed assessment by relevant specialist/s. The guidance also recommends that those who are unemployed and claiming incapacity benefit should be offered an integrated programme of support to help them enter or return to work. This advice is aimed at the Department for Work and Pensions in England and other relevant commissioning bodies and organisations.

More information at <http://www.nice.org.uk/Guidance/PH19>

## More voluntary donations of blood needed in Europe

Although safe blood donations in the World Health Organization (WHO) European Region are rising, the influenza pandemic puts extra strain on the pool of people who give blood. As World Blood Donor Day 2009 was being launched on 15 June in Melbourne, Australia, the WHO Regional Office for Europe noted that more people should be encouraged to donate regularly on a voluntary, non remunerated basis; 90% of those who could give blood are not doing so. At least twenty to twenty-five donations per 1,000 population are needed to maintain blood supplies, but donation rates per country across Europe region range from just four to sixty-eight per 1,000 population. Indeed due to the shortage of blood and ageing populations, the age limits for blood donation acceptability are becoming increasingly flexible: in some European countries they are now as low as seventeen and as high as seventy.

More information at <http://www.wbdd.org/>

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