

Eurohealth

RESEARCH • DEBATE • POLICY • NEWS

Volume 14 Number 1, 2008

Health system snapshots: perspectives from six countries



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Access to research data

Supporting and using publicly orientated health research

Irish private health insurance market • Pharmaceutical policy in Central and Eastern Europe
Diabetes risk • Lives saved vs life years saved • Pharmaceutical sector governance

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LSE Health

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Knowledge: our most precious commodity

O

We hear a lot about the soaring price of commodities such as oil and gas. The global energy crisis will not be resolved through further exploration for fossil fuels. Instead, that most precious of commodities, knowledge, can help find innovative ways of harnessing new sources of energy.

M

Knowledge is also priceless for health policy. Intelligence on the state of health systems is vital, yet it can be difficult to keep up with the rapid pace of change. In this issue of *Eurohealth* we include snapshots on six countries. Originally commissioned and funded by the New York based Commonwealth Fund, and prepared in a common format, they provide an opportunity to reflect on approaches to efficiency and quality improvement.

M

We are also delighted to include a contribution from historian Louis Galambos, who highlights challenges for the global vaccine industry and how these parallel past events. In an economic downturn, cost pressures may first be felt in areas viewed as low priorities. All too often public health research can suffer. As well as the potential lost health benefits, the economic consequences of reduced investment into vaccine research and development may be substantial: Europe currently produces around 90% of the world's vaccines. Professor Galambos argues that we should focus on the long-term benefits of vaccines to society, rather than just being mindful of short-term budgetary requirements.

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T

We also feature two articles looking at how knowledge can better inform policy making. Hans Stein looks at the role of international organisations in public health research across the EU. He calls for more emphasis on ensuring that research is feasible, policy relevant and linked to the policy making process. Philipa Mladovsky and colleagues, meantime, argue that we are losing an opportunity to make use of much existing knowledge. The European Commission, they contend, should adopt measures to promote much more open access to data collected within Research Framework projects. Again, secondary analyses of such data could prove invaluable in generating new knowledge that might be used in countering the global health crisis.

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The health system in England

Seán Boyle

Who is covered?

Coverage is universal. All those 'ordinarily resident' anywhere in the United Kingdom* are entitled to health care that is largely free at the point of use.

What is covered?

Services: the publicly-funded National Health Service (NHS) covers preventative services; inpatient and outpatient (ambulatory) hospital (specialist) care; physician (general practitioner) services; inpatient and outpatient drugs; dental care; mental health care; learning disabilities and rehabilitation.

Cost sharing: there are relatively few cost sharing arrangements for publicly-covered services. Drugs prescribed by general practitioners are subject to a co-payment (£7.10 (€8.85) per prescription), but about 88% of prescriptions are exempt from charges.¹ Dentistry services are subject to co-payments of up to about £200 (€250) per year; in some areas there is difficulty in obtaining NHS dental services. Out-of-pocket payments accounted for 11.9% of total expenditure on health in the UK in 2005.²

Safety nets: most costs are met from the public purse. There are measures in place to alleviate costs where these may have an undue impact on certain patient groups. The following are exempt from prescription drug co-payments: children under the age of sixteen years and those in full-time education up to age eighteen; people aged sixty years or over; people on low incomes; pregnant women and those having had a baby in the last twelve months; and people with certain medical conditions and disabilities. There are discounts through pre-payment certificates for those individuals who use a large

amount of prescription drugs. Transport costs to and from provider sites are also covered for people on low incomes.

How are revenues generated?

National Health Service (NHS): the NHS accounts for 86% of total health expenditure. It is mainly funded by general taxation (76%), but also by national insurance contributions (19%) and user charges (5%).³ Apart from the income the NHS receives for the provision of prescription drugs and dentistry services to the general population, there is some income from other fees and charges, particularly to private patients who use NHS services.

Private health insurance: a mix of for-profit and not-for-profit insurers provide supplementary private health insurance. Private insurance offers choice of specialists, avoidance of queues for elective surgery and higher standards of comfort and privacy than the NHS. United Kingdom-wide it covered 12% of the population and accounted for 1% of total health expenditure in 2005.

Other: individuals also pay directly out of pocket for some services – for example, care in the private sector. Direct out-of-pocket payments account for over 90% of total private expenditure on health.

How is the delivery system organised?

Physicians: general practitioners (GPs) are usually the first point of contact for patients and act as gatekeepers for access to secondary care services. Most GPs are paid directly by primary care trusts (PCTs) through a combination of methods: salary, capitation and fee-for-service. The 2004 GP contract introduced a range of

different local contracting possibilities, as well as providing substantial financial incentives tied to achievement of clinical and other performance targets. Private providers of GP services set their own fee-for-service rates but are not generally reimbursed by the public system.

Hospitals: these are organised as NHS trusts directly responsible to the Department of Health. More recently, foundation trusts have been established as semi-autonomous, self-governing public trusts. Both contract with PCTs for the provision of services to local populations. Public funds have always been used to purchase some care from the private sector, but since 2003 some routine elective surgery has been procured for NHS patients from purpose-built treatment centres owned and staffed by private sector providers. Consultants (specialists) work mainly in NHS hospitals but may supplement their salary by treating private patients.

Government: responsibility for health legislation and general policy matters rests with Parliament at Westminster. The NHS is administered by the NHS Executive and the Department of Health, and locally is provided through a series of contracts between commissioners of health care services (PCTs) and providers (hospital trusts, GPs, independent providers). PCTs control around 85% of the NHS budget (allocated to them based on a risk-adjusted capitation formula) and are responsible for ensuring the provision of primary and community services for their local populations. Recent policy developments include the introduction of patient choice of hospital and a move to the reimbursement of hospitals using a Diagnosis Related

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* Although coverage is applicable across the whole of the United Kingdom, the structure of health systems in Northern Ireland, Scotland and Wales are a matter for local devolved administrations and differ significantly from the system in England. The situation in these countries is not discussed in this paper. However it should though be noted that data on expenditure obtained from the World Health Organization refer to the entire United Kingdom.

Group (DRG) like activity-based funding system known as Payment by Results (PbR). PbR relates payment to the quantity and casemix of activity undertaken.

Private insurance funds: private insurers provide their subscribers with health care at a range of private and NHS hospitals. Patients generally can choose from a number of health care providers.

What is being done to ensure quality of care?

Quality of care is a key focus of the NHS. A Department of Health objective in 2007 was to enhance the quality and safety of health and social care services. Quality issues are addressed in a range of ways outlined below.

Regulatory bodies: a number of bodies monitor and assess the quality of health services provided by public and private providers. This involves regular assessment of all providers, investigation of individual providers where an issue has been drawn to the attention of a regulatory body and consideration of key areas of provision in order to recommend best practice. The three bodies primarily responsible for regulation in England (the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission) are due to be merged later in 2008.

Targets: targets have been set by the government for a range of variables that reflect the quality of care delivered. Some of these targets are monitored by the regulatory bodies mentioned above; others are monitored on a regular basis either by the Department of Health or its regional organisations (ten strategic health authorities).

National Service Frameworks (NSFs): since 1998 the Department of Health has developed a set of NSFs intended to improve particular areas of care (for example, coronary disease, cancer, mental health, diabetes). These set national standards and identify key interventions for defined services or care groups. They are one of a range of measures used to raise quality and decrease variations in service.

Quality and Outcome Framework: this is a new framework for measuring the quality of care delivered by GPs. It was introduced as part of the new GP contract in 2004, which provided incentives for improving quality, and has been operating since 2005. GP practices are awarded points related to payments for how well

the practice is organised, how patients view their experience at the surgery, whether extra services are offered, such as child health and maternity, and how well common chronic diseases such as asthma and diabetes are managed.

What is being done to improve efficiency?

Efficiency has always been a key focus of the NHS. The NHS seeks to improve efficiency in a range of ways including:

High-level efficiency targets: the government is committed to a programme to achieve efficiency gains of £6.5 (€8.1) billion by March 2008 through a range of policies known as the Gershon Efficiency Programme. These include increasing front-line productivity, centralising procurement to obtain more cost-effective deals, reductions in the costs of both NHS provider and central administration and increasing the efficiency of social care provision. Local NHS organisations are also set targets for efficiency savings.

Benchmarking: NHS organisations are benchmarked against the performance of their peers on a number of activity measures including day case rates and lengths of stay for common operative procedures, readmission rates and NHS reference costs (costs of standard procedures known as Healthcare Resource Groups). The Healthcare Commission reviews the performance of NHS trusts against these measures in providing an overall assessment of NHS performance through the Annual NHS Health Check.

Institute for Innovation and Improvement: the Department of Health supports the development of better and more efficient

ways of providing health care through the use of semi-autonomous bodies such as the Institute for Innovation and Improvement. The Institute helps the NHS to develop new ways of dealing with the introduction of new technology and changes to working practices, and helps to spread these throughout the NHS.

How are costs controlled?

The government sets the budget for the NHS on a three-year cycle. To control utilisation and costs, the government sets a capped overall budget for PCTs. NHS trusts and PCTs are expected to achieve financial balance each year. The centralised administrative system tends to result in lower overhead costs. Other mechanisms that contribute to improved value for money include arrangements for the systematic appraisal of both new and existing technologies through the National Institute for Health and Clinical Excellence (NICE).

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WHO European Ministerial Conference

“Health Systems, Health and Wealth”

Tallinn, Estonia, 25–27 June 2008

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- take stock of recent evidence on effective strategies to improve the performance of health systems, given the increasing pressure on them to ensure sustainability and solidarity.

www.euro.who.int/healthsystems2008



WHO European Ministerial
Conference on Health Systems:
“HEALTH SYSTEMS,
HEALTH AND WEALTH”
Tallinn, Estonia, 25–27 June 2008

The health system in France

Isabelle Durand-Zaleski

Who is covered?

Coverage is universal. All residents are entitled to publicly financed health care. Following the introduction of *Couverture Maladie Universelle* (CMU) in 2000, the state finances coverage for residents not eligible for coverage by the public health insurance scheme (0.4% of the population). The state also finances health services for illegal residents (*L'Aide Médicale d'Etat; AME*).

What is covered?

Services: the public health insurance scheme covers hospital care, ambulatory care and prescription drugs. It provides minimal cover for outpatient eye and dental care.

Cost sharing: cost sharing is widely applied to publicly financed health services and drugs and takes three forms.

Co-insurance rates are applied to all health services and drugs listed in the publicly financed benefits package. Rates vary depending on:

- the type of care: hospital care (20% plus a daily co-payment of €16), doctor visits (30%), dental care (30%);
- the type of patient: patients with chronic conditions and poorer patients are exempt from cost sharing;
- the effectiveness of prescription drugs: 0% for highly effective drugs, 35%, 65% and 100% for drugs of limited therapeutic value; and
- whether or not patients comply with the recently-implemented gatekeeping system (*médecin référent*). Visits to the gatekeeping general practitioner (GP) are subject to a 30% co-insurance rate, while visits to other GPs are subject to a 50% co-insurance rate; the difference

between the two rates cannot be reimbursed by complementary private health insurance (see below).

In addition to cost sharing through co-insurance, which can be fully reimbursed by complementary private health insurance, the following non-reimbursable co-payments apply from 2008, up to an annual ceiling of €50: €1 per doctor visit, €0.50 per prescription drug, €2 per ambulance journey and €18 for expensive treatments.

Reimbursement by the publicly financed health insurance scheme is based on a reference price. Doctors and dentists may charge above this reference price (extra billing) based on their level of professional experience. The difference between the reference price and the extra billed amount must be paid by the patient and may or may not be covered by complementary private health insurance.

Safety nets: exemptions from co-insurance apply to people receiving disability and work injury benefits, people with specific chronic illnesses and those on low incomes. Hospital co-insurance only applies to the first thirty-one days in hospital and some surgical interventions are exempt. Children and people on low incomes are exempt from making non-reimbursable co-payments.

Complementary private health insurance covers statutory cost sharing (the share of health care costs not reimbursed by the health insurance scheme). It only applies to health services and prescription drugs listed in the publicly financed benefits package. Most people obtain complementary private cover through their employment. Since 2000, individuals on low incomes are entitled to free complementary private cover (CMU-C) and free eye and dental care; in addition, they cannot be extra billed by doctors. Complementary private health insurance now covers over 92% of the population. In 2005, out-of-pocket payments and private health insurance accounted for 7.4% and 12.8% of total

health expenditure respectively.¹

How are revenues generated?

Publicly financed health care: the public health insurance scheme is financed by employer and employee payroll taxes (43%); a national income tax (contribution sociale généralisée; 33%) created in 1990 to broaden the revenue base for social security; revenue from taxes levied on tobacco and alcohol (8%); state subsidies (2%); and transfers from other branches of social security (8%). CMU is mainly financed by the state through an earmarked tax on tobacco and a 2.5% tax on the revenue of complementary private health insurers. There is no ceiling on employer (12.8%) and employee (0.75%) contributions, which are collected by a national social security agency. Public expenditure accounted for 79.1% of total expenditure on health in 2005.¹

Government: the public health insurance funds are managed by a board of representatives, with equal representation from employers and employees (trades unions). Every year parliament sets a (soft) ceiling for the rate of expenditure growth in the public health insurance scheme for the following year (*Objectif National de Dépenses d'Assurance Maladie, ONDAM*). In 2004, a new law created two new associations, the National Union of Health Insurance Funds (*Union Nationale des Caisses d'Assurance Maladie, UNCAM*) and the National Union of voluntary health insurers (*Union Nationale des Organismes Complémentaires d'Assurance Maladie, UNOCAM*), incorporating all public health insurance funds and private health insurers respectively. The law also gave the public health insurance funds responsibility for defining the benefits package and setting price and cost sharing levels.

Private health insurance: complementary private health insurance reimburses statutory cost sharing. It is mainly provided by not-for-profit employment-

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based mutual associations (*mutuelles*), which cover 87% to 90% of the population. It only covers those services that are already covered by the public health insurance scheme. There is some evidence to show that the quality of coverage purchased (in other words, the extent of reimbursement) varies by income group. Since 2000, people on low incomes (including the unemployed and those receiving single parent subsidies) and their dependants have been entitled to obtain complementary private cover at no or very low cost (CMU-C). CMU-C covers about two million people via a voucher which can be used to obtain cover from a variety of insurers, although most choose to obtain cover from the public health insurance scheme. More recently, for-profit commercial insurers have started to offer cover for services not included in the public benefits package. For example, the company AXA offered a plan offering faster access to renowned specialists, but this was outlawed by the physicians' association and parliament.

How is the delivery system organised?

Health insurance funds: public health insurance funds are statutory entities and membership is based on occupation so there is no competition between them. There is limited competition among mutual associations providing complementary private health insurance, but as they are employment-based, most employees usually only have a choice of one or two *mutuelles*. There is no system of risk adjustment among *mutuelles*, even though there is inadvertent risk selection based on occupation.

Physicians (non-hospital based physicians): the 2004 health financing reform law introduced a voluntary gatekeeping system for adults (aged 16 years and over) known as *médecin traitant*. There are strong financial incentives to encourage gatekeeping. Physicians are self-employed and paid on a fee for service basis. The cost per visit is slightly higher for specialists (€23) than for GPs (€22) and is based on negotiation between the government, the public insurance scheme and the medical unions. Depending on the total duration of their medical studies, physicians may charge above this level. There is no limit to what physicians may charge, but medical associations recommend tact in determining fee levels.

Hospitals: two-thirds of hospital beds are in government-owned or not-for-profit

hospitals. The remainder are in private for-profit clinics. All university hospitals are public. Hospital physicians in public or not-for-profit facilities are salaried. Since 1968, hospital physicians have been permitted to see private patients in public hospitals, an anachronism originally intended to attract the most prestigious doctors to public hospitals and one that has survived countless attempts to abolish it. From 2008, all hospitals and clinics will be reimbursed via a DRG (Diagnosis Related Group)-like prospective payment system (the original DRG scheme was only to be fully implemented by 2012). Public and not-for-profit hospitals benefit from additional non activity-based grants to compensate them for research and teaching (up to an additional 13% of the budget) and for providing emergency services and organ harvesting and transplantation (on average an additional 10-11% of a hospital's budget).

What is being done to ensure quality of care?

An accreditation system is used to monitor the quality of care in hospitals and clinics. The quality of ambulatory care rests on a system of professional practice appraisal. Both systems are mandatory, under the responsibility of the national health authority (*Haute Autorité de Santé*, HAS) created in 2004. Hospitals must be accredited every four years by a team of experts. The accreditation criteria and reports are publicly available via the HAS website (www.has-sante.fr). Every fifth year physicians are required by law to undergo an external assessment of their practice in the form of an audit. For hospital physicians, the practice audit can be performed as part of the accreditation process. For physicians in ambulatory practice, the audit is organised by an independent body approved by HAS (usually a medical society representing a particular specialty). Dentists and midwives will soon have to undergo a similar process.

What is being done to improve efficiency?

Improving efficiency is the major challenge facing the public health insurance funds, which are currently working on structural and procedural changes. Structural changes involve the creation of a national computerised system of medical records to limit duplication of tests, over prescribing and adverse drug side effects, and to facilitate the implementation of prospective payment for all hospitals and clinics from

2008.

Procedural changes on the supply side mainly focus on two issues: the reorganisation of inputs (for example, by transferring some physician tasks to nurses or other professionals) and improved co-ordination of care (particularly for patients with chronic illnesses). On the demand side, the main health insurance scheme is experimenting with patient education and hotlines. As of 2008 it will also transfer some drugs to over-the-counter status.

How are costs controlled?

Cost control is a key issue in the French health system as the health insurance scheme has faced large deficits for the last twenty years. More recently the deficit has fallen, from €10-12 billion per year in 2003 to an expected €6 billion in 2007. This may be attributed to the following changes, which have taken place in the last two years:

- a reduction in the number of acute hospital beds;
- limits on the number of drugs reimbursed; around six hundred drugs have been removed from public reimbursement in the last few years;
- an increase in generic prescribing and the use of over-the-counter drugs;
- the introduction of a voluntary gatekeeping system in primary care;
- protocols for the management of chronic conditions; and
- from 2008, new co-payments for prescription drugs, doctor visits and ambulance transport are not reimbursable by complementary private health insurance

At the same time, there has been an increase in the number of medical students admitted to university due to an expected shortage of doctors in the coming decade. Public funding has also had to increase to accommodate a rise in the fee schedule, since GPs are now considered as specialists and their cost per visit has risen from €20 to €22.

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The health system in Germany

Reinhard Busse

Who is covered?

Publicly-financed ('social') health insurance is compulsory for employees earning up to €48,000 per year and their dependants. Employees with earnings above this amount are currently not obliged to be covered. If they wish, they can remain in the publicly-financed scheme on a voluntary basis, they can purchase private health insurance or they can be uninsured. The publicly-financed scheme covers about 88% of the population. Around three quarters of those who are able to choose between public or private health insurance (less than 20% of the population) opt to remain in the publicly-financed scheme, which offers free cover of dependants. Most of the remainder purchase private health insurance. In total, 10% of the population are covered by private health insurance, mainly civil servants and self-employed people who generally do not fall under social health insurance. Less than 1% of the population has no insurance coverage at all. From 2009, health insurance will be compulsory for the whole population, depending on previous insurance and/or job status.

What is covered?

Services: the publicly-financed benefits package covers preventive services; inpatient and outpatient hospital care; physician services; mental health care; dental care; prescription drugs; rehabilitation; and sick leave compensation. Long-term care is covered by a separate insurance scheme, which has been compulsory for the whole population since 1995.

Cost sharing: traditionally the publicly-financed scheme has imposed few cost sharing provisions (mainly for pharmaceuticals and dental care). However, in 2004

co-payments were introduced for adult visits to physicians and dentists (€10 each for the first visit per quarter or subsequent visits without referral), while other co-payments were made more uniform: €5 to €10 per pack of outpatient prescription drugs (except if the price is at least 30% below the reference price*, which is the case for more than 12,000 drugs), €10 per inpatient day (up to twenty-eight days per year) and €5 to €10 for prescribed medical aids. For dental prostheses, patients receive a lump sum which covers, on average, 50% of costs. In total, out-of-pocket payments accounted for 13.8% of total health expenditure in 2005.¹

Safety nets: children up to the age of eighteen are exempt from cost sharing. Cost sharing is generally limited to an annual maximum of 2% of household income (or 1% for chronically ill people). For additional family members, a proportion of household income is excluded from this calculation.

How are revenues generated?

The publicly-financed scheme: this is operated by over two hundred competing health insurance funds (known as sickness funds - SFs): autonomous, non-profit, non-governmental bodies regulated by the government. The scheme is funded by compulsory contributions on the first €43,000 earned in a year. On average, the employee contributes almost 8% of gross earnings, while the employer contributes a further 7%. Dependants are covered through the primary SF member. Unemployed people contribute in proportion to their unemployment entitlements, but since 2004 the government employment agency has paid a flat rate per capita contribution for long-term unemployed people. Currently, SFs are free to set their own contribution rates for all other members.

However, from 2009, a uniform contribution rate will be set by the government and, although SFs will continue to collect contributions, all contributions will be centrally pooled by a new national fund, which will allocate resources to each SF based on an improved risk-adjusted capitation formula. In addition to this, SFs will be allowed to charge their members a flat-rate premium. In 2005 public sources of finance accounted for 77.2% of total health expenditure.¹

Private health insurance: private health insurance playing a substitutive role** covers groups excluded from publicly-financed health insurance (civil servants and self-employed people; the former have part of their health care costs directly reimbursed by their employers) and high earners who choose to opt out of the publicly-financed scheme. All pay a risk-rated premium, although contracts are based on life-time underwriting, so risk is assessed upon entry only. Substitutive private health insurance is regulated by the government to ensure that the insured do not face increasing premiums as they age (the old age reserves requirement) and that they are not overburdened by premiums if their income falls (access to a 'standard tariff' with benefits and premiums that match those of the publicly-financed scheme). From 2009, private insurers offering substitutive cover will be required to take part in a risk adjustment scheme to finance the costs of cover for people in ill health, who would otherwise not be able to afford a risk-rated premium. Private health insurance also plays a mixed complementary and supplementary role, providing SF members with cover for some health care costs and access to better amenities. In 2005, private health insurance accounted for 9.1% of total health expenditure.

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* The reference price is the maximum price reimbursed for a group of equal or similar drugs.

** Substitutive private health insurance covers people excluded from or allowed to opt out of the publicly-financed health insurance scheme.

How is the delivery system organised?

Physicians: individuals have free choice of ambulatory physician. General practitioners have no formal gatekeeper function. However, in 2004 SFs were required to offer their members the option of enrolling in a 'family physician care model' which may provide a bonus for complying with gatekeeping rules. Ambulatory specialist care is mainly delivered by private for-profit providers working in single practice, although polyclinic-type ambulatory care centres with employed physicians have been permitted since 2004. Physicians in the ambulatory sector are paid a mixture of fees per time period and per medical procedure. These are agreed following annual negotiations between SFs and regional physician associations to determine aggregate payments.

Hospitals: individuals have free choice of hospital (following referral). Hospitals are mainly non-profit, both public (about half of beds) and private (about a third of beds). The private, for-profit hospital sector has grown in recent years (about a sixth of beds), mainly through takeovers of public hospitals. Independent of ownership, hospitals are principally staffed by salaried doctors. Senior doctors may also treat privately-insured patients on a fee-for-service basis. Doctors in hospitals are typically not allowed to treat outpatients, although exceptions have been made when necessary care cannot be provided on an outpatient basis by specialists in private practice. Since 2004, hospitals may also provide certain highly specialised services on an outpatient basis. Inpatient care is reimbursed through a system of diagnosis-related groups (DRG) per admission, currently based on around 1,100 DRG categories. The DRG system was introduced in 2004 and is revised annually to take into account new technologies, changes in treatment patterns and associated costs into account.

Disease Management Programmes (DMPs): legislation in 2002 created DMPs for chronic illnesses in order to give SFs an incentive to care for chronically ill patients. DMPs exist for diabetes type I and II, breast cancer, coronary heart disease, asthma and chronic obstructive pulmonary disease. DMP participants are accounted for separately in the risk-adjustment mechanism for SFs, resulting in higher per capita allocations. At the end of 2007 there were 14,000 regional DMPs with 3.8 million enrolled patients.

Government: the German government delegates regulation to the self-governing corporatist bodies of the sickness funds and the providers' associations. The most important body is the Federal Joint Committee (G-BA) created in 2004 to increase efficacy and compliance. Greater purchasing power has also been given to individual SFs, for example, to contract providers directly, to negotiate rebates with pharmaceutical companies or to procure medical aids.

What is being done to ensure quality of care?

A range of measures have been introduced to ensure quality of care. Structural quality is addressed by the requirement for all providers to establish a quality management system; the obligation for continuous medical education for all physicians; health technology assessment for drugs and procedures, for which the Institute for Quality and Efficiency (IQWiG) was founded in 2004; voluntary hospital accreditation; and minimum volume requirements for a number of complex inpatient procedures (such as transplants). Process and (in part) outcome quality is addressed through the mandatory quality reporting system for all acute hospitals. Under this system, over one hundred and fifty indicators are measured for thirty medical conditions covering about a sixth of all inpatients. Hospitals receive individual feedback. Since 2007, around thirty indicators are required to be made public in the annual quality reports that all hospitals must publish.

What is being done to improve efficiency?

In addition to the quality measures noted above, a further set of measures aims to

address efficiency more directly. Since 2004, all drugs (patented as well as generic) have been subject to reference prices unless they can clearly demonstrate added value. Beginning in 2008, IQWiG will explicitly evaluate the cost-effectiveness of drugs, putting pressure on pharmaceutical prices. The DRG system for paying hospitals is based on average costs.

How are costs controlled?

In line with a greater emphasis on quality and efficiency, the cruder cost containment measures used in the past have been revised (notably, the use of sector-wide budgets for ambulatory physicians, hospital budgets and the collective regional drug prescription cap for physicians). The drug prescription cap, which complemented reference pricing for pharmaceuticals, was lifted in 2001, initially leading to an unprecedented increase in spending on pharmaceuticals by SFs. Following this, drug prescription caps with individual physician liabilities were introduced. More recently, contracts involving rebates and incentives to lower prices below the reference price are being used to control pharmaceutical spending. In 2009 hospital budgets will be fully replaced by the DRG system (using state-wide base rates). From 2009, budgets for ambulatory care will be replaced by a more sophisticated resource allocation mechanism that accounts for population morbidity.

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New policy brief on capacity planning

This policy brief published by the European Observatory on Health Systems and Policies reviews approaches to capacity planning in Canada, Denmark, England, Finland, France, Germany, Italy, the Netherlands and New Zealand. It aims to show a range of approaches to health care financing and organisation, as they impact capacity planning.

The book is available for free download at:
<http://www.euro.who.int/Document/E91193.pdf>

The health system in Denmark

Karsten Vrangbæk

Who is covered?

Coverage is universal. All those registered as resident in Denmark are entitled to health care that is largely free at the point of use.

What is covered?

Services: the publicly-financed health system covers all primary and specialist (hospital) services based on medical assessment of need.

Cost sharing: there are relatively few cost sharing arrangements for publicly-covered services. Cost sharing applies to dental care for those aged eighteen and over (co-insurance of 35% to 60% of the cost of treatment), outpatient drugs and corrective lenses.

An individual's annual outpatient drug expenditure is reimbursed at the following levels: below DKK520 (no reimbursement, 50% reimbursement for children); DKK520-1,260 (50% reimbursement); DKK1,260 - 2,950 (75% reimbursement); above DKK2,950 (85% reimbursement).¹ In 2005, out-of-pocket payments, including cost sharing, accounted for about 14% of total health expenditure.²

Safety nets: chronically ill patients with a permanently high use of drugs can apply for full reimbursement of drug expenditure above an annual ceiling of DKK3,805. People with very low income and those who are dying can also apply for financial assistance, and the reimbursement rate may be increased for some very expensive drugs. Complementary private health insurance provided by a not-for-profit organisation reimburses cost sharing for pharmaceuticals, dental care, physiotherapy and corrective lenses. In 1999 it covered about 36% of the population. Coverage is relatively evenly distributed across social classes.

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How are revenues generated?

Publicly-financed health care: a major administrative reform in 2007 gave the central government responsibility for financing health care. Health care is now mainly financed through a centrally-collected 'health-contribution' tax set at 8% of taxable income. The new proportionate earmarked tax replaces a mixture of progressive central income taxes and proportionate regional income and property taxes. The central government allocates this revenue to five regions (80%) and ninety-eight municipalities (20%) using a risk-adjusted capitation formula and some activity-based payment. Public expenditure accounted for around 82% of total health expenditure in 2005.²

Private health insurance: around 36% of the population purchase complementary private health insurance covering statutory cost sharing from the not-for-profit organisation 'Danmark'. Supplementary private health insurance provided by for-profit companies offers access to care in private hospitals in Denmark and abroad. It covers around 13.5% of the population and is mainly purchased by employers as a fringe benefit for employees. Some individuals have both types of cover. In 2005, private health insurance accounted for 1.6% of total health expenditure.²

How is the delivery system organised?

Government: The five regions are responsible for providing hospital care. They own and run hospitals. The regions also finance general practitioners, specialists, physiotherapists, dentists and pharmaceuticals. The ninety-eight municipalities are responsible for nursing homes, home nurses, health visitors, municipal dentists (children's dentists and home dental services for physically and/or intellectually disabled people), school health services, home help and the treatment of alcoholics and drug addicts. Professionals involved in delivering these services are paid a salary.

Physicians: self-employed general practi-

tioners act as gatekeepers to secondary care and are paid via a combination of capitation (30%) and fee for service. Hospital physicians are employed by the regions and paid a salary. Non-hospital based specialists are paid on a fee for service basis.

Hospitals: Almost all hospitals are publicly owned (99% of hospital beds are public). They are paid partly via fixed budgets determined through soft contracts with the regions and partly on a fee for service basis.

What is being done to ensure quality of care?

A comprehensive standards-based programme for assessing quality is currently being implemented. The programme is systemic in scope, aiming to incorporate all health care delivery organisations and including both organisational and clinical standards. Organisations are assessed on their ability to improve performance measured against standards for standards processes and outcomes.

The core of the assessment programme is a system of regular accreditation based on annual self assessment and external evaluation (every third year) by a professional accreditation body. The self assessment involves reporting of performance against national input, process and outcome standards, which allows comparison over time and between organisations. The external evaluation begins with self assessment and goes on to assess status for quality development. Some quality data is already being published on the internet (www.sundhedskvalitet.dk) to facilitate patient choice of hospital and encourage hospitals to raise standards.

What is being done to improve efficiency?

In the last few years, many national and regional initiatives have aimed to improve efficiency, with a particular focus on hospitals. For example, Denmark has been at the forefront of efforts to reduce average lengths of stay and to shift care from inpatient to outpatient settings. The adminis-

trative reforms of 2007 aimed to enhance the coordination of service delivery and to benefit from economies of scale by centralising some functions and enabling the closure of small hospitals. The reforms lowered the number of regions from fourteen to five, and the number of municipalities from two hundred and seventy five to ninety-eight.

The introduction of a Danish DRG (diagnosis-related groups) system in the late 1990s has facilitated various partially-activity-based payment schemes (for example, for patients crossing county borders) and benchmarking exercises. The national Ministry of Health also publishes regular hospital productivity rankings. These show that productivity in public hospitals increased by 1.9% in 2005–06 and by 2.4% in 2003–04.³ The total number of treatments increased by 5.5% in 2007–08.⁴

How are costs controlled?

Annual negotiations between the central government and the regions and municipalities result in agreement on the economic framework for the health sector, including levels of taxation and expenditure. The negotiations contribute to control of public spending on health by instituting a national budget cap for the health sector. They also form the basis for resource allocation from central government. At the regional and municipal level, various management tools are used to control expenditure, in particular contracts and agreements between hospitals and the regions, and ongoing monitoring of expenditure development. Policies to control pharmaceutical expenditure include generic substitution by doctors and/or pharmacists, prescribing guidelines and systematic assessment of prescribing behaviour. Health technology

assessment is now an integral part of the health system, with assessments carried out at central, regional and local levels.

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The health system in the Netherlands

Niek Klazinga

Who is covered?

Since the beginning of 2006, everyone resident or paying income tax in the Netherlands is required to purchase health insurance coverage.* Coverage is statutory under the Health Insurance Act (*Zorgverzekeringswet*; ZVW), but provided by private health insurers and regulated under private law. The uninsured proportion of the population is estimated to be 1.5%, a figure that is likely to rise further.¹ Asylum seekers are covered by the government and several mechanisms are in place to reimburse the health care costs of illegal immigrants unable to pay

for care. New legislation regarding the health care costs of illegal immigrants is being debated in parliament.

Prior to 2006, people with earnings above €30,000 per year and their dependants (around 35% of the population) were excluded from statutory coverage provided by public sickness funds. If they required health insurance they could purchase cover from private health insurers. This form of substitutive private health insurance** was regulated by the government to ensure that older people and people in poor health had adequate

access to health care and to compensate the publicly-financed health insurance scheme for covering a disproportionate amount of high risk individuals. Over time, growing dissatisfaction with the dual system of public and private coverage led to the reforms of 2006.

What is covered?

Services: insurers are legally required to provide a standard benefits package covering the following: medical care, including care by general practitioners (GPs), hospitals and midwives; hospitalisation; dental care (up to the age of eighteen; from eighteen cover is confined to specialist dental care and dentures); medical aids; medicines; maternity care; ambulance and patient transport services; and paramedical care (limited physio-

* The exceptions are those with conscientious objections and members of the armed forces on active service.

** Substitutive private health insurance covers people excluded from the publicly-financed health insurance scheme.

therapy/remedial therapy, speech therapy, occupational therapy and dietary advice).

Insurers may decide by whom and how this care is delivered, which gives the insured a choice of policies based on quality and cost. In addition to the standard benefits package, all citizens are covered by the statutory AWBZ (Exceptional Medical Expenses Act) scheme for a wide range of chronic and mental health care services such as home care and care in nursing homes. Most people also purchase complementary private health insurance for services not covered by the standard benefits package. Insurers are not required to accept applications for private health insurance.

Cost sharing: the insured pay a flat-rate premium (set by insurers) to their private health insurer. Everyone with the same policy pays the same premium. In 2006, an insured person was eligible for a refund of €255 if they incurred no health care costs. If they incurred costs of less than €255, they would receive the difference at the end of the year. This 'no claims bonus' system was abolished in 2007, following a change of government, and has been replaced by a system of deductibles. Every insured person aged eighteen and over must now pay the first €150 of any health care costs in a given year (with some services excluded from this general rule). Out of pocket payments as a proportion of total health expenditure have not changed following the 2006 reforms (around 8%).^{2,3}

Safety nets: children are exempt from cost sharing. The government provides 'health care allowances' for low income citizens if the average flat-rate premium exceeds 5% of their household income.

How are revenues generated?

Statutory health insurance: the statutory health insurance system (ZVW) is financed by a mixture of income-related contributions and premiums paid by the insured. The income-related contribution is set at 6.5% of the first €30,000 of annual taxable income. Employers must reimburse their employees for this contribution and employees must pay tax on this reimbursement. For those who do not have an employer and do not receive unemployment benefits, the income-related contribution is 4.4%. The contribution of self-employed people is individually assessed by the Tax Department. Contributions are collected centrally and distributed among insurers based on a

risk-adjusted capitation formula. In 2006, the average annual premium was €1,050. The government pays for the premiums of children up to the age of eighteen. In 2005, public sources of finance accounted for 65.7% of total health expenditure.² In 2006, this proportion had risen to around 78%.³

Private health insurance: substitutive private health insurance was abolished in 2006. Most of the population purchase a mixture of complementary and supplementary private health insurance from the same health insurers who provide statutory cover. This has given rise to concerns about the potential for risk selection, as the premiums and products of voluntary cover are not regulated. In 2005, private health insurance accounted for 20.1% of total health expenditure.² In 2006 this proportion had fallen to about 7%.³

How is the delivery system organised?

Health insurance funds: insurers are private and governed by private law. They are permitted to have for-profit status. They must be registered with the Supervisory Board for Health Insurance (CTZ) to enable supervision of the services they provide under the Health Insurance Act and to qualify for payments from the risk equalisation fund. The insured have free choice of insurer and insurers must accept every resident in their coverage area (although most already operate nationally). A system of risk equalisation/adjustment is used to prevent direct or indirect risk selection by insurers.

Physicians: physicians practise directly or indirectly under contracts negotiated with private health insurers. GPs receive a capitation payment for each patient on their practice list and a fee per consultation. Additional budgets can be negotiated for extra services, practice nurses, complex location, etc. Experiments with pay-for-performance for quality in primary and hospital care are underway. Most specialists are hospital based. Two-thirds of hospital-based specialists are self-employed, organised in partnerships and paid on a capped fee-for-service basis. The remainder are salaried. In future, payment will increasingly be related to activity through the Dutch version of Diagnosis Related Groups (DRGs) known as Diagnosis Treatment Combinations (DTCs).

Hospitals: most hospitals are private non-profit organisations. Hospital budgets are developed using a formula that pays a fixed amount per bed, patient volume and

number of licensed specialists, in addition to other factors. Additional funds are provided for capital investment, although hospitals are increasingly encouraged to obtain capital via the private market. From 2000, payments to hospitals were rated according to performance on a number of accessibility indicators. Hospitals that produced fewer inpatient days than agreed with health insurers were paid less, a measure designed to reduce waiting lists. A new system of payment for specific treatments (DTCs) is currently being implemented. 10% of all hospital services are now reimbursed on the basis of DTCs (up to 100% of all services in some hospitals). In future, it is expected that most care will be reimbursed using DTCs, although there is still considerable debate about the desired speed of further liberalisation of the hospital market (for example, through giving hospitals greater freedom in negotiating the price and quality of DTCs).

What is being done to ensure quality of care?

At the health system level, quality of care is ensured through legislation regarding professional performance, quality in health care institutions, patient rights and health technologies. A national inspectorate for health is responsible for monitoring and other activities. Most quality assurance is carried out by health care providers in close cooperation with patient and consumer organisations and insurers.

Mechanisms to ensure quality in the care provided by individual professionals involve re-registration/re-validation for specialists based on compulsory continuous medical education; regular onsite peer assessments organised by professional bodies; as well as profession-owned clinical guidelines, indicators and peer review. The main methods used to ensure quality in institutions include accreditation and certification; compulsory and voluntary performance assessment based on indicators; and national quality improvement programmes based on the breakthrough method (*Sneller Beter*). Patient experiences are systematically assessed and, since 2007, a national centre has been working with validated measurement instruments comparable to the Consumer Assessment of Health Plans Survey (CAHPS) approach in the United States. The centre also generates publicly available information for consumer choice.

What is being done to improve efficiency?

The main approach to improving efficiency in the Dutch health system rests on regulated competition between insurers, combined with central steering on performance and transparency about outcomes via the use of performance indicators. This is complemented by provider payment reforms involving a general shift from a budget-oriented reimbursement system to a performance-related approach (for example, the introduction of DTCs). In addition, various local and national programmes aim to improve health care logistics and/or initiate 'business process re-engineering'. At a national level, health technology assessment is used to enhance value for money by informing decision-making about reimbursement and encouraging appropriate use of health technologies. At the local level, several mechanisms are used, including those to ensure appropriate prescribing.

How are costs controlled?

The new Health Insurance Act aims to increase competition between private health insurers and to encourage providers to control costs and increase quality, but it is still too early to say whether these aims have been achieved. Increasingly, costs are expected to be controlled by the new DTC system in which hospitals must compete on price for specific treatments.

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The health system in Sweden

Anders Anell

Who is covered?

Coverage is universal. All residents are entitled to publicly-financed health care.

What is covered?

Services: the publicly-financed health system covers public health and preventive services; inpatient and outpatient hospital care; primary health care; inpatient and outpatient prescription drugs; mental health care; dental care for children and young people; rehabilitation services; disability support services; patient transport support services; home care; and nursing home care. Possibilities for residents to choose primary care provider and hospital vary by county council.

Cost-sharing: cost sharing arrangements exist for most publicly-financed services. Patients pay SEK 100–150 per visit to a primary care doctor, SEK 200–300 for a visit to a specialist or to access emergency care and up to SEK 80 per day in hospital.¹ For outpatient pharmaceuticals, patients pay the whole cost up to SEK 900 per year, while costs above this are subsidised at different rates (50%, 75%, 90% and 100%) depending on the level of out-of-pocket expenditure. Out-of-pocket payments accounted for 13.9% of total health expenditure in 2005.²

Safety nets: the maximum amount to be paid out-of-pocket for publicly-financed care in a twelve month period is SEK 900 for health services and SEK 1,800 for outpatient pharmaceuticals. Children are exempt from cost sharing for health services. An annual maximum of SEK 1,800 for pharmaceuticals applies to children belonging to the same family. Limited subsidies are available for adult dental care.

How are revenues generated?

The publicly-financed system: public funding for health care mainly comes from central and local taxation. County councils and municipalities have the right to levy proportional income taxes on their residents. The central government provides funding for prescription drug subsidies. It also provides financial support to county councils and municipalities through grants allocated using a risk-adjusted capitation formula.

One-off central government grants focus on specific problem areas such as geographical inequalities in access to health care. County councils provide funding for mental health care, primary care and specialist services in hospitals. Municipalities provide funding for home care, home services and nursing home care. Local income taxes account for 70% of county council and municipality budgets; the remainder comes from central government grants and user charges. Overall, public funding accounted for 85% of total health expenditure in 2005.²

Private health insurance: about 2.5% of the population is covered by supplementary private health insurance, which provides faster access to care and access to care in the private sector. In 2005 private health insurance accounted for less than 1% of total expenditure on health.²

How is the delivery system organised?

Government: the three levels of government (central government, county councils and municipalities) are all involved in health care. The central government determines the health system's overall objectives and regulation, while

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local governments determine how services are to be delivered based on local conditions and priorities. As a result, the organisation of the delivery system varies at the local level.

Primary care: organisation of primary care varies across county councils. Most health centres are owned and operated by county councils and general practitioners and other staff are salaried employees. Traditionally, health centres have been responsible for providing primary care to residents within a geographical area. This model is being replaced, with increased possibilities for residents to choose their provider and physician. Primary care has no formal gate-keeping function. Residents may choose to go directly to hospitals or to private specialists contracted by county councils. Increasingly, residents are encouraged to visit their primary care provider first. Higher co-payments for specialist visits are used to support such behaviour. Payment of public primary care providers is largely based on capitation, topped up with fee-for-service and/or target payments. The number of private primary care providers and ambulatory specialists working under a public contract is increasing; in some county councils about half of primary care physicians are private. Fee-for-service arrangements with cost and volume contracts are more common for payment of private providers, in particular for ambulatory specialists.

Hospitals: almost all hospitals are owned and operated by the county councils. There are no private wings in public hospitals. Hospitals have traditionally had large outpatient departments, reflecting low levels of investment in primary care. For tertiary care the county councils collaborate in the six regions with at least one university hospital. Private hospitals mainly specialise in elective surgery and work under contract with county councils. Physicians and other hospital staff are salaried employees. Payment of hospitals is usually based on DRGs (diagnosis-related groups) combined with global budgets.

What is being done to ensure quality of care?

At the national level, the Swedish Council on Technology Assessment in Health Care (SBU) and the National Board of Health and Social Welfare support local government by preparing systematic reviews of evidence and guidance for

priority setting respectively.

At the local and clinical level, medical quality registers managed by specialist organisations play an increasingly important role in assessing new treatment options and providing a basis for comparison across providers. Transparency has increased and some registers are now at least partly available to the public. Since 2006, performance indicators applied to county councils and, to some extent, providers are systematically applied by the county councils in collaboration with the National Board of Health and Welfare. Further improvements in the transparency of national quality assessment include setting up a register of drug use.

Concern for patient safety has been growing. The five most important areas with potential for improvement are: unsafe drug use, particularly among older people; hospital hygiene; falls; routines to control for fully avoidable patient risks; and communication between health care staff and patients.

What is being done to improve efficiency?

Several initiatives are being implemented to improve general access to health services and to treatment. According to an agreement between the county councils and the central government, all non-acute patients should be able to see a primary care physician within seven days, visit a specialist within ninety days of referral by a GP and obtain treatment within ninety days of the prescription of treatment by a specialist. Most county councils struggle with longer waiting times for some patients and services (particularly for elective surgery). If patients are required to wait more than ninety days they can choose an alternative provider with assistance from their county council.

In primary care, residents in several counties are encouraged to choose a provider based on their own assessment of access and quality, with money following the patient. A parallel policy is to increase the number of private primary care providers and encourage general competition for registration by residents. At the same time, however, there is a call for closer collaboration between primary care providers, hospitals and nursing home care, particularly where care of older people is concerned. There are similar calls for increased integration of health and social services for mental health patients.

How are costs controlled?

County councils and municipalities are required by law to set annual budgets for their activities and to balance these budgets. In the past the central government has introduced temporary financial penalties (by lowering its grant) for local governments that raised their local income tax rate above a specified level. For prescription drugs, the county councils and the central government agree on subsidies to the county councils for a period of five years. The national Pharmaceutical Benefits Board (Läkemedelsförmänsnämnden) engages in value-based pricing of prescription drugs, determining reimbursement based on an assessment of health needs and cost-effectiveness.

At the local level, costs are controlled by the fact that most health care providers are owned and operated by the county councils and municipalities. Most private providers work under contract with county councils. Financing of health services through global budgets and contracts and paying staff a salary also contributes to cost control. Although several hospitals are paid on a DRG basis, payments usually fall once a specified volume of activity has been reached, which limits hospitals' incentives to increase activity. Primary care services are mainly paid for via capitation or global budgets, with minimal use of fee for service arrangements. In several county councils, primary care providers are financially responsible for prescribing costs, which creates incentives to control pharmaceutical expenditure.

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What are the prospects for a new golden era in vaccines?*

Louis Galambos

Summary: From 1945 through the 1970s, vaccines experienced a golden era in innovation, production and distribution. Paradoxically, this era was followed in the United States by a sharp contraction of the industry – the first crisis of the vaccine commons. A second crisis followed in the 1990s, and efforts to revive the industry failed. While Europe was shielded from the first crisis, globalisation and a wave of industry mergers removed that protection. Currently the UK industry is expanding and Europe now leads the world in vaccine innovation and production. The author concludes, however, that the global vaccine industry, vital to public health, is still vulnerable to another crisis created by the tendency of vaccines to become narrow-margin, high-risk commodities.

Key words: vaccines, innovation, globalisation, commodification, crises

The prospects for a new era of vaccine innovation will be shaped not only by science and technology but also by the political and economic environments in developed nations like the United Kingdom and the United States. The first golden era from 1945 through the 1970s saw the introduction of nineteen new vaccines against a wide range of infectious diseases. As a result, decisive improvements were achieved in life expectancy and morbidity throughout the world. So beneficial were the vaccines developed in the post-war years that the World Health Organization (WHO) mounted two global immunisation campaigns. By the end of the 1970s, smallpox was eradicated, and the second campaign, the Children's Vaccine Initiative, significantly increased the vaccination rate among children in developing nations^{1,2} (although vaccination rates are falling in the developing countries).

The first crisis – the 'vaccine commons'^{***}

Paradoxically, the golden era was followed by the first vaccine crisis. Narrow margins

and high risk in the US began to squeeze vaccine producers out of the industry. A number of major firms left vaccine innovation and supply. Governments were the largest purchasers of vaccines, and public agencies exerted downward pressure on prices. Costs increased faster than prices, adding to the problems being created by liability cases. Vaccines became low-margin commodities. Soon, only five major firms were left in the US industry, with a study by Merck concluding that "No company currently not in the vaccines business would (logically) choose to get in."³

At first, the European vaccine industry was protected from the changes taking place in America. The major innovators were developing and producing vaccines for their respective national markets, and this insulated Europe from the American 'problem of the commons'.

Efforts in the US to solve the problem failed. Some progress was made in

reducing the risks of litigation, (principally via the US National Childhood Vaccine Injury Act), but the cost-price squeeze persisted and prevented re-entry by major pharmaceutical firms. Neither government studies nor an investigation by the National Academy of Sciences brought relief to the industry or to a public that periodically had reason to be concerned about vaccine innovation and supply.

Globalisation and the second crisis

In subsequent years, globalisation and a wave of mergers changed the vaccine industry. The age of national champions gave way to a drive to lower barriers to trade. As a result of mergers, the number of major vaccine producers in the world actually declined further. During these years, competitors in the industry also had greater freedom to develop alliances, such as the joint venture in the EU between Sanofi Pasteur and Merck Sharp & Dohme.

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* The title of this article is adapted from a quote by Gregory A Poland who stated that "we are entering a new golden era of vaccinology" in an article by G Paschal Zachary, Vaccines and Their Promise Are Roaring Back, published in the *New York Times* on 26 August 2007 [<http://www.nytimes.com/2007/08/26/business/yourmoney/26ping.html>]

** The 'Tragedy of the Commons' is a type of social trap, often economic, that involves a conflict between individual interests and the common good. It states that free access and unrestricted demand for a finite resource ultimately structurally dooms the resource through over-exploitation. Here, while low prices and successful liability cases benefit individuals, these ultimately lead to the decline of an industry vital to public health.

It was in this setting that the second vaccine crisis began with a political attack on the industry from an entirely new angle. In 1993, the Clinton Administration accused US vaccine producers of preventing immunisation by charging high prices for paediatric products. There was no reliable evidence that this was true, indeed there was substantial evidence to the contrary. But legislators could not appear to be opposed to preventive medicine for children, and Congress passed legislation to promote immunisation of certain selected groups of children.^{4,5}

After the smoke had cleared from this political mess, the public concern about vaccines shifted back to the two issues that had been of great concern in the 1980s: innovation and supply. The supply issue surfaced in 2004, when the UK's regulatory authority, the Medicines and Healthcare products Regulatory Agency (MHRA) suspended the manufacturer's licence of the Chiron influenza vaccine plant in Liverpool, which was scheduled to supply forty-six to forty-eight million doses to the US.

The Chiron problem had one prominent silver lining because it was followed by a decision on the part of Novartis to buy the share of Chiron that it did not yet own. The Swiss firm was the type of research-oriented company with significant production and distribution capabilities that the vaccine business had lost in the years since the mid-1970s. Novartis was the world's fourth largest pharmaceutical company (based on sales in 2006) and by purchasing Chiron, it became immediately the world's fifth largest vaccine firm.

Meanwhile, a number of small research firms also entered what had become a truly global industry. The biotechs focused on vaccine research and development. By themselves however, the biotechs were no more able than governments or professional organisations had been to solve the problems of supply and innovation – the problem of the vaccine commons. For insight into what might be the solution to that problem, we need to look into recent developments in the UK vaccine industry.

Monopsony and oligopoly in the United Kingdom

The vaccine sector in the UK is similar to that of the US, but the demand side of the UK market is very close to being a monopsony (with a single buyer). The Department of Health, General Practi-

tioners, and the National Health Service (NHS) trusts all purchase vaccines.* For a substantial number of their products, they use restricted bidding: only those invited to participate are allowed to present tenders (that is, make bids). Other vaccines are tendered under open procedures. Both the Department and NHS receive technical guidance on the need for vaccines, on immunisation practices, the quality of vaccines, and other specific matters from the Joint Committee on Vaccination and Immunisation, and sub-groups of experts within the Committee.

Predictably, the Department and MHRA attempt to encourage the development of more than one source of supply. Increased competition on the supply side increases the market power of the monopsonist. This creates a paradox because “the main reasons for the narrow market relate to the high and increasing cost of vaccine development and production, merger of manufacturers and the relatively low profit margins compared with other pharmaceutical products”.⁶ In that regard, the UK and the US demand-side situations have produced similar results: in the short-term, narrow profit margins; in the long-term, concentration on both sides of the market.

Despite the problems of confronting monopsony in the UK, the major UK firms have remained innovative – in part, because globalisation leaves them less dependent upon any single national market. GlaxoSmithKline (GSK) is a prime global competitor and innovator in vaccines. The company, headquartered in London, now produces a number of the important vaccines used in the UK, and its global vaccine business had sales in 2007 of £2 billion – an increase of 20% over the previous year.⁷ The firm's leading products include hepatitis A and B vaccines, combination A/B vaccine, a new vaccine against human papillomavirus (HPV), and the influenza vaccine. GSK Bio currently has twenty-four vaccines in clinical trials – many of them the combined vaccines that facilitate immunisation.⁸ Both GSK and Novartis have, as well, tackled the thorny problems of discovering and producing vaccines for the developing world. GSK Bio is working on vaccines that could be effective against malaria and Dengue fever. The Novartis Vaccines Institute for Global Health is also focusing its research efforts

on diseases that have been devastating to the populations of developing nations.

Sanofi Pasteur MSD Limited combines in a joint EU-oriented venture the vaccine capacity and research facilities of two leading vaccine companies. Sanofi Pasteur has roots that reach back into the beginnings of modern medicine and the era of the world's first successful vaccines and serums. Sanofi Pasteur, which is the vaccines division of Sanofi-Aventis Group, provided global markets in 2006 with over a billion doses of vaccine directed against twenty diseases.

There are a number of other important vaccine producers in the UK market. Wyeth Vaccines has introduced the world's first billion dollar vaccine: *Prevenar* prevents serious diseases caused by *Streptococcus pneumoniae*. Wyeth also produces a meningococcal C vaccine and distributes an influenza vaccine for the UK market. In October 2006, Pfizer came back into vaccines by acquiring PowderMed, and AstraZeneca has acquired MedImmune and with it the FluMist vaccine. The suppliers of pandemic influenza vaccine include Baxter International Inc., and Solvay Pharmaceuticals is producing seasonal influenza vaccine. While UK biotech firms have been less aggressive about vaccine research than their US counterparts, several of these small organisations have entered the field in recent years.

This brief overview of the UK vaccines industry suggests that it is on the threshold of a new era of expansion and innovation, an era that might see the global vaccine commons restored. The sources of this revival are not public or professional reform efforts; instead, the primary factors are the lower levels of innovation in pharmaceuticals and the new science and technologies flowing from the molecular genetic revolution and biotech. This push and pull have edged some of the world's large pharmaceutical firms back into the business.

This recent transition in the industry has swung the balance in supply and to a lesser extent in innovation of vaccines back toward Europe and away from the US. While North America is still the largest single market for vaccines, almost 90% of the world's production now takes place in Europe. Two-thirds of vaccine research

* This section concentrates on practice in England. Health care is a devolved responsibility in the UK and different organisational structures operate in Northern Ireland, Scotland and Wales.

and development (R&D) is now being conducted by European firms. Almost all of the European investment in R&D (22.5% of sales) comes from the private sector, and almost all of it is focused on new vaccines.^{9,10} If these developments continue, we may indeed have a second golden age of vaccines.

What are the current threats to innovation and supply in vaccines?

While the vaccine industry has thus experienced some encouraging changes, this has not removed the threat to the global vaccine commons. Margins will remain tight and may become tighter. Pressure to reduce health care costs is likely to continue for many years. In the UK, the medicines bill is currently under scrutiny, with likely reform to the Pharmaceutical Price Regulation Scheme, while in the US health insurance protection is declining. There is no mechanism in either country for ensuring that each individual purchasing organisation will not drive the best bargain possible for its clients. Indeed, all are under significant pressure to continue doing just that. Where they have market power, they are likely to exercise it and once again threaten the commons.

Any general economic decline that reduces public health budgets for preventive medicine will negatively impact on investment in vaccine R&D and investment in increased capacity. As the American situation of the 1970s and 1980s clearly indicated, governments are slow to respond to structural changes in vaccines. There is often substantial political capital to be acquired by attacking big pharmaceutical companies on almost any issue, including vaccines. If such attacks and narrower margins start another decline, the public sectors in both nations will probably be as poorly equipped as they were in the past to restore or sustain the health of this vital industry.

Does that mean we can do nothing to improve the prospects for a new golden era in vaccines? No, I think there are three measures that will help ensure a golden future in this wing of preventive medicine. First, we should continue to support the basic science that has been the necessary foundation for success in vaccine R&D. Second, we should do everything possible to counteract poorly conceived and short sighted political and media attacks on the industry. Third, we should attempt to promote in all of our public health agencies attitudes toward negotiating that recognise

the long-term needs of society – the commons – as well as the short-term needs of the governments' budgets.

What are the chances that we can be successful on all three counts? The first proposal seems achievable in both the US and the UK without radical change in either the public or private sectors. The second calls for statesmanship, a long term vision, and greater political collaboration, all of which are likely to be in greater supply in the UK than in America. The third will be the most difficult to achieve in the foreseeable future. The problem has been well-defined for over two decades now. But the solution may require more transparency, industry-government collaboration and compromise than either nation is capable of mustering. That being the case, we may be facing more tragedies of the vaccine commons.

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Values in Health – From visions to reality

**11th European Health Forum Gastein
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Inspirational goals such as 'Health for all' and 'Health in all policies' are based on seemingly shared values, but how are such values translated into policy and practice? This will be the guiding question for the following topics at the EHFG 2008:

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Access to research data in Europe

Philipa Mladovsky, Elias Mossialos and Martin McKee

Summary: The European Commission's Seventh Framework Programme (FP7) is much more ambitious than its predecessor and health research has been boosted, taking €6 billion of the overall budget of €50.5 billion. Yet, in contrast to other leading research funders, FP7 is largely silent on the issue of access to research data. Sharing health research data is in many ways more complex than other types of research data because of the ethical and regulatory issues. However, these and other technical, legal, cultural and institutional barriers to increasing access to research data should not discourage policy development in this area, since there are many potential benefits.

Keywords: Data, Data Sharing, Research Funding, European Commission

2007 marked the beginning of the European Commission's (EC) Seventh Framework Programme (FP7) for research and technological development, its main instrument for funding research in Europe over the subsequent seven years. It is much more ambitious than its predecessor, the Sixth Framework Programme (FP6), with a large funding increase (63% compared to FP6) and includes the creation of a European Research Council, which aims to fund more high-risk research at the frontiers of science.

Health research has been boosted, taking €6 billion of the overall budget of €50.5 billion. Yet, in contrast to other leading research funders, the EC has done relatively little to promote access to data whose collection it has financed. This paper reviews the current international situation regarding access to research data, focusing mainly on the field of health, and provides a contribution to discussions on future European research policies.

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Access to research data

FP7 is largely silent on the issue of access to research data. In the 1990s, European legislation actually increased barriers to data sharing by means of the European Database Directive¹ which gave significant copyright protection to databases. The directive benefited commercial providers with a modest, one-time growth spurt, but it has been accused of eroding data sharing in the public domain, with particularly harmful consequences for academic (and commercial) science.² However, a debate is now underway within the EC, with the Commission's Directorate General for Research having organised some exploratory workshops on this subject and earmarking funding to develop and link digital repositories and create data preservation mechanisms.³

The lack of concrete policies on data access within FP7 is in stark contrast to the proliferation of international initiatives over recent years. Initiatives to increase access to data have been particularly successful in the fields of genomics and proteomics (the large scale study of proteins, particularly their structures and functions)⁴ and more recently in the field of chemistry,⁵ but they have also been used with effect in health (Box 1).

Benefits of open access to data

Sharing data in health research is, in many ways, more complex than in genomics and proteomics research, because of the ethical

and regulatory aspects of using information that could, in some circumstances, be linked to individuals. However, it is important that this does not create an insurmountable barrier to data exchange, for several reasons.

Firstly, as a matter of principle, publicly funded research is a public good and ensuring that research data are easily accessible is primarily a matter of sound stewardship of public resources.⁶ Secondly, the responsible sharing of data through open access has a plethora of benefits to society. Thus, access to survey data facilitates the development of alternative conceptual frameworks and the ability to test new hypotheses.

Access to clinical trial data is important for undertaking meta-analyses, the application of enhanced econometric models and validity checking. It fosters a more critical approach to the interpretation of results, something which is currently perceived to be lacking, particularly in relation to trials funded by the pharmaceutical industry.⁷⁻¹¹ Access to clinical trial data also confronts the selective reporting of favourable results, although this issue is addressed to some extent by increasing requirements for advance registration of protocols of clinical trials, such as those by ClinicalTrials.gov in the USA and the International Committee of Medical Journal Editors. In Europe, as a result of the European Clinical Trials Directive (Directive 2001/20/EC), since May 2004 all clinical

trials conducted in member states of the European Union have to be registered in the EudraCT database, which is supervised by the European Medicines Agency. However, this registry is confidential and cannot be publicly accessed.

Challenges associated with open access to data

There are, however, a number of issues that arise when considering data sharing at a European level. First, for data to be meaningful to researchers, they will ideally have to be made available as individual records. It will be necessary to ensure that data are anonymised before being made available; including provisions to prevent reverse processing that could allow individuals to be identified. Complicating this issue, in some circumstances, it will be necessary for individual records to be linked to other data sets. This will require a mechanism to make this possible, while safeguarding the privacy of the individuals involved. Where this is the case, it will be necessary to negotiate access and linkage on a case by case basis since release will depend on a variety of factors, including the nature of consent for data use and governance arrangements in the setting where the data were collected. This will require a complex approval system and it remains unclear whether the benefits of creating a Europe-wide system to facilitate this, as opposed to ad hoc arrangements, would be outweighed by costs incurred.

Another strategy to protect confidentiality is providing access only in a 'safe setting', such as on the premises of the custodian of the data,¹² although this hardly seems adequate if the benefits of Europe-wide collaboration are to be achieved. Digital tools that provide security and control access are another alternative, but these may be difficult to manage on a large scale. They also need to be open-source licensed.⁴ Furthermore, maintaining good relations with survey participants is important, particularly in longitudinal studies, and researchers may be wary of jeopardising this by risking a breach of consent.¹² Other legal considerations include concerns about privacy, national security, patents, royalties, time-proof rights, ownership or intellectual property rights.^{4, 13-16}

In some contexts the challenges of sharing of individual level data may be too great to overcome. However, in the case of clinical trials, full disclosure and availability of all summary level data would still be a signifi-

Box 1: Selected initiatives to promote access to research data relevant to health policy research

United Kingdom

- The Economic and Social Research Council has a mandatory Datasets Policy linked to the UKDA (the UK Data Archive).
- The Medical Research Council and Wellcome Trust both require grantees to share data.
- The National Cancer Research Institute (NCRI) aims to ensure that data generated across different organisations can be integrated and linked, nationally and internationally.
- The 'National Strategy for Data Resources for Research in the Social Sciences' includes plans for linking different government administrative data sources with census and survey records, a methodology which is already established in other countries, such as in Canada under the Institute for Health Information.

Rest of Europe

Despite the lack of explicit policy, several initiatives to improve data sharing at the European level are already underway, with some receiving Framework Programme funding:

- CESSDA (Council of European Social Science Data Archives);
- The Madiera project (Multilingual Access to Data Infrastructures of the European Research Area);
- MetaDater (Metadata Management and Production System for surveys in Empirical Socio-Economic Research);
- The East European Data Archive Network (EDAN); eContentplus; and European Research Observatory for the Humanities and Social Sciences (EROHS).

Several European datasets that are used for health research have developed provisions for shared access:

- The European Social Survey (ESS);
- The Survey of Health, Ageing and Retirement in Europe (SHARE);
- The European Community Household Panel (ECHP), now replaced by EU-SILC, the Survey on Income and Living Conditions;
- Eurobarometer;
- The European Core Health Information Survey (ECHIS).

North America

- The American Medical Informatics Association (AMIA) initiatives to develop a national framework on the acquisition and use of health data and the Global Trial Bank;
- The Clinical Data Interchange Standards Consortium Laboratory Model (CDISC);
- The Inter-University Consortium for Political and Social Research (ICPSR);
- Healthcare Cost and Utilisation Project (HCUP);
- The Canadian Association of Public Data Users (CAPDU);
- National Institutes of Health Data Sharing Initiative.

International

- The International Association of Social Science Information Service and Technology (IASSIST);
- The OECD 'Draft Recommendation Concerning Access to Research Data from Public Funding';
- The WHO International Clinical Trials Registry Platform is working on defining a minimum set of trial results to be reported about every trial worldwide.

cant improvement over the status quo and would also mitigate the problem of outcomes reporting bias.⁷⁻¹¹

A second challenge in data sharing relates to the significant technical barriers that may need to be overcome, relating to inter-

operability of systems at computing and semantic levels and the use of a variety of storage formats. Technical and software standards and protocols, such as standardisation of methods, syntax and semantics (within fields and in labelling), are needed to ensure the access and usability of data.^{4,6}

Third, there may be cultural and institutional issues, such as linguistic barriers or managerial impediments. These hurdles may include:

- negotiating degrees of collaboration between researchers sharing data;
- co-authorship issues;
- lack of incentives to supply data;
- anticipating data sharing needs at the beginning of the data lifecycle;
- the burden of managing data sharing, for example making secondary users of data aware of each others' research to avoid duplication;¹²
- providing/explaining meta-data or logs of research protocol to secondary users;
- the lack of international standards for infrastructures including network capacity and security of access;
- the lack of international or even national standards for data formats;
- cost of time spent negotiating data sharing standards across different organisations; and
- the burden of archiving responsibilities.⁴

There may also be financial barriers, such as the arrangements for costs of data management between disparate agencies; securing resources for data sharing activities from funders; and the need to anticipate the costs of data sharing costs when setting budgets.

Fourth, there is the issue of quality. Secondary researchers will not be willing to make use of data unless its quality can be assured.⁴ From the perspective of the custodians of data and the funders of the research, sharing data raises questions about responsibility for ensuring the quality of secondary research. However, there is no consensus on appropriate standards, let alone how they might be ensured.¹²

Despite these challenges, there has been some progress in sharing health related data at the European level (Box 1). The Survey on Income and Living Conditions (EU-SILC), the European Core Health Information Survey (ECHIS), both administered by Eurostat, and Eurobarometer are coordinated by the EC and provide access to data, but in some cases users are charged for access. Since this research is funded by European taxpayers, it is not clear why European public insti-

tutions should have to pay to access this data. Two important academically led health related initiatives funded by FP6, the European Social Survey (ESS) and the Survey of Health, Ageing and Retirement in Europe (SHARE), on the other hand, have taken it upon themselves to provide open access to data, free of charge.

Conclusion

There are many unresolved issues in improving access to research data. In terms of health research, as well as the clear benefits for improving access to survey and clinical trial data, there are also a multitude of costs and barriers. The research community has started to address some of these issues, but there remains much to be done. As major public funders of research, the Framework Programmes should develop policies to facilitate access to data generated by grant recipients. Since it has already been launched, it may be too late for FP7 to take these forward. If it is not possible to amend FP7, frustratingly, the next opportunity is probably FP8, not due to begin until 2014.

In the meantime, steps that the EC could take include: developing a framework within which clear policies on access to research data can be agreed; funding and developing European data repositories; encouraging national and international public funders to develop data access policies; and supporting initiatives aimed at understanding and overcoming technical, legal, cultural and institutional barriers to increasing access to research data. Future data sharing policy within the Framework Programmes can also be informed by good practice manifest in existing FP funded initiatives such as ESS and SHARE.

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Supporting and using policy-oriented public health research at the European level

Hans Stein

Summary: Interest in public health research in Europe, so as to provide 'evidence-based' policy, is growing, at both the international and national levels. Yet the links between the scientific research community and policy makers are not as close as they could be: the scientific community remains reluctant to meet policy needs; pragmatic policy-makers do not readily accept advice coming from research. Strengthening of public health research in Europe can only be achieved if a strategy is developed and implemented to bridge the gap. As part of work undertaken within SPHERE (Strengthening Public Health in Europe), this article examines how the European Union (EU) and the World Health Organization (WHO), have contributed to supported research in Europe and then makes recommendations on how links and cooperation could be improved.

Keywords: health policy, public health, research, Europe

Health policy activities and obligations at the national level are similar across Europe. Each country has to have a health system. There need to be laws and regulations for the establishment, organisation, development and funding of the system. Health remains a national competence: international organisations, governments and even citizens, are very much concerned that international institutions in their activities "fully respect the responsibilities of the Member States for the organisation and delivery of health service and medical care" as indicated in Article 152 of the EU Treaty.

This may be considered to limit the content and character of actions by international institutions. Yet EU Treaties and WHO documents confirm that these institutions can complement national health policies, monitor and evaluate processes, assist governments (though, as a rule, only

on request), give advice, encourage and promote co-operation, propose solutions, foster activities, provide information, counsel and assistance and develop international standards. But while the scope of international action is wide, the instruments to achieve these aims are not well documented. There is relatively little health legislation at the international level, although notable exceptions include EU directives on tobacco and several WHO international health regulations, all of which have to be transposed into national law.

Research is the only instrument mentioned as a policy tool in both EU treaties and the WHO Constitution. Yet, perhaps surprisingly, while Member States look suspiciously at all international actions in health policy, until now they have shown very little interest in health research, even though this can often go far beyond policy actions. The freedom research enjoys, coupled with its international character and the need to make use of research in health system development, suggest that support for research by international institutions could strengthen public health.

This article reports on work to analyse the role of the EU and the WHO in public health research conducted as part of *SPHERE* (Strengthening Public Health in Europe, <http://www.ucl.ac.uk/public-health/sphere/spherehome.htm>) project. The overall aim of *SPHERE* was to describe European public health research activities, including support from international institutions and national governments and to advise how policy related research might better be integrated with European health policy and practice.

Two communities: research and policy

In 2006, the European Public Health Association published ten statements on the future of public health in Europe.¹ Three were concerned with research, emphasising that it should meet the needs of policy and practice, with researchers better interacting with politicians and practitioners. Although several EU Health Council resolutions since 1999 have stated that research must have an essential role in underpinning the Community's public health actions, little has been done to bridge the gap between research and

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policy. In Council conclusions (June 2006) on 'Common Values and Principles in EU Health Systems', there was no specific reference to the EU's 7th Research Framework programme (FP7).² Research funded by the European Commission (EC) contains only a small (albeit growing) number of policy related projects, interaction between researchers and politicians is limited, while the dissemination of research results is fragmented, project-related and not strategically directed at priority policy needs.

Institutional and organisational differences

Much has been written about the two communities of research and policy making.³ Health research and health policy making have distinct organisational structures and programmes and place a very different emphasis on dissemination and implementation. Research is often driven by scientific priorities with little regard for policy relevance, unlike health policy which is usually led by legal arrangements (laws, regulations) and often requires the consensus of a range of stakeholders.

Moreover, the impact of health systems research, in contrast to clinical research, may have little impact on policy makers. As a consequence, many suppliers and users of social research are dissatisfied: the former because they are not listened to, the latter because they do not hear much that they want to listen to. In a characterisation of opposing perspectives the research community "asks questions we already know the answers to", while the policy community "wants simple answers to difficult questions delivered yesterday, proposing answers that will lead to results tomorrow, costing as little as possible".

Similarly, the former editor of the *British Medical Journal*, Richard Smith in describing the "disconnect between practice and research" observed that researchers value basic science, discovery and originality, while practical questions are seen as dull, unoriginal and "unimportant in scientific terms".⁴ He noted that there is often no mechanism to transmit the questions of practitioners to researchers, while scientists are wary of directed research and health policy may boast that they do not make use of research results. At both a national and international level the differing interests of the principle stakeholders in the research and policy making communities have been strong enough to block real changes in the past. Cooperation across Europe could

contribute to towards overcoming these obstacles and perhaps might even play a leading role.

Research and health as EU policies

Research

Fifty years ago, with the Treaty of Rome in 1957, neither science and technology, nor health, were on the EU policy agenda. The first steps were undertaken in both areas without a specific Community competence. The decisive breakthrough of a comprehensive Community strategy on research was made by the Single European Act in 1987, which brought science and technology within the formal competence of the EC. Since then, research has steadily developed into an undisputed EU key priority on the same level as agriculture and regional policy. The annual budgets of the research programmes have risen continuously from €3.75 million for the FP1 programme to €50 billion for FP7 where health (including public health) is the number one priority.

Within FP7 one key strand is the programme 'Cooperation – Collaborative Research', which includes core research funding of €2.45 billion for health-related research. Health also features in other thematic areas: Food, Agriculture and Biotechnology, and Information and Communication Technologies have allocated 50% and 10% of their respective budget to health topics. The focus of the EU health research programme continues to be biomedical research including the "strengthening of the competitiveness" of industry. However, public health research is considered in a one programme strand "Optimising the Delivery of Health Care to European Citizens", which has three components: translating clinical research into clinical practice (medicines, behavioural and organisational interventions, and health technologies); quality, efficiency and solidarity of health care systems (health systems); and enhanced health promotion and disease prevention. There is also support for 'horizontal' research, including a section on policy implementation.

Public health

The development of public health as an EU policy area has followed a similar path to research. It took more than three years for the EU to agree a budget for the first Public Health Programme in 2002. The links between research and policy that had been considered necessary by experts and

previous Council resolutions were hardly visible. There was no specific statement on the issue of cooperation and coordination between policy and research, nor common action or strategy, nor structured mechanisms or a permanent link and interface between the two areas. Consequently, research had no formal role in underpinning the Community's public health actions; health research and health policy remained two independent, perhaps even rival, areas.

Public health is still not a European top priority. Member States remain reluctant to give the Commission a strong position in health policy affairs, particularly when matters of organisation and funding of health care are involved. The entire Community action programme for public health is just €360 million over the period 2008–2013. Moreover, a decisive shortcoming is that the programme lacks legally binding measures, or harmonisation, that can be used to influence Member States health policies directly

Yet the political context is changing; health including public health is today more accepted as a relatively important EU policy area. This change is influenced by growing health threats such as communicable diseases, including HIV/AIDS, SARS, and bio-terrorism, as well as by health care related developments (cross-border care, patient and professional mobility) triggered by European Court of Justice rulings. The Commission's Public Health Strategy leaves room for links with research, if there is political will and, more importantly, power for action. The programme contains the possibility of joint strategies and actions in other unnamed sectors.

Links between public health research and public health policy

The need for close links between research and policy at EU level, as well as mechanisms to set research priorities, have long been expressed in conferences, workshops and official EU documents. For instance, in 1994 in Celle, Germany, a meeting discussed the development of a European public health research strategy that would both respect the need for high quality research and fit public health policy objectives and needs in relation to FP4 and BIOMED II. While a meeting was proposed between Commission DG Research, DG Health (Sanco) and Celle, it was not forthcoming. Similarly, a recommendation that the Commission should

develop mechanisms for establishing appropriate working partnerships with public health authorities at European and national levels was not implemented.

Another conference at Potsdam in 1999, under the German presidency, entitled *The new public health policy of the European Union*, contained a working group on the contribution of research to EU public health policy. It acknowledged that better coordination of research and health actions would greatly improve the quality of research and dissemination of results, but again there was no follow up.

In Granada, in 2002 under the Spanish presidency, a conference entitled *Research in the health systems of the European Union: needs and priorities* recommended that research should be based on health needs, while health policies should be based on research results. It called for multi-institutional and multidisciplinary co-operation networks, with their own agendas for research priorities, focussing on the context for application, on health problem solving, and promoting a permanent exchange of knowledge and technologies, with evaluation criteria taking a predominant role, and where social relevance was considered alongside scientific quality.

Later that year, the Commission (three directorates -- Research, Employment and Social Affairs, and Health and Consumer Protection) organised a joint workshop to "bring together a broad range of experts, researchers and administrators to discuss how European research collaboration can be developed and what types of health and social policies can best be addressed using cross-national research". There was consensus that many policy issues provided a large agenda for research and that research programmes should provide relevant, well-focused inputs into the policy cycle, to ensure that the results have an impact on policy decision-making.

The role of WHO in health research

The WHO has long played an important role in health research and has co-operated on this issue with the European Commission since the early 1970s. More recently, a Memorandum on the framework and arrangements for cooperation between the two organisations was published in 2001. It noted the importance of "promoting health-related research and technological development, taking stock of its results and developing advice on applications in the health and health-related

fields". Activities to be pursued included an exchange of information, setting up of databases, as well as joint analysis, financing and participation in committees and working groups.

At a European level the WHO Regional Office for Europe developed a *Health for All Strategy* in 1984. This contained a very ambitious target that "before 1990, all Member States should have formulated research strategies to stimulate investigations which improve the application and expansion of knowledge needed to support their Health for All developments".⁵

The target called for Member States to develop mechanisms for:

- effective application of new knowledge in the development of health policies and programmes;
- identification of knowledge gaps;
- setting research priorities;
- involving health policy makers in the planning and coordinating of research;
- stimulation multidisciplinary research;
- allocation of sufficient resources to conduct the research needed.

The WHO strategy paper also recommended clear (national) strategies for *Health for All*, as well as (national) research strategies, both drawn up by government bodies. It stated that scientists and health policy makers should regularly review new knowledge emerging from research that could be of use for health policies and health care programmes. This ambitious, but somewhat unrealistic target was not achieved, perhaps illustrating perfectly what does not work!

In 1998, the WHO policy framework was updated in accordance with the ten targets adopted by the World Health Assembly in 1998. The new document, *Health21 – the Health for All Policy Framework for the WHO European Region*, reduced the original thirty-eight health targets to twenty-one.⁶ It stated that the EU was "an international organisation with a strong mandate for multi-sectoral action for health that has a large potential for contributing to this development". A new target focused on *Research and Knowledge for Health*. It stated that "by the year 2005, all Member States should have health research, information and communication systems that better support the acquisition, effective utilisation, and dissemination of knowledge to support *Health for All*."

This was grouped with other targets, including the creation of health and health-related information bases to support monitoring and evaluation of health policies; and the use of the media and communication sector to "inform, educate and persuade all people".

Acknowledging that "only a few" Member States had followed the advice given by WHO on health research policies and programmes, and that "hardly any country has a systematic mechanism for ensuring that new evidence from research is actually introduced into daily practice", it encouraged international research collaboration at the European level to be strengthened. An emphasis was placed on needs-based research, an increase in the number of inter-country research programmes and better exchange of research information.

The Health for All strategy was last updated in September 2005 in Bucharest. This revision makes little reference to research.⁷ Indeed both revisions of the Health for All Strategy since 1984 suggest that the extent of the problems in fostering research may have been underestimated and the potential to overcome them overestimated. Whereas all countries, even the smallest, now have health systems and policies that provide for health promotion and care for the whole population, many countries still do not have the capacity for health research. Even in those countries where capacity exists, research priorities are often determined independently and in a rather rigid fashion, rather than being set by specific policy sectors or international institutions.

While targets related to research have not been accomplished, this does not mean that research should be dropped. Targets may be modified in a realistic way, taking into account the limited capacities in many countries, as well as the growing international cooperation on policy-related health research, including financial and personal resources. Indeed today the research aims of WHO are much more pragmatic: to influence the research agenda, especially at a national level, identifying research needs and gaps; making use of research evidence for its own decisions and in providing advice and recommendations to its Member States. These aims could represent a WHO contribution to greater international cooperation, acting as a 'neutral broker'.

Strengthening public health and public health research

There are no clearly defined criteria on how the strengthening of public health research could be measured. Several criteria might be considered as signs of improvement, including greater priority, resources, funding and outputs for public health research, as well as increased application in policy making.

Using these criteria there can be little doubt that in the past twenty years the activities of the EU and WHO have made a positive contribution. There has been a substantial upgrading of public health research at a political level – internationally as well as nationally. A great variety of international projects have increased knowledge and broadened the evidence base in a way that national projects alone could never achieve. EU-funded research programmes have contributed to an increased investment of financial, professional and structural resources, not only at international, but also at a national level; while international cooperation has led to new structures and institutions.

The *Health in All Policies* movement of the EU, in combination with the WHO Health for All Strategy, with its approach for integrating health into relevant European policies and with its analytical and scientific roots, cannot however be implemented without strong support from the public health sciences. Shortcomings remain. There is little integration of policy needs into priorities setting for research programmes, reflecting a lack of cooperation and common strategic approach. The use of research evidence in policy making has been limited. While FP7 names “reinforcing health-policy driven research” as one of its aims, and has also significantly increased the topics and projects aimed at “underpinning informed policy decisions”, this is neither the “clear strategy” nor “joint action” proposed by experts and supported by the EU Health Council for many years. Furthermore no common mechanisms have been established. It is obvious that national research administrations are willing and able to fund policy-related projects, but they are not willing to change their structures and integrate the policy process.

The application of research results to policy needs is done through a continuous, long term and interrelated process with many different stages from initial development of a research programme through to dissemi-

nation and implementation of results. At all of these stages there needs to be co-operation between researchers and policy makers. The present situation, where policy makers highlight relevant research issues and then wait patiently for many years before receiving (perhaps outdated) results, is satisfactory neither for policy, nor for research. Pragmatically this might be improved through better use of existing research mechanisms and structures.

Subsidiarity

The decisive criterion for justifying such EU activities is that they can only be better achieved at an international rather than at national level. Subsidiarity is one of the fundamental principles of the EU and the basis for all international activities. The extent to which public health activities are consistent with this principle continues to be the subject of debate, but there can be no doubt that public health research as a whole meets this requirement. Some European countries, especially the smaller ones, may not be able to establish and implement full public health research strategies, or at best only develop individual projects. The failure of Member States to implement the (albeit over-ambitious) WHO research targets shows this clearly.

There is a growing consensus that some future efforts should be made at an international level, enabling research otherwise not possible on a national scale to be conducted, and in turn permitting all Member States to benefit from the ensuing research results. The principle of subsidiarity thus not only provides a legal justification for EU public health research, but also a political mandate and obligation. The progression of EU public health research over the last two decades, which has culminated in health as a priority area of FP7, illustrates how this can be achieved.

Structures

Full or partial integration of public health research with health policy structures at European level is not recommended. Instead, cooperation and consultation should be strengthened between research and policy, making use of existing structures and mechanisms. In the case of the EU, the highest policy-making institution would be the European Council (Summit). This body provides the EU with the necessary impetus for its development and defines general political directions and priorities, but does not have a legislative

function. Action can be led by the Council of Ministers who, together with the European Parliament, exercises legislative and budget functions.

There should be agreement between the different European institutions on long-term strategic goals and targets for health, as well as short-term priorities for both health and research. These objectives could be achieved by a strategy or white or green paper submitted by the Commission to the Council of Ministers and European Parliament for endorsement or amendment. This process is already used for other policy areas that receive research support. Once a strategy was agreed, implementation would be facilitated through appropriate legal and administrative instruments. In respect of research, this would be within the Framework Research Programme through its thematic programmes, whilst in respect of public health policy there would be the action programme or binding legal measures such as regulations or directives. The new Health Strategy as proposed by the Commission in its White Paper “Together for health” and presently being discussed at the Council is a step in this direction, but by itself does not solve the problem.

The work programme, as well as the call for proposals, should contain more detailed information about the policy context, especially research needs and expected research impact. The present practice of referring to the policy context by just naming policy documents is insufficient. In the same way, health policy documents should describe research more specifically and not just refer to the Framework Programme. In some cases, calls for proposals describe a project in great detail, while in others the description is quite general. Unless the research requirements of a policy are very specific, this should leave sufficient room for innovative ideas and solutions.

Dissemination

High quality research is not enough: effective dissemination of results and establishment of trusted policy links and contacts are essential to the success of a policy-related research project. Quite often, especially at the European level, researchers lack the knowledge and experience on how this could best be achieved. Past experience could be used to establish standard criteria and procedures.

Conferences or workshops might be used to promote an exchange of experience with

the results published as a handbook to guide future projects. This would be especially helpful for inexperienced first time applicants unfamiliar with the policy context at the EU level. Better links with policy could be established through the participation of policy experts/ representatives as full partners in projects. They might be responsible for the policy context and provide information about changing political developments and needs. Apart from the (usually very lengthy) official report of a project, targeted publication of key findings is an essential element of any dissemination strategy. This should be specified along with key target audiences to be reached in the project proposal itself.

Additional efforts may have to be made to create a new kind of link between research and policy at the project level. Activities for this purpose might include regular health policy conferences aimed at exploring and identifying future challenges for health systems, including health services; and projects aimed at “brokering research into policy” intended to transfer new as well existing knowledge into policy initiatives.

Conclusions

Tremendous progress in policy-related public health research has been made in Europe in the past three decades. It has firmly established itself as an area whose objectives cannot be achieved by individual countries alone, it needs international cooperation. This is demonstrated through the high priority given to health within FP7, while research has contributed to public health activity, the development of EU health policy and international cooperation.

Despite this progress, this is not a total success story. The ambitious objective that every country should have a formulated public health research strategy has not been achieved. The integration of policy needs into research programmes and the use of research results in policy decision-making, can be improved. In particular, the mechanisms for interaction between research and policy remain a challenge. The way forward is greater collaboration between the EU, Member States and the WHO.

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Health sector experts address the importance of strategic purchasing

In May 2008, the World Bank in collaboration with the WHO, the European Observatory on Health Systems and Policies, and the Center of Excellence in Finance organised a two-day workshop on ‘Strategic Purchasing’ in Bled, Slovenia.

The workshop focused on:

- Strategic purchasing: analysing the relationship between providers and discussing the contextual factors as well as the tools influencing its performance;
- Governance of strategic purchasing: focusing on the relationship between the Ministry of Health and health insurers, highlighting the regulatory environment required for ensuring that strategic purchasing aligns with health priorities and targets.

Strategic purchasing refers to a coherent set of incentives for providers through contracting and the provider payment mechanisms to encourage them to provide the best available treatment in a cost-effective manner. It also requires incentives and managerial capacity on the purchasers' side to engage in effective strategic purchasing policies.

The presentations are available for download at <http://www.cef-see.org/index.php?location=634&sublocation=860&nId=68>

Typically, these policies have to answer:

- what areas of performance are important;
- who will make the purchases of what and for what groups of people.

There are several governance tools for strategic purchasing, including quality councils; report cards or scorecards; and performance-management instruments, such as accountability agreements and provider profiling. The workshop focused on how strategic purchasing works in the context of single or multiple and public or private insurance systems; as well as how strategic purchasing is influenced by contextual factors such as growing shortages of providers, increased consumer choice and competition regulation.

Presenters included: Josep Figueras (European Observatory), Maureen Lewis (World Bank), Tamás Evetovits (WHO) and Pia Schneider (World Bank), along with prominent presenters from Estonia, Hungary, Iceland, Ireland, Macedonia, the Netherlands, Portugal, Slovenia and the Slovak Republic.

Celtic Tiger, Health Care Dragon:

Fiery debates in the Irish private health insurance market

Brian Turner

Summary: The Irish private health insurance market covers over 50% of the Irish population, despite universal access entitlements to the public health care system. Having had a monopoly for forty years, the statutory insurer, VHI, faced competition following deregulation in the mid-1990s. Currently there are three insurers competing in the market, and a number of regulatory measures have generated much debate. In particular, the introduction of risk equalisation and VHI's differential prudential regulatory regime are being challenged.

Keywords: Private health insurance, Ireland, risk equalisation, prudential regulation

The Irish private health insurance (PHI) market was formally established by the Voluntary Health Insurance Act, 1957. This Act established the Voluntary Health Insurance Board (VHI), which was intended to provide voluntary health insurance to the top 15% of earners who, at that time, were not entitled to free access to the public hospital system. Since then, access entitlements have been broadened, and currently all Irish residents are entitled to free, or almost free, access to public hospital accommodation and treatment by public hospital consultants. Despite this, the take-up of PHI has far exceeded the originally anticipated 15%, and currently over two million people, or more than 50% of the population, are covered by PHI, paying almost €1.25bn in premiums in 2006¹ (see Table 1).

According to two surveys^{2,3} carried out on behalf of the Health Insurance Authority (HIA) – the independent statutory regulatory body for the industry in Ireland –

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the main reasons underlying the high penetration rate include a belief that PHI gives consumers faster access and better services, and a widespread lack of confidence in the public health care system. PHI is seen by most people as a necessity rather than a luxury and as providing peace of mind.

Legislative foundation

The Irish PHI market is based on the three 'pillars' of community rating, open enrolment and lifetime cover. Under community rating, insurers are prohibited from varying premiums or benefits between consumers subscribing to the same plan, subject to certain exceptions, such as permitted discounts for children, students and members of group schemes, although within each of these categories

insurers must charge the same premium. Therefore age, gender, current or prospective state of health, or any other factor which may reflect the risk a consumer represents to an insurer, may not be taken into account when setting premiums or determining benefits.

Open enrolment means insurers cannot refuse cover to anyone, although they may impose three types of waiting periods, for initial applicants, pre-existing conditions and upgrades in cover. The maximum permitted waiting periods are age-related, which gives insurers some protection against hit-and-run or hit-and-stay behaviour by consumers. Lifetime cover mandates that once a consumer has PHI an insurer cannot refuse to renew cover, except in very limited circumstances. The

Table 1: Membership and premium trends, 2001–2006

Year	2001	2002	2003	2004	2005	2006
Membership (000s at end-of-year)	1,871	1,941	1,999	2,054	2,115	2,174
Premiums (€m full-year)	N/A	821.9	978.2	1,061.1	1,152.7	1,236.2

Source: Health Insurance Authority, 2007¹

combination of open enrolment and lifetime cover means that consumers may switch between insurers without penalty, in particular without having to serve additional waiting periods other than any they might already be serving with their previous insurer.

In addition to these 'pillars', there are regulations specifying a set of minimum benefits that any eligible health insurance plan must cover. This is primarily designed to ensure that consumers do not underinsure due to a lack of information or understanding. In order to safeguard community rating, a risk equalisation scheme was also brought forward. This aims to equitably neutralise differences in insurers' claims costs resulting from differing risk profiles, by obliging insurers with lower-risk membership profiles to pay into a risk equalisation fund, administered by the HIA, from which payments are made to insurers with higher-risk membership profiles.

This scheme was first introduced in 1996, but transfers were never made and the regulations governing the scheme were revoked in 1999. A new scheme was established pursuant to the Health Insurance (Amendment) Act, 2001, and came into force on 1 July 2003. In October 2005, the HIA recommended the commencement of payments under the scheme and the Minister sanctioned the commencement of payments, beginning on 1 January 2006.

There is broad cross-party parliamentary support for the legislative 'pillars' on which the market is based, and also for risk equalisation, though perhaps not quite as broadly-based for the latter.

Development of competition

In 1992, the European Third Non-Life Insurance Directive obliged EU Member States to open their non-life insurance markets to competition from insurers based in other Member States. This directive was transposed into Irish legislation by the Health Insurance Act, 1994. This Act, and associated regulations, formalised the principles of community rating, open enrolment and lifetime cover, which VHI had previously been operating on a de facto basis.

Subsequent to the opening of the market to competition, BUPA Ireland began selling health insurance in 1997. VIVAS Health entered the market in 2004. In late 2006, BUPA Ireland announced its decision to withdraw from the market

owing to the triggering of risk equalisation payments. In early 2007, the Quinn Group, which already operated in other non-life insurance markets in Ireland, took on BUPA Ireland's business, which is now trading as Quinn Healthcare. Although a number of relatively small restricted membership undertakings (for example, for the police and Electricity Supply Board workers) are in operation, Quinn Healthcare, VHI and VIVAS Health are the only three insurers operating in the open market for PHI in Ireland. Approximate market shares are 73% for VHI, 20% for Quinn Healthcare and 7% for VIVAS Health.

Having had a monopoly for forty years, VHI had built up a substantial customer base prior to deregulation. Since then, many of these customers have stayed with VHI, with relatively few switching provider. The HIA's second consumer survey showed that, by 2005 – eight years after the introduction of competition – only 10% of consumers had ever switched their health insurer, mostly from VHI to BUPA Ireland. It also showed that switchers tended to be younger than average consumers when they switched.

Risk equalisation

The first market feature that has caused considerable controversy was the introduction of risk equalisation. In practice, BUPA Ireland/Quinn Healthcare and VIVAS Health were/are net contributors to the risk equalisation fund, while VHI and one of the restricted membership undertakings are net recipients.

Although the original scheme was in place when it entered the market, BUPA Ireland was strongly opposed to risk equalisation on the basis that it would be required to make payments to VHI, which it saw as having a dominant market position. Following a complaint from BUPA Ireland, the European Commission examined whether risk equalisation in the Irish market constituted illegal state aid and decided in 2003 that it did not, thus paving the way for the introduction of the 2003 scheme. BUPA Ireland challenged the Commission's decision in the European Court of First Instance, but in a judgment delivered in February 2008 the Court dismissed this challenge.

BUPA Ireland also challenged the legality of the scheme in the Irish courts, and in a judgment delivered in November 2006, the High Court dismissed BUPA Ireland's case. BUPA Ireland appealed this decision

to the Irish Supreme Court, which heard the case in November 2007, although judgment has been reserved. In the meantime, a stay remains on payments under the scheme. BUPA Ireland currently has two cases pending in the Irish courts, including the Supreme Court appeal, while Quinn Healthcare also has two cases pending, one challenging the risk equalisation scheme, the other challenging emergency legislation that was passed in early 2007 to close a loophole that could have allowed Quinn Healthcare to benefit from a three-year exemption for new entrants from risk equalisation payments.

Prudential regulation

The other main source of tension is the prudential regulation of competing insurers. When VHI was established, it was exempted from the application of the Insurance Acts in Ireland. In amending legislation to the 1957 Act, it was also given the opportunity to engage in other activities besides its core health insurance business, subject to approval from the Minister for Health and Children. In recent years, VHI has begun selling travel insurance and dental insurance, operating an online health shop and establishing minor injury clinics.

In practice, this means that VHI is not currently subject to the prudential requirements applying to other non-life insurers in the Irish market. Prior to BUPA Ireland's withdrawal from the market, each of the three insurers in the market was subject to a different supervisory regime, with BUPA Ireland regulated by the Financial Services Authority in the UK, VHI overseen by the Minister for Health and Children and VIVAS Health regulated by the Financial Regulator in Ireland. Since Quinn Healthcare's entry to the market, it too is regulated by the Financial Regulator. From a health insurance standpoint however, all health insurers are regulated by the HIA.

What the differential prudential regulatory requirements mean in particular is that VHI is not required to hold the level of solvency reserves that its competitors must hold (equating to 40% of premium income), although it has built up its reserves in recent years in anticipation of the removal of this derogation. It is also claimed that VHI's ability to engage in other activities gives it an advantage, as its competitors would have to set up subsidiary companies if they wished to do so.

Following a complaint from VIVAS Health, the European Commission has insisted that VHI's derogation be removed. Such a change was mooted some time ago, as outlined in a White Paper produced by the then government in 1999,⁴ but not acted upon. Legislation to put this into effect is currently being debated in parliament.

Where do we go from here?

While risk equalisation has been given legal backing by the Irish High Court and the European Court of First Instance, the Supreme Court judgment is still awaited, and it remains to be seen whether the Court of First Instance judgment will be appealed to the European Court of Justice. Further legal challenges are also pending in the Irish courts, and Sean Quinn, Chairman of the Quinn Group, has vowed to continue fighting risk equalisation.

The legislation being debated in the Irish parliament aims to oblige VHI to meet the same prudential regulatory standards as its competitors by the end of 2008. It is not yet clear whether this will satisfy the European Commission, which gave the Irish government two months from November 2007 to comply.

It would appear therefore, that whatever the short-term outcomes, it could be some time before these issues, and in particular risk equalisation, are fully resolved.

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Governance in the pharmaceutical sector

Armin Fidler and Wezi Msisha

Summary: Pharmaceutical products are an important element of health systems that often make a difference in health outcomes, particularly for the poorest people. Despite this, global inequalities in access to pharmaceuticals persist, due to a number of factors including poor governance and corruption. This article provides a general overview of the pharmaceutical sector's vulnerability to corruption, reviews initiatives to improve governance in this sector within the Eastern Europe and Central Asia region and concludes by making recommendations for further addressing this issue.

Key words: Governance, Corruption, Pharmaceuticals

Pharmaceuticals are an indispensable ingredient of modern health technology and as such also constitute an important and increasing share of health expenditures globally. In many transition economies in Europe the allocation for pharmaceuticals routinely exceeds a quarter of the annual health budget. For economic and health impact reasons, sound pharmaceutical policies and regulations, minimum quality standards for drugs, transparent licensing, registration and procurement and evidence-based prescription practices are a concern for both consumers and policy makers. Good governance and absence of corrupt practices is important for the performance of health systems in general, and international evidence shows that governance break-downs and corruption in the pharmaceutical sector has serious negative repercussions for the effectiveness of the health system in general.^{1,2}

The importance of governance in public policy and development

The World Bank renewed its commitment to focus on governance and anti-corruption as a key development challenge and has developed a new strategy on good

governance.³ Indeed, corruption has been identified by development practitioners as one of the most important obstacles to economic and social development, as it distorts the rule of law and weakens the institutional foundations which are necessary for economic growth. Importantly, the poor are the ones most affected by bad governance and corrupt practices as they often depend on the provision of public services and are least able to afford the costs associated with bribery and fraud.⁴

For these reasons the World Bank has come up with a new strategy and plan for strengthening its engagement with and support for client countries on these issues. Since the mid-nineties, the World Bank's world-wide "Governance Indicators Project"⁵ has periodically reported on individual and aggregated governance indicators covering six aspects: (i) voice and accountability; (ii) political stability and the absence of violence; (iii) government effectiveness; (iv) regulatory quality; (v) rule of law; and (vi) control of corruption. This exercise covering 212 countries allows assessment of their progress on these governance aspects.⁵ Good governance in

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all sectors has therefore emerged as a crucial aspect of the global development agenda, as it has been shown empirically to affect income levels, economic growth and macroeconomic policies. One of the key areas in the fight against poverty is to invest in human capital, which entails improvements in the social sectors, particularly education, social protection and health.

Governance is a critical element in the management of health systems

Global research has shown that wide discretion, lack of transparency in decision making and lack of accountability for decisions made are some of the conditions that create opportunities for corrupt practices and increase the likelihood of governance breakdowns.⁶ Good governance within health systems and accountability of service providers are therefore essential for functioning health systems to deliver preventive and curative services to their constituency and hence contribute to improved health outcomes.

According to Transparency International, more than US \$3 trillion is spent on health services globally each year.² But on average, 10–25% of public procurement spending in the health sector is lost to corruption. Despite increasing awareness of the consequences of poor governance in general, the specific issue of governance in health care has somehow received less global attention thus far. Recent work on corruption in the pharmaceutical system^{7,8} has highlighted the particular importance of governance in the pharmaceutical area as an important element within the health sector and its important contributions to health care and health status in general. As a result, this has become a priority concern of international agencies and foundations.

Governance and the pharmaceutical system

Pharmaceuticals are a critical, high value input for health delivery systems that often make a difference in health outcomes for individuals and an entire population. Access to high quality medicines is a non trivial issue, especially for disadvantaged, poor and vulnerable populations. Despite international aid, the advent of specialised agencies and funds (such as the Global Fund to Fight AIDS, Tuberculosis and Malaria) and many government sponsored or donor programmes devoted to improving global pharmaceutical access, there is still a concerning drug supply gap.

The value of the global pharmaceutical market is estimated at over US\$500 billion, making the pharmaceutical sector highly lucrative but also increasingly vulnerable to corruption and unethical practices. Because of their therapeutic and curative qualities, access to quality pharmaceuticals oftentimes means the difference between life and death. Despite this, poor access to drugs remains a major global health problem with close to two billion people or one third of the global population lacking regular access to essential medicines.

According to World Health Organization (WHO) estimates, approximately ten million lives could be saved every year through the improvement in access to essential medicines and vaccines.⁹ Several factors contribute to the problem of unequal access to pharmaceutical products and these include market failures, government inefficiencies, costly drug

“ten million lives could be saved every year through the improvement in access to essential medicines and vaccines”

prices, poverty, poor health infrastructure and corruption. Transparency International estimates that globally two thirds of medicine supplies in hospitals are lost through corruption and fraud.²

A governance breakdown in the pharmaceutical sector not only generates a negative economic impact but also puts at risk the health gains of patients. A more intangible side effect of inefficiency and lack of transparency and corrupt practices is that it undermines the credibility of public institutions and erodes public and donor confidence in government capacity. Not surprisingly, in the opinion of European citizens in transition economies, the public health system was perceived as the public service institution where corruption occurred most frequently according to results from the recent Life in Transition Survey conducted in Eastern Europe and Central Asia.¹⁰

The procurement and sale of pharmaceutical products (together with other high technology investments in health) is a lucrative business in most countries, because of the high value of the goods involved and because final consumers are more susceptible to opportunism than

they are with other products due to information asymmetry between consumers and prescribers. There is a significant level of governmental involvement required in regulating this sector, therefore creating increased opportunities for corruption and mismanagement due to the breakdown of ethical business practices after the transition. All too often it has been shown that in many transition economies, checks and balances and governance and business processes are not transparent and only a few individuals exercise a high level of discretion in decision-making, allocation of resources and staffing of key posts.

Other growing challenges are market distortions and counterfeit drugs. In many transition countries with emerging pharmaceutical markets and weak government regulatory capacity (and virtually no self regulation by professional associations, such as doctors, pharmacists, or wholesalers of drugs), aggressive marketing tech-

niques by physicians for specific drugs, lead to a high rate of prescriptions that are not based on medical evidence, best practice or the patients need. Unscrupulous importers, wholesalers and distributors tend to maximise their profits and exploit unregulated or under-regulated markets. Similarly, corruption and taking advantage of weak regulatory and enforcement capacity underpins the lucrative counterfeit drugs trade.

Payoffs at every step of the supply chain allow the flow of counterfeit drugs from their source to consumers in many transition economies, with a particular problem arising in Central Asian countries. With pharmaceuticals often being the largest household health expenditure in developing countries, (often more than 50% of total individual out of pocket health expenses) corruption in the pharmaceutical industry has a direct impact on low income patients.¹¹

Finally, the complex processes and the many steps involved in the pharmaceutical supply chain in order for drugs to get from production to market to the final consumer also increase the chance that fraudulent activity will thrive, as the

example of the sale of counterfeit or low quality drugs to patients in many countries demonstrates. WHO estimates that up to 25% of drugs consumed in developing countries are counterfeit or sub-standard. Furthermore, corruption in this sector can eventually have a negative effect on national health budgets.^{12,13} Poor governance in the pharmaceutical sector results in the waste of scarce public resources which reduces the ability of governments to provide access to high quality essential medicines and this in turn increases the potential for unsafe medical products to enter the market.

For example, an assessment of governance in Bulgaria's pharmaceutical system found that the selection and procurement of pharmaceuticals was insufficiently transparent and too vulnerable to conflicts of interest. There was little effective oversight in the drug selection process and very limited public input. The study also found evidence of attempts by some international and local drug producers to exert influence at almost every level of the system.⁸

In many transition economies, in particular in South Eastern Europe, the rapid deregulation and decentralisation in the pharmaceutical sector, combined with unstable economic and political environments created governance vulnerabilities in the health sector. In particular the procurement practices were vulnerable to undue influence during drug selection, kickbacks or bribes that enabled bidders' to access confidential information and use of direct procurement instead of competitive bidding.¹⁴

Albania and Macedonia are among the countries in the region that have made significant strides to introduce a more transparent public procurement and international tendering system. Azerbaijan advanced in modernising the central drug laboratory and retrained critical technical staff. Furthermore the country succeeded in implementing regular batch testing of drugs, introducing tamper proof packaging and establishing a hotline for consumers and drastically increased the seizure of unregistered drugs on the market.¹⁵

Good governance is key to ensuring a sound and well functioning pharmaceutical system that provides good access to essential medicines for the population of any country. Governments are obliged to establish and maintain sound institutional structures and policies in order to ensure the wellbeing of their citizens. Govern-

Box 1. Decision points and selected strategies

Manufacturing	<p>Establish and secure legal framework for Good Manufacturing Practice (GMP) for local manufacturers in respective country and introduce appropriate fines for industry for non-compliance with legal stipulations and quality standards and post publicly a list of compliant manufacturers.</p> <p>Retain a sufficient number of trained and well-paid inspectors and on a rotating schedule carry out regular random inspections to assure GMP compliance.</p>
Registration	<p>Establish transparent, effective and uniform laws and standards for drug registration to assure adequate drug quality control capacity.</p> <p>Publish drug registration information on the Internet and educate the public and professionals to identify unregistered drugs.</p> <p>Implement market surveillance and random batch testing.</p>
Selection	<p>Define and publish clear criteria for selection and pricing based on international standards as established by the WHO.</p> <p>Publish drug selection committee membership and meetings schedule and results obtained/decisions made.</p>
Procurement	<p>Assure transparent procurement procedures, written procedures and explicit criteria for contract awards with strict adherence to announced closing dates.</p> <p>Monitor supplier selection and keep written records for all bids received; make adjudication available to all participating bidders and the public.</p> <p>Report regularly on key procurement performance indicators.</p>
Distribution	<p>Develop information systems to ensure drugs are allocated, transported, and stored appropriately.</p> <p>Assure regular communication between every level of the system to control inventory and deliveries.</p> <p>Secure appropriate storage facilities and transport.</p> <p>Establish electronic monitoring of stock in distribution and check delivery orders against inventories of products delivered to identify theft.</p> <p>Develop and engage professional associations to improve adherence to professional codes of conduct.</p>
Pharmaceutical prescribing and dispensing	<p>Use information systems to monitor physician prescription patterns.</p> <p>Impose penalties for breaches of legal and ethical standards.</p> <p>Regulate industry interaction with prescribers through explicit criteria that limit industry gifts and payments and require physicians to post industry gifts.</p> <p>License and inspect pharmacies.</p>

Source: Adapted from¹⁷. Framework originally developed by USAID.

mental responsibility in the pharmaceutical sector is two-fold; first, it involves regulation of the manufacturing, distribution, sale and use of pharmaceutical products. Second, it relates to selecting, purchasing, and logistically managing drugs for use in public health care systems in those situations where governments are the primary providers of drugs to the public.

Government involvement, especially through regulation of pharmaceutical policies on procurement, quality control, pricing and prescribing, is crucial in order to maintain an efficient pharmaceutical sector. Tools such as Health Technology

Assessments and other means of sharing international evidence and best practice are helpful in attaining this goal.¹⁶ Governmental regulation of the pharmaceutical industry must balance the concern for the health of the population on one hand with the promotion of industrial and trade policies to strengthen competitiveness, foster innovation and promote cost-effectiveness on the other hand.¹⁷

Soft spots in the pharmaceutical supply chain

The pharmaceutical supply chain is different from other commodities in the

market as it is highly complex, technically challenging and fraught with market failures due to information asymmetry and hence more vulnerable to governance breakdowns and corruptions at every link in the chain. Based on a framework originally established by USAID, and further adapted by Cohen et al¹⁸ the drug supply chain can be broken down into manufacturing, registration, selection for reimbursement, procurement, warehousing and distribution and prescription/service delivery. Box 1 demonstrates key decision points and required minimum policies at every link in the chain.

The potential for mismanagement and corruption exists at all these decision points unless there are strong institutional checks and balances maintained and oversight mechanisms in place to prevent abuse. In many transition economies government officials often have a (near) monopoly on a number of these decision points, which increase the system's susceptibility to mismanagement, fraud and corruption. For instance, government officials are involved in determining the selection of drugs for inclusion in national formularies, a process which can be marred by corrupt practices, since it is in the interest of manufacturers (and often a significant economic windfall) to have their products included on essential drug lists. Weak institutional processes therefore can result in national formularies including drugs that are not necessary or the most cost-effective.⁸

Governance initiatives and assessment tools in the pharmaceutical sector

Given the negative consequences that corruption in the health sector, and in the pharmaceutical area in particular, can have on the lives of people, there is a strong case for government regulation of this market. Based on international evidence it is essential for governments to exercise strong leadership and establish a framework for the rule of law and good governance practices as a key element to regulate the health and pharmaceutical sector. An important first step is the identification of market failures and the causes and motivation underlying corrupt practices, the people involved, as well as the areas most susceptible to corruption.^{12,13,17} Measuring, documenting and communicating instances of abuse, corruption and mismanagement is critical, as this can high-

Box 2. Application of the WHO Pharmaceutical System Assessment Tool

Assessment of Albania's pharmaceutical system

The WHO Assessment Tool was recently used to conduct an assessment of Albania's Pharmaceutical System. Most of the drugs in Albania are imported, with a smaller number produced locally. Drugs are procured by the public sector for use in hospitals and the private sector supplies drugs for outpatient use. Payment for these pharmaceutical products is through the national health insurance fund as well as private out of pocket payments.

The procurement, selection, registration, inspection and promotion activities of the system were assessed through a series of quantitative and qualitative interviews and assigned points on a ten point rating scale ranging from zero (extremely vulnerable to corruption) to ten (minimally vulnerable to corruption). The assessment produced the following results; procurement, registration, inspection and promotion components of the system were rated as marginally vulnerable, inspection was rated moderately vulnerable, while the selection process was rated as very vulnerable to corruption.

As a follow up to this, Albania is drafting a Health System Strategy (2007–2013), which highlights investments and capacity building for governance as a key priority area. Additionally, health, drug and health financing laws are currently being revised

Source: Forzley M, 2008.²¹

light areas where interventions can be made.

Useful policy tools have been developed to attempt to assess weak links within pharmaceutical systems. One of these is the Pharmaceutical Assessment Tool, first developed by Cohen et al¹⁹ and further enhanced and adapted by the WHO¹² which builds on early work done by Klitgaard.* According to Klitgaard's schematic equation, corruption [C] equals monopoly [M] plus discretion [D] minus accountability [A], resulting in:

$$C = M + D - A$$

This equation identifies key conditions that facilitate corruption in a system, including in a country's pharmaceutical system.²⁰ The WHO assessment tool utilises standardised questionnaires to assess vulnerability at key decision points in the pharmaceutical system. A ten point rating system which ranges from 'extremely vulnerable' to 'minimally vulnerable' is used to assess a system's degree of vulnerability to corruption. This was first tested successfully in Costa Rica and has since been used in a number of countries, including in some transition countries in Europe, such as in Albania (Box 2).

Since 2004, the World Health Organization (WHO) has undertaken the *Good Governance for Medicines Program* the goal of which is to reduce corruption in

pharmaceutical systems "through the application of transparent, accountable administrative procedures and the promotion of ethical practices among health professionals".¹²

A three step approach has been identified in implementing this initiative and it includes:

- (i) a national assessment of transparency and vulnerability to corruption, which involves the use of a standardised assessment instrument that builds on the tool described above;
- (ii) the development of a national programme on good governance for medicines; and
- (iii) implementation of the programme (see Box 2).

The programme is currently operational in ten countries and is expected to further expand to other countries based on requests from concerned governments.¹² Related to this, the WHO has also developed *The Manual for Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector*, which details fifty-one indicators that can be collected to monitor transparency under the areas of registration, promotion, inspection, selection, and procurement.^{12,13} In addition to this, the World Bank has through projects and technical assistance worked with countries to identify and address policy issues in their pharmaceutical sectors as well as improve their pharmaceutical procurement systems among other things.^{22,23}

* Robert Klitgaard did seminal work that defined corruption and its characteristics

Conclusion

Pharmaceuticals are a key input into health care and cover a large, and for many countries a growing share of the health budget. They are a high tech, high value input to achieve and maintain health outcomes for a population. In its extreme, access to drugs can mean the difference between life and death in many circumstances, especially for the poor and vulnerable populations. As in the health sector in general, pharmaceuticals are no exception to the issue of market failures due to information asymmetry. As such, this sector requires strong and effective regulation and governance practices in order to avoid mismanagement and opportunities for corruption and to ultimately minimise the occurrence of adverse outcomes for the consumers of drug products.

Europe's transition countries and developing countries in general often lack a sufficient legal and regulatory framework in the health sector and are oftentimes just in the process of establishing the rule of law in public policy. Similarly, professional associations have only begun to establish codes of conduct and standards for their members and are only starting to attempt to enforce self regulation for transgressors among their membership.

In order to achieve a coherent evidence and rules based system for pharmaceutical governance, it has been shown to be important to ensure intergovernmental collaboration, (health, law enforcement, customs, judiciary, etc). Additionally, the consumer increasingly also has an important role to play. As consumers are getting better informed, they will demand greater transparency in pharmaceutical systems and from their service providers. Evidence has shown that increasing consumer awareness can result in achieving support for particular challenges such as the control of counterfeit drugs etc.

Governments, in addition to establishing the legal and regulatory framework described above should also get involved in monitoring their pharmaceutical systems performance through international benchmarking and promote accountability of the respective stakeholders involved. Finally, professional organisations, particularly in transition countries, should be supported but also be held accountable for implementation of policies and professional guidelines that promote ethical behaviour of their members.

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Pharmaceutical policy challenges in Central and Eastern Europe

Andreas Seiter

Summary: Most of the transition countries in Central and Eastern Europe are under cost pressure from run-away pharmaceutical expenditure. Some of the factors leading to increased drug consumption are inevitable, while others could be contained with appropriate policy measures. Commercial interests of well resourced market participants give them an advantage in blocking or defusing attempts to control drug expenditure. Implementing cost containment measures successfully will require political backing from the most senior political level, a significant effort to increase human and technical capacity and partnerships between countries to address more complex scientific questions.

Keywords: transition countries; pharmaceutical expenditure; cost containment

Economic transition creates pressure from consumers and providers

During the last two decades, the former socialist countries in Central and Eastern Europe have gone through a partially turbulent political and economic transition. In most of these countries, a 'Western' model of a free market society with democratic rule has been more or less solidly established. In parallel, rapid economic growth has created a significant middle class of citizens who feel 'European' and adopt a lifestyle similar to their peers in Western Europe. At least in urban areas, one can see the same brands of cars, fashion, cosmetics and other lifestyle products as for example in German, Dutch, French and Italian cities.

When it comes to health care, it is easy to understand that citizens of transition countries also look towards their wealthier brothers and sisters in the West to determine the aspired standard. They demand access to the same level of diagnosis and care and, in particular, the same quality of medicines as available in the 'old' EU countries – drugs are 'tangible' and therefore become a proxy for health care quality. This 'sense of entitlement' poses a challenge for politicians, who have

to make ends meet with budgets that represent, on a per capita basis, only a fraction of the funds available to Western European countries.

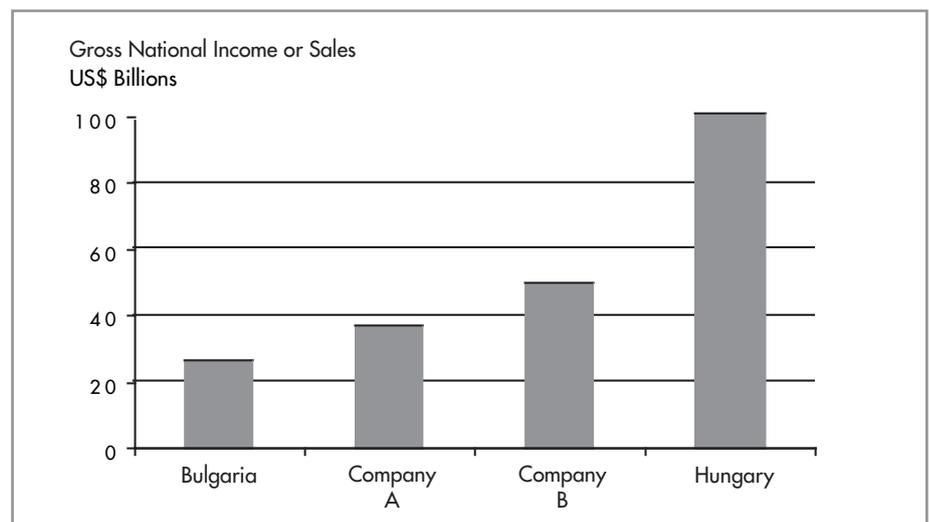
Several factors contribute to run-away pharmaceutical expenditure

Patient demand for more sophisticated (and expensive) medicines is triggered by self-education via the internet and through peer-to-peer networks. On the supply side, there is a sophisticated industry that markets products to regulators, clinical experts, specialists, family physicians,

pharmacists and indirectly (as direct-to-consumer advertising is illegal in Europe) also to patients. As Figure 1 illustrates, the resources at the disposal for industry are enormous. The worldwide sales of just two multinational pharmaceutical companies alone are greater than the entire economy of Bulgaria and combined they are nearly as big as the Hungarian economy.¹

While it is easy to blame manufacturers and providers for stimulating over-prescribing and unnecessary use of expensive drugs despite cheaper alterna-

Figure 1 : Comparison of incomes of two European countries and two multi-national pharmaceutical companies



Source: World Bank, 2008¹ and Annual Reports 2006 for pharmaceutical companies A and B

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tives being available, it is hard to argue against some other factors that contribute to growing drug bills:

- Some innovative medicines are in fact life-saving, creating an ethical pressure on health insurance systems to include them into their reimbursement lists
- In the generic drug market (dominant in most of the Central and Eastern European countries and served mostly by domestic manufacturers) upgrades to quality standards to comply with Good Manufacturing Practices lead to higher manufacturing costs, which can have an impact on retail prices
- Improved primary health care services lead to higher utilisation of facilities and the discovery of more chronic pre-existing conditions such as diabetes, high blood pressure or chronic-obstructive lung disease. Practically each newly discovered case leads to incremental drug spending – even if the most rational form of treatment is used
- Ageing societies and the prevalence of unhealthy lifestyle habits create an increasing pool of chronically ill people

Corruption and mismanagement

As a consequence of these factors, the overall drug bill is likely to grow faster than national income can even under optimal management. In reality, management systems are under-developed and governance in public sector institutions is weak. In addition to the imbalance of resources between private sector providers and the public sector that is in charge of controlling costs, there is significant potential for leakage and inefficiency if due to corruption.² This might take various forms, such as:

- Inappropriate inducements to decision makers and prescribers in form of cash, travel, gift cards, free use of cars, scholarships, consulting contracts for spouses and relatives.
- Free goods for wholesalers and retailers to crowd out competitors in the distribution chain.
- Manipulation of invoices at customs to increase margins or reduce taxes and tariffs.
- Collusion between bidders in public procurement.
- Manipulation of data submitted for price regulation.

- Collusion between doctors and pharmacists to charge insurance funds for drugs that are not dispensed – the proceeds being split between the partners in the collusion.

By definition, the impacts of such practices are very hard to assess, as they go unrecorded and the actors are rarely identified or brought to justice in countries with limited law enforcement capacity. But on some occasions there is anecdotal evidence that the financial losses can be significant. One example is Montenegro, where the introduction of a system for tracking the prescribing and dispensing of medicines paid for itself within very short time - prescribers changed their behaviour when they became aware that their actions would become transparent, leading to cost savings of about 20% from baseline.

Coping strategies

Different countries in the region employ different strategies to cope with the challenge of run-away expenditure. Some stick to rigid budgets and force providers to apply rationing tactics – in the end this means that patients may not get the medicines they need from public sources and have to pay out of pocket (if they can afford it). One example of strict budget enforcement is Poland, which has tried to mitigate the impact by providing certain expensive but clinically important drugs through special treatment programmes outside the health insurance system.

Other governments are more permissive and give in to pressure from patients and providers, covering drug budget deficits at the end of every year from the general budget. One of example of this is Romania, which shows several high priced drugs for rare indications on the top ten list of drugs paid for by health insurance. Nevertheless, all countries try to implement some cost containment measures, targeting parameters such as drug prices, reimbursement lists, reimbursement levels, patient co-payments and prescription volumes.

The problem with these measures is that they require a range of skills and capacities in order to be successful, such as a sound legal basis, political will, enforcement capacity, management skills and systems to collect data for measuring both the baseline and impact of a given measure. It has been shown repeatedly in rich countries (generally facing the same issues of run-away drug expenditure although on a higher level) that many cost containment

measures have only temporary effects. This is due to provider adaptation (for example doctors prescribing more antibiotics when simple cough and cold medicines were removed from the reimbursement list) and a multi-factoriality of effects – making it difficult to measure the impact of single interventions. This means that pharmaceutical cost containment is an ongoing effort.

While regulatory agencies, insurance funds and ministries in developed countries employ dozens or hundreds of well-trained specialists equipped with modern equipment, many of the smaller young states in Eastern Europe have much more limited resources. Government officials are not trained in modern management methods; they frequently operate without standard operating protocols (SOPs) or clearly defined decision making rules. Salaries in the public sector do not keep up with free market salaries, leading to skills erosion in the public sector workforce. Parliaments, under the influence of well funded lobbying groups and external advisors, create complicated laws that frequently are not assessed for their practicality, leaving the administration alone to work out how to apply the law. This creates a backlog in decision making. Overall, what has been ongoing for a while in several countries is a painful trial-and-error strategy that has the potential to further undermine the standing of public health insurance funds and weaken the perception of their managers in the eyes of private sector counterparts.

Leadership, simplicity, and technology as key ingredients for reform

Given the significant profits at stake, private sector providers are unlikely to support proposals from administrators to limit their entrepreneurial freedom for the benefit of public health budgets and outcomes. Organised provider resistance can only be overcome by strong and fearless political leadership. Unfortunately such leadership is difficult to mobilise; sometimes it materialises after an obvious and massive failure in the system that creates near-bankruptcy of the public payer or public outrage over performance problems such as drug shortages. These windows of opportunity need to be used to make sensible adjustments in the distribution of power and clean up decision making processes.

Simplicity should be the guiding principle for all laws and by-laws. If laws contain

too many technical specifications, the administration may get stuck with outdated ways of doing things while the market has moved on and adjusted, as any change in the law requires a parliamentary hearing and vote. This is relevant for example for pricing regulations, which may need to be modified in regular intervals in response to counter-moves deployed by providers.

By-laws that are written under the influence of external consultants, using models from more developed countries, sometimes turn out to be very challenging to implement by small, relatively powerless administrations with limited technical capacity. Less is more in this case – for example a simple formula to limit the price of generic drugs based on the last price of the original version minus a certain percentage is easy to calculate and transparent. A sophisticated external reference price system, as it is currently employed in some countries, may lead to data overload and interpretation problems that slow down decisions or open the door for costly and time consuming appeals procedures and lawsuits.

The available technical and managerial expertise should be focused on drafting specific implementation rules and procedures (SOPs) at the administrative level, which have two main functions:

1. Protecting the decision makers against outside pressures, which are easier to resist if decision criteria are clear.
2. Protecting those who depend on the decisions from reviewer bias and inconsistent application of vague rules.

Cross-country partnerships for more complex tasks

Some aspects of decision making on pharmaceuticals are highly complicated from the scientific, technical and process perspective. A key example is the decision on the inclusion of new drugs into a reimbursement list, based on evaluation of costs and benefits versus available alternatives and against the reality of finite budgets. This decision is critical for the manufacturer of a new drug as it provides access to financing; manufacturers usually spend big money to present a convincing dossier and win over members of expert committees, who routinely are consulted in these decisions.

In developed countries, specialised institutions set up as independent scientific bodies play the role of providing neutral assessment (the best known example is the National Institute for Health and Clinical Excellence, NICE, in England and Wales). For many countries, setting up such an institution is beyond their financial and human resources. A potential solution to address this problem would be to develop

regional partnerships. This could lead to a single institution funded by several countries, or a network of specialised institutions of smaller scale, which share methodology and results and recognise each others work. In the longer term, there may even be a European solution that could benefit smaller countries by providing an authoritative opinion on the cost-effectiveness of new drugs similar to the regulatory opinion provided by the European Medicines Agency (EMA).

Cost-effectiveness data cannot be easily transferred from country to country, if the underlying costs in the system are different. Some national capacity to interpret and potentially recalculate results from another country is therefore required. Again, a simple rules-based approach like a scoring system that quantifies expert perceptions in the absence of exact data is preferable over an academic approach that tries to achieve exact outcomes but is vulnerable due to lack of data or fights over the methodology.

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Moderate activity reduces diabetes risk

Hands up everyone who knows what a MET is? Answer is a Metabolic Equivalent Task, which is the amount of energy expended in performing various activities compared with sitting down doing nothing. It is commonly used in medicine to express metabolic rates measured during a treadmill test. Two definitions of the MET are used, essentially equivalent:

One MET is equivalent to a metabolic rate consuming 3.5 millilitres of oxygen per kilogramme of body weight per minute.

One MET is equivalent to a metabolic rate consuming 1 kilocalorie per kilogramme of body weight per hour.

In more common parlance, a slow walk or promenade is equivalent to about two METs, a brisk walk about four METs, and gym work more like six METs and above. A new systematic review of observational studies links moderate periods of moderate intensity exercise with reduced risk of developing type 2 diabetes in adults.¹

Table 1: Evidence associating physical activity and walking with reduction in risk of developing type-2 diabetes

Observation	Studies	People	Relative risk	Percent risk reduction
Total physical activity				
Development of type 2 diabetes, no BMI adjustment	9	213,314	0.69 (0.58 to 0.83)	31
Development of type 2 diabetes, with BMI adjustment	9	295,231	0.83 (0.76 to 0.90)	17
Walking				
Development of type 2 diabetes, no BMI adjustment	4	152,698	0.70 (0.58 to 0.84)	30
Development of type 2 diabetes, with BMI adjustment	4	234,615	0.83 (0.75 to 0.91)	17

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Systematic review

The review sought observational studies up to March 2006 associating moderate exercise with incidence and prevalence of type 2 diabetes. Moderate intensity exercise was that with a MET score of 3–6.

Results

Ten cohorts were found with just over 300,000 persons of both sexes aged mostly between their late-30s to early-60s. Follow up in these studies tended to be long with seven of the studies longer than seven years, and the shortest four years. The mean follow up period, weighted by study numbers, was 8.2 years.

In most of the studies exercise included walking, but cycling and light gardening were also included. The definition of diabetes varied, including glucose tolerance test results, the use of primary care or national registers, and, mostly, by self-report of a diagnosis by a physician, usually validated.

There were 9,400 cases of diabetes, a prevalence of 3.1%. This meant that type 2 diabetes occurred in 0.4% of these older adults every year, a risk of 1 in 263 per year. Compared with sedentary persons, the risk was substantially lower in people who took moderate exercise (by about 30%), whether all activity or only brisk walking was used in the tests of association (Table 1). Because people who take no exercise tend to be fatter, there was adjustment of risk for BMI, and here the reduction of risk was about 17%.

Comment

The amount of exercise examined in this paper was not heroic, amounting to no more than about 2.5 hours of brisk walking every week. The message is that to help avoid developing diabetes, you don't necessarily have to go into the gym, just walk down there and then walk back again. Given that walking does other good things positively affecting the heart, circulation, bone, balance and weight, this is something of a no-brainer. Diabetes is worth avoiding.

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VALUING “LIVES SAVED” VS. “LIFE-YEARS SAVED”

James K Hammitt

“Theory and empirical evidence suggest that neither VSL nor VSLY is constant over an individual’s life. Accurate valuation requires using values that depend on characteristics of the affected individuals.”

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Introduction

There is long-standing debate whether to count ‘lives saved’ or ‘life-years saved’ when evaluating policies to reduce mortality risk. Historically, the two approaches have been applied in different domains. Environmental and transportation policies have often been evaluated using lives saved, while life-years saved has been the preferred metric in other areas of public health including medicine, vaccination, and disease screening. For benefit-cost analysis, the monetary value of risk reductions can be calculated either by multiplying expected lives saved by the ‘value per statistical life’ (VSL) or by multiplying expected life-years saved by the ‘value per statistical life-year’ (VSLY).

The choice between metrics can affect the apparent merits of regulatory programmes that affect people with different life expectancies. For example, the air pollution measures that dominate the US regulatory agenda may disproportionately benefit people who are older or in poor health and have shorter-than-average life expectancies. The benefits of these rules may appear larger when counting lives rather than life-years saved. Conversely, policies to protect children such as car-seat requirements may appear to be larger when counting life-years saved. The US Office of Management and Budget has encouraged federal agencies to analyse regulations using both the lives-saved and life-years-saved approaches.

This *Risk in Perspective* article describes how the value of any intervention that alters mortality risk can be expressed using either lives saved or life-years saved and the appropriate VSL or VSLY. However, because theory and empirical evidence suggest that *neither* VSL nor VSLY is constant over an individual’s life, accurate valuation requires using values that depend on characteristics of the affected indi-

viduals. The extent to which VSL and VSLY vary with life expectancy, age, health, and other factors is not clear; better empirical evidence is required.

Key concepts

Describing environmental, health, and safety interventions as ‘saving lives’ or ‘saving life-years’ can be misleading. Reduction in exposure to a hazard typically reduces some people’s chances of dying from that hazard by a small amount, thereby ‘saving lives’ (at least from that hazard). Reducing the risk of dying now increases the risk of dying later, so these lives are not saved forever but life-years are gained. It is usually impossible to know either beforehand or afterward whose death will be or was averted, so the lives or life-years that are saved are anonymous.

Value per Statistical Life (VSL)

An individual’s value per statistical life (VSL) is defined as her rate of trade-off between wealth and small changes in mortality risk in a defined time period. For example, if a typical individual is willing to pay at most \$5 to reduce her chance of dying this year by 1 in a million, her VSL is $\$5 \div (1 \text{ in a million})$ or \$5 million. The term ‘value per statistical life’ can be understood by recognising that if each of 1 million people were willing to pay \$5 to reduce his or her chance of dying this year by 1 in a million, a total of \$5 million dollars would be pledged and one fewer death would be expected.

VSL is defined for very small changes in risk. Theoretically, an individual’s VSL is the slope of an indifference curve representing her preferences for wealth and survival probability. As illustrated in Figure 1, an individual’s rate of trade-off between wealth and risk will depend on the size of the risk change. A typical person who

Figure 1: Value per statistical life (VSL) is equal to the slope of the individual's indifference curve at her wealth and survival probability, i.e., WTP/dp for a small increase in survival probability and WTA/dp for a small decrease in survival probability. As the risk change dp increases, willingness to pay (WTP) increases less than proportionately to dp and willingness to accept (WTA) increases more than proportionately to dp .

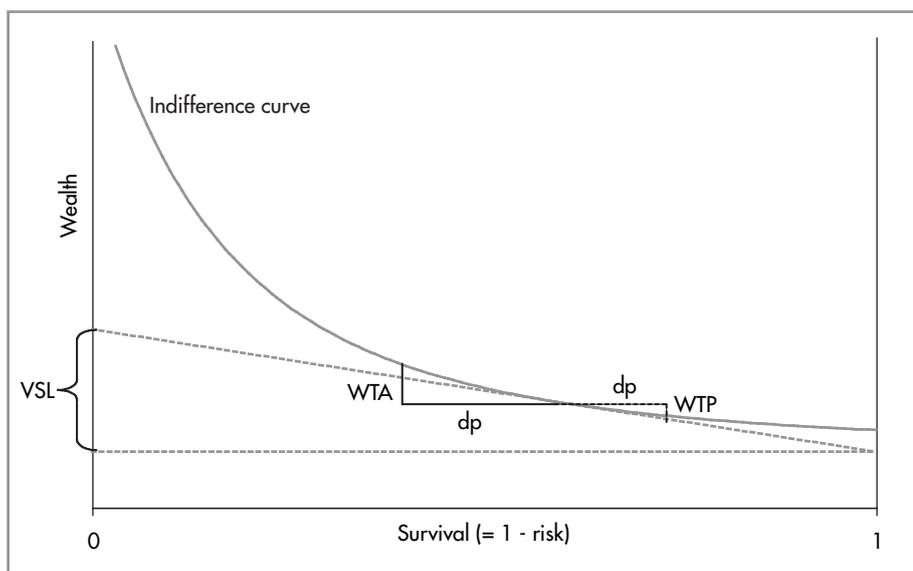
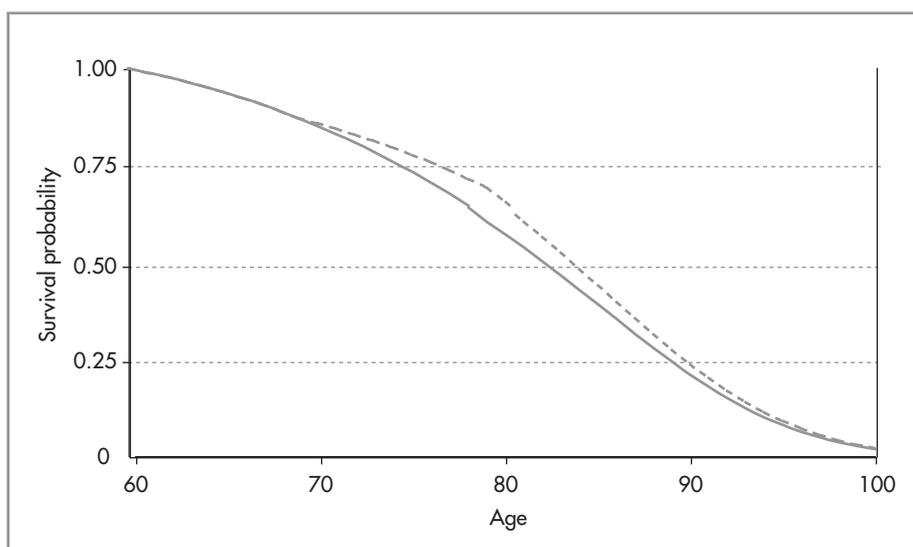


Figure 2: Survival curves from age 60. Solid line is for the US population. Dashed line corresponds to decreasing mortality risk at each age from 71 to 80 by one third.



would pay \$5 to reduce her chance of dying this year by 1 in a million could not afford to pay \$1 million to reduce her chance of dying this year by one in five (for example, from 21% to 1%). Similarly, she would not accept certain death this year in exchange for \$5 million. (As illustrated in Figure 1, she might not accept certain death in exchange for any amount of wealth.)

Value per Statistical Life-Year (VSLY)

It seems intuitive that the value to an individual of delaying her death depends on the duration of the delay. Postponing death by years is usually preferred to postponing

it by only days (even if those days are precious). The VSLY approach values a reduction in mortality risk in proportion to the gain in life expectancy. Under this approach, reducing an individual's risk of dying in the current year produces a gain equal to the increase in the chance of surviving the year multiplied by her life expectancy conditional on survival. The value of this gain is equal to the expected number of life-years saved multiplied by the VSLY. (Future life-years are usually discounted and the value of reducing the risk of dying this year is proportional to the expected present value of future life-years.)

Survival curves

Changes in mortality risk are most accurately described using survival curves. Survival curves can be constructed for an individual or a population. An individual survival curve plots the probability that an individual will remain alive as a function of age (or calendar date). A population survival curve plots the fraction of a population that remains living as a function of age or date. A survival curve can be constructed beginning at any age or date. The height of the curve begins at one and declines as age and time increase. The slope of the curve depends on the mortality risk, with steeper decreases in periods of higher mortality risk.

The survival curve for the US population beginning at age 60 is illustrated by the solid line in Figure 2. Life expectancy at any age is the area under the survival curve that begins at that age. For the solid curve, life expectancy at age 60 is 22 years.

Any pattern of change in mortality risk over time can be described by the corresponding shift in the survival curve. Moreover, any change in a survival curve implies a unique expected number of life-years saved (the change in the area under the curve) and a unique expected number of lives saved at each point in time (the vertical shift in the curve at that time). The total number of lives saved during a time period (which may include saving the same life multiple times) depends on the period examined; for periods much longer than a century or so, the number of lives saved (among a cohort) must be zero. Note that there is no unique change in the survival curve corresponding to a specified number of life-years saved or to a specified number of lives saved in a time period. The survival curve and how it shifts are the fundamental concepts; the numbers of life-years saved and lives saved in a specified time period are alternative and partial summary measures of the shift.

To illustrate, consider an intervention that decreases annual mortality probability by one-third, persists for ten years, and begins after a ten year lag. The dashed line in Figure 2 illustrates the effect of this intervention for the average 60 year old. There is no change in survival probability during the lag period (ages 60 to 69). The survival curve is flatter over the period during which risk is reduced (ages 70 to 79) and remains higher than the baseline survival curve for later years (ages 80 and above). For each 60 year old affected, this inter-

vention saves one life-year and 0.08 lives (between ages 70 and 79).

Valuing reductions in mortality risk

Each person's willingness to pay (WTP) for a specified shift in her survival curve can be estimated by dividing the shift into a series of instantaneous changes in risk and summing her WTP for each of these 'blips'.¹ WTP for each blip depends on the size of the risk reduction, time of payment, conditions under which the individual can save and borrow against future income, and other factors.

WTP for a shift in the survival curve can be described using either VSLY or VSL. The individual's average VSLY for a shift is her WTP for the shift divided by the expected number of life-years saved. Her average VSL for a shift is her WTP divided by the expected number of lives saved in a specified time period. If an individual is willing to pay at most \$80,000 for the (very large) shift in the survival curve illustrated in Figure 2, her average VSLY for this shift is \$80,000 (= \$80,000 ÷ 1 life-year saved) and her average VSL is \$1 million (= \$80,000 ÷ 0.08 lives saved).

Estimating WTP to reduce mortality risk

Average VSL and average VSLY for a shift in a survival curve may depend on the initial survival curve, the details of the shift, and other factors. Economic theory does not predict that either VSL or VSLY will be constant across interventions or individuals. In theory, both VSL and VSLY may change with age, life expectancy, anticipated future health, income, and other factors.

Most studies of WTP to reduce mortality risk estimate the value of a reduction in current risk, i.e., VSL. These studies do not provide information on how VSL varies with life expectancy per se, but some provide information on how it varies with age. Although it seems intuitive that WTP to reduce current risk decreases with age, as the number of future life-years at stake declines, VSL may remain constant or even increase with age. One reason is that income and wealth usually rise with age, at least over part of the lifecycle. Higher income and wealth increase ability to pay and hence increase VSL. In addition, as life expectancy declines an individual may have less reason to conserve her wealth for future needs. Some economic models suggest that VSL follows an inverted U, rising through middle age and falling at older ages.

Empirical estimates are derived using either 'revealed-preference' or 'stated-preference' methods. Revealed-preference studies are based on observation of behaviours that affect mortality risk and wealth. The most common are wage-differential studies that estimate the extra pay workers receive for more hazardous jobs. In contrast, stated-preference studies ask survey respondents about hypothetical choices. Many of these ask about choices between safer but more expensive food or transportation or about hypothetical medicines or disease-screening programmes.

Recent wage-differential studies that examine how VSL varies with age support the inverted-U hypothesis.² These studies are limited in that they necessarily include only employed workers and thereby exclude the elderly and those in poor health. Stated-preference studies, which can include a broader population, yield mixed results. Some suggest little or no effect of age on VSL and others suggest a modest decrease at older ages.³

It is not possible for both VSL and VSLY to remain constant over the lifecycle since life expectancy changes with age. The empirical evidence suggests that neither VSLY nor VSL is constant over the lifespan. If VSL follows an inverted U, then VSLY must increase at young ages when VSL is increasing and life expectancy is decreasing. VSLY could be roughly constant at older ages if the rate at which VSL decreases coincides with the rate at which life expectancy decreases. Some wage-differential studies suggest VSL declines more rapidly than life expectancy, which implies that VSLY decreases with age.² If VSL is roughly constant with age or decreases only modestly at older ages, as the stated-preference studies seem to suggest,³ then VSLY increases over the lifespan.

Estimating lives saved and life-years saved

In practice, it may be more difficult to estimate the effect of an intervention on either lives or life-years saved. For mortality risks where victims are identifiable *ex post*, such as motor-vehicle crashes and deaths from a signature disease (for example, mesothelioma from asbestos exposure), the number of lives saved can be estimated but the number of life-years saved cannot without information about the life expectancy of the affected population. Similarly, time-series studies that analyse how daily air pollution levels affect

the number of deaths each day provide estimates of the number of lives that may be saved by reducing pollution, but not the number of life-years. The problem is the difficulty in knowing whether the people who succumb to these hazards have the same life expectancy as others of their age and sex or are more susceptible to these (or other) risks.

In contrast, cohort studies that monitor populations exposed to different levels of pollution (for example, those living in different cities) provide estimates of the survival curve and how it depends on pollution. These studies can be used to estimate the number of life-years saved but not the number of lives saved. The same shift in the population survival curve can be the result of extending the lives of many people for a short time or the lives of fewer people for a longer time.⁴ To illustrate, consider a stylised example: In a 'polluted' city, half the population dies at age 60 and the other half at age 70. In a 'clean' city, half the population dies at 70 and the other half at 80. Living in the clean city is associated with an increase of ten statistical life-years per capita. However, it is impossible to determine from the survival curves alone whether the difference arises because everyone in the clean city lives ten years longer than they would in the dirty city, or because the people who die at 60 in the dirty city would have lived to 80 in the clean city. In the first case, the number of lives saved (at ages 60 and 70) is equal to the population; in the second, it is equal to half the population.

For risks associated with exposure to chemicals that may cause cancer or other disease, epidemiological data may not exist and risk estimates are often based on studies of laboratory animals. In these cases, estimation of either lives saved or life-years saved requires strong assumptions about how to extrapolate from effects observed in highly exposed laboratory animals to effects in less highly exposed humans, including the type of cancer or other disease, the probability of lethality, the latency of the disease, and the life expectancy of the affected population.

Conclusion

The effects of environmental, health, and safety interventions on mortality risk are most accurately characterised as shifts of individuals' survival curves. The monetary value to an individual of a change in her survival curve depends on the magnitude and timing of changes in her mortality risk.

Any shift in a survival curve implies expected numbers of both life-years gained and lives saved in a specified time period. Hence the value of the shift can be described by the corresponding average value per life-year saved (VSLY) or value per life saved (VSL); the choice between these measures is arbitrary.

Note that an individual may assign different monetary values to alternative changes in her survival curve, even if they produce the same number of life-years saved or the same number of lives saved in a specified time period, resulting in different average VSL and VSLY.

Accurately valuing changes in mortality risk requires using values that are appropriate to the risk change, which may depend on the age, health, life expectancy, and other characteristics of the affected population. The existing empirical literature offers conflicting evidence about how VSL and VSLY change with age; better empirical evidence is needed.

Note: This essay is adapted from Hammitt, 2007⁵; Peer reviewer: Henrik Andersson.

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New publications from the European Observatory on Health Systems and Policies



Pharmaceutical policies in Finland. Challenges and opportunities

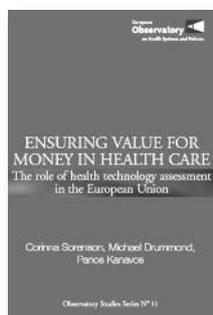
Health systems are under continuous pressure to meet the demands of their populations. In Finland, one area currently under review is that of pharmaceutical policy. Following a request made by the Health Department, Ministry of Health and Social Affairs, this new report, by the Observatory, provides a policy review of the regulatory system of pharmaceutical policies in Finland.

The assessment by authors Elias Mossialos and Divya Srivastava suggests that despite the challenges within a very developed system of pharmaceutical regulation, there are practical options:

- to improve transparency and pricing policies
- to strengthen the institutional environment
- to improve the development of pharmacotherapy practices.

The purpose of the report is not to provide prescriptive solutions but to suggest a range of options for policy-makers to reflect on so as to assist them in the process of policy review. The report offers a range of views from an international perspective and it is intended that this study might stimulate further debate on the continuing development of pharmaceutical policies.

Available for free download at <http://www.euro.who.int/Document/E91239.pdf>



Ensuring value for money in health care. The role of health technology assessment in the European Union

This new book from the Observatory provides a detailed review of the role of health technology assessment (HTA) in the European Union. It examines related methodological and process issues in the prioritisation and financing of modern health care, and presents extensive case studies on the situation in Sweden, the Netherlands, Finland, France, Germany and the United Kingdom.

Written by Corinna Sorenson, Michael Drummond and Panos Kanavos, the book aims to highlight ways in which the HTA process in Europe could be improved by examining key challenges and identifying potential opportunities to support value and innovation in health care. A number of issues are examined and there is a particular emphasis on the responsibility and membership of HTA bodies, assessment procedures and methods, the application of HTA evidence to decision-making, and the dissemination and implementation of findings.

The authors observe that overall, “HTA can play a valuable role in health care decision-making, but the process must be transparent, timely, relevant, in-depth and usable. Assessments need to use robust methods and be supplemented by other important criteria. Maximisation of HTA will enhance potential decision-makers’ ability to implement decisions that capture the benefits of new technologies, overcome uncertainties and recognise the value of innovation, all within the constraints of overall health system resources.”

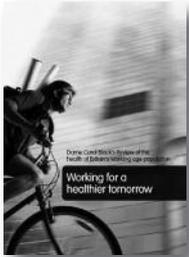
Available for free download at <http://www.euro.who.int/document/E91271.pdf>

Also, visit the Observatory web site at <http://www.euro.who.int/observatory>

NEW PUBLICATIONS

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

Dame Carol Black's Review of the health of Britain's working age population



London: The Stationery Office,
March 2008

ISBN 978 0 11 702513 4

125 pages

Freely available on line at:
<http://www.workingforhealth.gov.uk/Carol-Blacks-Review>

Based on the fact that improving the health of the working age population is crucial to securing both higher economic growth and increasing social justice, this review seeks to establish the foundations for a new vision for health and work in Britain. The vision has three principal objectives: prevention of illness and promotion of health and well-being; early intervention for health conditions; and an improvement in the health of those out of work.

The review sets a baseline by detailing and assessing the health of the working age population. It was found that common mental health problems and musculoskeletal disorders are the major causes of sickness absence and worklessness due to ill-health. Furthermore, the annual economic costs of sickness absence and worklessness associated with ill-health are estimated to be over £100 billion.

Thus, Dame Black calls for a shift in attitudes to ensure that employers and employees recognise the key role that the workplace can play in promoting health and well-being. She proposes a case-

managed, multidisciplinary approach, called Fit for Work, which would aim to provide treatment, advice and guidance for people in the early stages of sickness absence. Furthermore, she calls for specialist mental health provision to be fully integrated in government employment support programmes.

In summary, Dame Black recommends an expanded role for occupational health, placing it within a broader collaborative and multidisciplinary service. This service should be available to all, including those entering work, seeking to stay in work, or trying to return to work following illness or injury.

Contents: Foreword; Executive summary; Key Challenges and Recommendations; Introduction; The Health of the Working Age Population; The Role of the Workplace in Health and Well-being; Changing Perceptions of Fitness for Work; Developing a New Model for Early Intervention; Helping Workless People; Developing Professional Expertise for Working Age Health; The Next Generation; Taking the Agenda Forward; Appendix – Glossary.

Health Technology Assessment on the Net

Prepared by: L Chan, S Collins,
L Dennett, and J Varney



Edmonton: Institute of Health Economics,
June 2007

ISBN 978-0-9780024-7-3

26 pages

Freely available online at: http://www.ihe.ca/documents/ihe/publications/reports/IHE_Report_Health_Technology_Assessment_on_the_Net_Jun_2007.pdf

The purpose of Health Technology Assessment (HTA) is to provide health care decision-makers with the evidence they need to help make informed decisions concerning the introduction, allocation and cost effective use of medical technologies. The ninth edition of this guide focuses on websites that are likely to be of interest to those involved in HTA.

The sites listed in the guide tend to be developed by non-profit agencies (such as government-funded organisations and universities), are updated regularly and contain valuable information for HTA. The bibliographic databases identified generally contain peer-reviewed studies, while the HTA and evidence-based health sources usually follow accepted methods for ensuring the comprehensiveness, transparency and reliability of the methods used in their systematic reviews. The sites included are fairly easy to navigate and search. An effort has been made to also include qualitative

research sources.

This guide provides resources available in English, with an emphasis on those from Canadian, UK and American sources. Additionally, there is a 'bookmarks' file to accompany the guide which can be downloaded to provide easy access to the sources [<http://www.ahfmr.ab.ca/publications/?search=Internet+sources+of+information&type=1>].

Contents: Introduction; Bibliographic Databases; Fee-based Bibliographic Databases; Government & Research Information; Clinical Trials; Practice Guidelines; Complementary & Alternative Medicine; Health Economics; Quality of Life; Further Information; Distance Learning in HTA; Evidence-Based Medicine; Critical Appraisal; Knowledge Transfer and Research Utilisation; Listservs; Literature Searching Guides; Open Access (Free) Electronic Journals.

Health Programme of the Slovenian Presidency of the EU

http://www.mz.gov.si/en/predse_dovanje_eu_in_evropske_zadeve

This section of the Slovenian Ministry of Health web site, available in Slovenian and English, contains information on conferences, ministerial meetings, and EU and WHO meetings taking place in the framework of the Slovenian Presidency.

DIPex

<http://www.dipex.org>

The DIPex English-language web site is aimed at patients, their carers, family and friends as well as health professionals as a teaching resource. The web site contains an open-access database of personal experiences of around 40 conditions or health issues, built from systematic collections of hundreds of qualitative research interviews of people in the UK. The interviews are collected (maximum variation sampling) and analysed by experienced and trained social scientists. The site also provides information about each illness, answers to frequently asked questions, video clips, an online forum, press releases and academic papers.

European Agency for Safety and Health at Work

<http://osha.europa.eu>

The Agency is a tripartite organisation, working with governments, employers and workers representatives. Their web site provides a single reference point for occupational safety and health (OSH) information and is available in over 20 European languages. Information, guidelines for good practice and publications are available to download, searchable by topic, sector, country, priority group and other categories. Information on European legislation is made available, as well as sources of statistics. There is also information on the Agency's campaigns, press releases and news and events. Linked to the main site is the site of the European Risk Observatory which provides information on OSH risks, emerging risks and OSH monitoring systems and surveys, by country.

German Reference Centre for Ethics in the Life Sciences (DRZE)

<http://www.drze.de>

The English and German language web site of the DRZE comprehensively provides scientific information which is required for a qualified formation of opinion and judgment in the area of ethics in the life sciences and medicine. A series of publications are available (mostly in German with English summaries) and a German and English language newsletter. BELIT, the Bioethics Literature Database, provides access to about 320,000 records from integrated German, American and French databases and a thesaurus of terms related to the field. A second database, BEKIS, lists academic institutions, projects, working groups, individual researchers and funding bodies working in the field of ethics in the life sciences throughout Europe. A diary of ethics-related events is also available.

Medical Women's International Association (MWIA)

<http://www.mwia.net>

The MWIA is an international non-governmental organisation (NGO) representing women doctors from five continents. The English-language web site provides publications on issues for women doctors, focusing on gender mainstreaming and health, adolescent sexuality, and domestic violence. Publications include articles, manuals, congress reports, annual reports and a newsletter. There is information on events and links to related web sites.

The Netherlands Institute for Health Services Research (NIVEL)

<http://www.nivel.eu>

NIVEL contributes to the body of scientific knowledge about the provision and use of health care services by carrying out research activities at the national and international level. Research focuses on need for health care, supply of health care, the care process and health care policy. The Dutch and English language web site makes available hundreds of research papers (in both languages) to download through the searchable database as well as providing a news section.

NEWS

EUROPEAN MONITOR

New Health Commissioner approved by European Parliament

The European Parliament has voted in favour of approving the new Commissioner for Public Health, Food Safety, Animal Health and Welfare, Androula Vassiliou.

Mrs Vassiliou's appointment follows the resignation of fellow Cypriot, Markos Kyprianou, who left to take up the post of foreign minister in the new Cypriot government in February.

Prior to joining the Commission Mrs Vassiliou practiced law in Cyprus for twenty years before becoming First Lady when her husband, George Vassiliou, was elected President of the Republic of Cyprus in 1988. In 1996 she was elected Member of the Cyprus House of Representatives representing the Movement of United Democrats. During this period she was also a member of the Joint Parliamentary Committee of Cyprus and the EU.

During her three-hour confirmation hearing before the European Parliament Ms Vassiliou began by stating that "health is wealth and I am determined to work hard towards ensuring high standards for our citizens, be they in Romania, Sweden, the UK or Cyprus". She also said she was "committed to ensuring a firm enforcement of EU law relating to health by all Member States".

Concerning the ongoing debates on patients' rights in cross-border healthcare she said that she was "already working on the proposal and [is] determined to submit it for adoption by the Commission in June." She agreed with UK MEP John Bowis who said that the proposal was needed soon to avoid policy being decided by the Court of Justice and lawyers rather than politicians. She said she would persuade critics "that

we are not talking about the freedom of movement of services but about the right of citizens to get health care all over Europe". Reacting to concerns raised by UK MEP Linda McAvan she said that her intention was "not to damage the existing health systems, but to improve them by cooperation and the exchange of the best practices available".

Answering Adamos Adamou from Cyprus on the planned directive on organ safety, Mrs Vassiliou said that she intended to introduce standards applying to organ donation, but that these measures should not lead to excessive bureaucracy or intervention if the system is working, as for example, in Spain. Replying to fellow Cypriot Marios Matsakis on cancer screening, she added that the Commission would examine whether the targets had been reached in the Member States and, if appropriate, would review the relevant EU directive, to include other types of cancer that require early screening.

Asked by French MEP Françoise Grossetête about what she intended to do in the field of Alzheimer's disease, she responded by affirming her commitment to the "primary importance to mental health". Reacting to Greek MEP Evangelia Tsambazi on guarantees for the health and safety of the most vulnerable groups, like women, young people and people with disabilities, she said that where there was proof that these issues have an impact on public health she would work with her colleagues to deal with them. Concerning people with disabilities, she would cooperate with Social Affairs Commissioner Špidla.

Another subject that arose during the Parliamentary hearing was the subject of tobacco. Dutch MEP Jules Maaten questioned whether new legislation on tobacco could be expected before the end of the

legislature. Mrs Vassiliou replied that "like her predecessor, she was interested in continuing the efforts to fight tobacco" and that it "is important not to impose rules but to make people understand", adding that she would make appropriate proposals in the forthcoming third report on the tobacco products directive.

Responses to written questions:
http://www.europarl.europa.eu/hearings/commission/2008/questionnaires/specific_en.pdf

Information on the Hearing:
http://www.europarl.europa.eu/hearings/commission/2008/default_en.htm

€2 billion boost for pharmaceutical research

On 30 April work began on implementing the Innovative Medicines Initiative (IMI), a unique public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It aims to remove bottlenecks in the drug development process and cut development costs through innovative research projects, and so accelerate the discovery and development of new medicines.

The initiative arises out of the EU's Seventh Framework Programme for Research Initiatives (JTIs). These are meant to establish long-term, public-private partnerships on specific research areas, combining private-sector investment with national and European public funding. The novelty of these initiatives is that the research topics would be defined by industry. They also represent a move away from the traditional approach of case-by-case public funding of projects to concentrate resources on a few strategic issues, defined by industry in specific fields. One of six areas earmarked for JTIs is innovative medicines.

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

IMI has a total budget of €2 billion until 2013. A first call for proposals for research projects in the areas of brain disorders, metabolic and inflammatory diseases was launched, with submissions due by 15 July. Some €123 million will be granted to the most promising research projects in these areas later this year. This will be augmented by funding from industry of €175 million. In future calls IMI will also cover cancer and infectious diseases. These areas have been chosen because they are, primarily, important areas of unmet medical need, affecting the lives of millions of European citizens. As well as improvements in safety measurement and prediction of efficacy, other bottlenecks that the IMI seeks to overcome include knowledge management: supporting safety and efficacy of projects, as well as information sharing, modelling and simulation tasks, and gaps in education and training: supporting the medicine development process.

European Science and Research Commissioner, Janez Potočnik, underlined the ambitious goals of the initiative saying that “IMI is about pooling public and private efforts so that Europe can be a big player. We want to be the best in the world and become a champion’s league for biopharmaceutical research by moving from individual project-funding, to joint programme funding involving industry and public stakeholders.”

Arthur Higgins, President of EFPIA and Chief Executive Office of Bayer Health Care, emphasised the need to join forces with partners to address the main cause of delays in drug innovation, noting that “the challenges behind innovation are complex, and the decline in the number of new drugs is due to a combination of scientific, regulatory and economic factors. We as an industry are ready to play our part in bringing forward medical innovation but cannot solve all these issues by ourselves”. He added that the IMI is “a tremendous illustration of how the European industry can join forces with the EU and all the stakeholders like small and medium size enterprises, academia, patient groups, regulators and unlock the full innovation potential of Europe.”

Drug development for a new chemical or biological candidate is estimated to cost over €1 billion and takes on average 12.5 years to bring a new medicine to the market. Out of every 10,000 substances

synthesised in laboratories, only one or two will successfully pass all the stages to become marketable medicines.

Until 1998 seven out of ten new medicines originated from Europe. Today this has fallen to about three out of ten. It is hoped that IMI will boost Europe’s competitiveness in biopharmaceutical innovation and foster Europe as the most attractive place for pharmaceutical research and development. The pharmaceutical industry is a knowledge based sector that has a huge impact on employment for highly trained people. It provided Europe with 612,000 high skilled jobs in 2004, of which 103,000 were in research. Europe produces more than 35 % of the world’s pharmaceutical output, worth some €161 billion, making it the second most important manufacturing location after the US.

“IMI brings together experts from the laboratory and the clinic working on new approaches to better predict as early as possible whether a drug works in a patient and whether it is safe. Earlier access by patients in need to new effective treatments is the ultimate goal of this joint initiative,” stated Jonathan Knowles, the chairman of the IMI governing board.

The initiative also foresees the establishment by 2013 of a European Medicines Research Academy (EMRA), a pan-European platform for educating and training current and future professionals involved in biomedical R&D, including regulatory officers.

More information on IMI, including the call for proposals is available at <http://imi.europa.eu>

New Directive on road safety

The Commission has adopted a proposal for a Directive aimed at facilitating the cross-border prosecution of traffic offences which imperil road safety. Technical measures and legal instruments are to be put in place which will enable EU drivers to be identified and thus prosecuted for offences committed in a Member State other than the one where his or her vehicle is registered. It is hoped that this will make an appreciable difference to road safety in Europe by bringing about a positive change of behaviour in both non-resident and resident drivers.

The proposed Directive will cover four types of road traffic offence: speeding,

drink-driving, not wearing a seat belt and failing to stop at a red light. These four offences are the leading causes of accidents and road deaths: they are involved in almost 75% of all road deaths.

Since 2001, the EU’s goal in the field of road safety has been to halve the number of victims of fatal accidents in ten years. In that year (2001) 54, 000 people were killed on the roads of the twenty-seven Member States. In 2007, for the first time since 2001, there was no annual progress in cutting the number of deaths on the roads: it was still 43,000.

In October 2003 the Commission adopted a Recommendation dealing with best practice on enforcement in the field of road safety (2004/345/EC). The trend in accidents shows that this non-coercive instrument is not enough to achieve results.

More information at http://ec.europa.eu/transport/roadsafety/index_en.htm

Health inequalities highlighted for heads of states

Social protection reforms and active inclusion policies have visibly contributed to higher growth and more jobs in Europe over the past year. But more needs to be done to ensure that these benefits reach those at the margins of society and improve social cohesion, says a Commission report discussed by Employment and Social Affairs Ministers. The 2008 *Joint Report on Social Protection and Inclusion* focuses on priorities and progress made in the areas of child poverty, working longer, private pension provision, health inequalities and long-term care. The report was sent for discussion by heads of governments at the Spring European Council to highlight the social dimension of the jobs and growth package.

16% of EU citizens remain at risk of poverty while some 8% are at risk of poverty despite being employed. Out of the seventy-eight million Europeans living at risk of poverty, nineteen million are children. Social policies have a major impact on health and health is an important determinant of life chances. There are currently wide disparities in health outcomes across the EU, with men’s life expectancies ranging from 65.3 years (Lithuania) to 78.8 (Cyprus and Sweden) and those for women from 76.2 (Romania) to 84.4 (France). Health concerns could be adopted in all policies,

including promoting healthy life styles, while social protection could ensure access for all to quality healthcare and long-term care and promote prevention, including for those most difficult to reach.

The report is available at http://ec.europa.eu/employment_social/spsi/joint_reports_en.htm#2008

European Commission consultation on providing information to patients

The European Commission has launched a public consultation on a new proposal to ensure that information given to patients on prescription-only medicines reaches the highest standards. A Commission report published on 20 December 2007 (under Directive 2004/27/EC), studied current practices across Member States and concluded that rules and practices on information provision vary widely. It expressed concerns that patients and the public were not always able to find sufficiently detailed and reliable information on prescription medicines.

Following this, the regulations on information provision will be harmonised so that a clear distinction is made between material which advertises a product and that which informs the consumer. It will be designed to ensure that patients across the EU have access to clear, objective and reliable information. They will also establish quality criteria for all relevant information, ensuring patient access to unbiased objectivity, reliability and clarity in the information they receive.

While maintaining the ban on direct to consumer advertising of prescription products, dissemination via the media of information on such products will continue, monitored by national regulatory bodies established for this purpose and overseen by an EU-wide Advisory Committee. This includes Internet sites containing product information, which could also be used to monitor any consumer complaints to pharmaceutical companies. It will not be permitted to draw comparisons between products and all statements must be evidence-based, protecting consumers from any misleading claims.

More information at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_02/info_to_patients_consult_200802.pdf

Demands for quality and quantity of long-term care services bound to rise, says EU report

The demands for and costs of long-term care provision in the EU will rise significantly by 2050, according to a new report presented by the European Commission at a conference on inter-generational solidarity organised by the Slovenian EU Presidency on 28 April in Brdo. Meanwhile, the vast majority of Europeans (almost nine out of ten) favour home or community-based care over care in an institutional setting. The projected growth in demand for long-term care services presents a major challenge for national governments. But the report also shows that Member States are striving to guarantee access for all to quality care by providing adequate resources to meet this demand.

The report reveals the challenges of long term care in the future. It also shows that Member States are already preparing a wide variety of solutions and that there is also strong commitment at European level to provide access to quality care for all. "I am convinced that working together at European level gives Member States a unique added value and helps them to improve care for our vulnerable citizens by coordinating strategies and setting common objectives", said Social Affairs Commissioner Vladimír Špidla. He added that "we should not close our eyes to reality but act now to ensure high-quality long-term care now and for the future."

The Commission's report, *Long-term Care in the European Union*, analyses the main challenges Member States face in the field of long-term care, their strategies for tackling them and presents possible solutions. It draws on the national reports submitted as part of the EU's system of common objectives, assessment and reporting for social protection and inclusion – the 'Open Method of Coordination'. It identifies the main challenges for national governments as:

- Ensuring access for all to long-term care services;
- Securing financing for long-term care through an adequate mix of public and private sources of finance and potential changes in the financing mechanisms;
- Improving coordination between social and medical services, often

involved in the provision of long-term care services;

- Promoting home or community-based care rather than institutional care to help dependent people remain in their own homes for as long as possible;
- Improving the recruitment and working conditions of formal carers and supporting informal carers.

Europe's 80+ population is projected to rise from eighteen million in 2004 to nearly fifty million by 2050. If the additional life years are spent in ill health or in need of assistance, the number of dependent persons would more than double by 2050. Under the more optimistic scenario which assumes that the increase of a disability-free life expectancy will be in line with the gains in life expectancy as such, there would still be a 31% increase in the number of dependent people.

This will lead to an increase in formal and informal care, so jobs will be created, but expenditure is also likely to increase. According to projections in the report, average public spending on long-term expenditure across the EU-25 countries is expected to almost double from 0.9% of GDP in 2004 to 1.6% in 2050. The most pessimistic scenario could see an even bigger rise to 2.3% of GDP.

According to a Eurobarometer report carried out in 2007, most Europeans expect to need long-term care at some point in their lives (with an EU average of 13% seeing this as inevitable, 32% likely and 29% unlikely but possible). However, 86% of Europeans would prefer to be cared for in their own homes or that of a relative should they become dependent, as opposed to only 8% preferring an institution.

The report can be downloaded at http://ec.europa.eu/employment_social/news/2008/apr/long_term_care_en.pdf

NEWS FROM THE ECJ

Tougher stance on management of pharmaceuticals by the ECJ?

A case involving GlaxoSmithKline's stock management policy of certain drugs in Greece was referred to the European Court of Justice. The company's policy in question involved the limiting of quantities of products sold to wholesalers to levels adequate to meet the needs of the Greek market.

GSK stated that this policy was intended to limit the levels of parallel trade from Greece. However, wholesalers claimed that this policy was an abuse of a dominant position. The case was prompted by a reference from the Athens Court of Appeal of certain questions based on those raised in the earlier Syfait case.

On 1 April 2008, the ECJ released Advocate General Ruiz-Jarabo's opinion. He considers that a restriction of supply by a dominant pharmaceutical company in order to limit parallel trade can in principle be a breach of Article 82 of the EC Treaty. This is a much tougher stance than the opinion of AG Jacobs related to the Syfait case. AG Jacobs took the view that given the particular characteristics of the pharmaceutical sector, such a restriction could be justified as a reasonable and proportionate measure in defence of that company's commercial interests.

AG Ruiz-Jarabo does not agree that the restriction is justified due to the negative impact of parallel trade on GSK's incentives to innovate. Overall, this opinion creates unwelcome uncertainties about the legality of stock management systems operated by pharmaceutical companies for dominant products. The ECJ's judgment in the case is now awaited and the opinion of AG Ruiz-Jarabo is not binding.

The full opinion is available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-468/06>

COUNTRY NEWS

England: NHS ban on asylum seekers ruled unlawful

In London on 11 April regulations banning failed asylum seekers from receiving free NHS treatment were declared unlawful in England and Wales by a High Court judge.

In Scotland, those who have applied for asylum or still within the asylum process are already entitled to free NHS treatment until they leave the country.

Potentially the decision could have implications for 11,000 people currently awaiting removal from the UK. The ruling was made in the case of a Palestinian man who claimed that the denial of care for his chronic liver disease breached his human rights.

People who are unable to return home because of travel restrictions or because they are too ill have until now been banned from free NHS treatment. These people are deemed to be 'ordinarily resident', which means their return home has been delayed for over a guideline period of more than six months. The judge said the existing guidance was unlawful because the definition of 'ordinarily resident' was not restricted in time and authorities had discretion as to who qualified for 'ordinarily resident' status.

The man whose case brought the issue to the High Court is unable to return to the West Bank owing to travel restrictions and problems over documentation. In his 30s and known only as A, he applied for asylum when he arrived in England three years ago. His case was rejected and he agreed to return to the West Bank.

The Home Office provides him with accommodation and gives him £35 (€44) per week to live on. But his local hospital has refused to treat him as officially he is a failed asylum seeker, although he has been cared for while the case is heard. Adam Hundt, of human rights specialists Pierce Glynn and who represented the man, said the rules were leading to "grotesque human suffering". "My client is effectively stuck in the UK, even though he is doing all that he can to return home. He has never broken the law, and the Home Office recognises that it has to provide him with accommodation so as not to breach his human rights."

He added that "it seems perverse that housing is considered a basic human right and that health care is not." The Terrence Higgins Trust (THT) said the ruling would benefit those failed asylum seekers with HIV. Lisa Power, head of policy for THT said: "the outcome of this ruling is a sensible, humane decision for many people we work with. If someone is living in the UK, they should be treated the same as any other resident."

Deborah Jack, chief executive of the National Aids Trust, which helped bring the case to court, said "for years failed asylum seekers have been denied free treatment for long term conditions including HIV. Many have faced enforced ill-health as government policy has left them destitute and without health care."

The Department of Health in England is appealing the ruling.

Wales: Failed asylum seekers to be allowed NHS care

While legal proceedings are ongoing in England, failed asylum seekers in Wales will now be given access to free NHS care. Welsh Health Minister Edwina Hart said her decision was the right one and that the mark of a civilised society was how it treated the sick and dying. The opposition Conservative party said, however, that while the NHS should be open to emergency cases, they opposed 'health tourism'.

Previously, the Welsh Assembly had passed regulations to introduce charging for secondary health care for refused asylum seekers. The regulations, which meant charges for all forms of secondary care, except treatment provided in accident and emergency departments, were passed in April 2004.

Speaking to BBC Radio Wales, Minister Hart said that offering failed asylum seekers free NHS treatment and putting it on a legitimate footing was the "right thing to do". She referred to the parable of the Good Samaritan saying that "no-one would want to see a pregnant woman turned away from hospital if they were having difficulty with the pregnancy and people are fundamentally decent and they will understand this argument." "I'm simply looking at the human being at the end of the chain and saying if they've got severe health problems and they require help and assistance, as a civilised country we should give it."

The Archbishop of Wales, Barry Morgan, said he wholeheartedly supported the minister's view that Wales has a moral obligation to care for vulnerable people, regardless of their asylum status.

Sweden tightens health care rules for illegal immigrants

On 21 May Sweden's parliament approved the centre-right government's proposal to deny subsidised public health care services to illegal immigrants as of 1 July 2008. The law, which is largely a formalisation of current practice, stipulates that illegal immigrants and rejected asylum seekers can only receive emergency medical care if they pay for it themselves.

The parliament voted 265 to 33 in favour of the proposal, with the left-wing Green Party and Left Party voting against it on humanitarian grounds. The vote was postponed by a day to allow for an extended debate. The government plans to create a commission later this year to examine whether some illegal immigrant groups should still receive care. All parties in parliament are, for instance, in favour of giving illegal immigrant children the right to subsidised medical care.

Earlier Migration Minister, Tobias Billström, hinted that he is open to offering some health care coverage to immigrants who find themselves in Sweden without proper residence permits. As reported by the English language daily *The Local*, he told a television channel (TV4) that pregnant women and children lacking residence permits would be offered free health care.

The suggestion entails providing free maternity care, care during childbirth, and health services to children. "You can't punish children – born or unborn – for their parents' decision to live here in hiding," he said. Refugees in hiding and undocumented immigrants without documentation are currently unable to receive care without paying tens of thousands of kronor in healthcare costs.

Scotland: Review of free personal care

On 28 April, an independent review of *Free Personal and Nursing Care in Scotland* was published. The review was commissioned by the Scottish Government to look at the total levels and distribution of funding for the policy, and how to secure its long-term sustainability. Chaired by Lord Sutherland of Houndwood, previously Chair of the Royal Commission on the Funding of Long-Term Care for Older People, the six strong panel comprised experts from nursing, social work, dementia care and local government.

The policy to provide personal and nursing care in Scotland, which is free at the point of delivery and assessed according to need, was modelled on the Royal Commission Report *With Respect to Old Age* published in 1999. The relevant Act was passed by the Scottish Parliament in 2002.

The review found that the new policy "was implemented with expedition, and on the whole the process has gone well;

one might even say, granted the constrained timetable, surprisingly well." This was aided by strong resolve from the Scottish Parliament, the rapid actions of local authorities to implement the policy, and support from the private and voluntary sectors.

The review noted that "one response which was less than supportive was that of the UK Department for Work and Pensions (DWP) which ruled that Attendance Allowance should be withdrawn from Scots receiving free personal care in a residential setting and that the expenditure savings resulting should fall to DWP, rather than be transferred to the Scottish budget to offset the costs of the policy. The sum in question is now estimated to amount to around £30 million a year."

The review concluded the policy had proved popular and had few complaints in contrast to the situation in England. Twelve recommendations on the future of free personal care were made, which fall into three groups. The first group call for action in the short term and among other issues, are intended to address the immediate funding and variability of provision problems. In particular, it was noted that uncertainty associated with projecting future costs of long-term care means demand and costs must be reviewed and re-modelled regularly.

In the medium term, because of the projected growth in the numbers of older people, it was recommended that there should be a further review of the scheme within five years. This should look at better coordination of all sources of funding from a holistic perspective, including UK government benefits such as Attendance Allowance and Disability Living Allowance. In the longer term, they recommended that government at all levels should seek to establish a new vision for dealing with the challenge of demographic change, not just looking at long-term care, but also pensions, housing, transport, etc.

Welcoming the report, Cabinet Secretary for Health and Wellbeing, Nicola Sturgeon, said that "Lord Sutherland confirms that the policy of Free Personal and Nursing Care (FPNC) has both widespread support, and is delivering real benefits for tens of thousands of our most vulnerable older people. However the report clearly states that the UK Government should not have withdrawn

the Attendance Allowance resources previously paid to residents in care homes – providing savings ... that should have been made available to benefit elderly people across Scotland."

The report can be accessed at <http://www.scotland.gov.uk/Publications/2008/04/25105036/0>

Russia joins global anti-smoking convention

On 25 April, the Russian Daily *Novosti* reported that outgoing Russian President Vladimir Putin signed a law which will see the country join the World Health Organization's anti-smoking convention. Under the convention, which was ratified by Russia's lower house of parliament earlier in the month, a tobacco advertising ban should be implemented within five years, and at least 30% of tobacco packets should contain a health warning.

The WHO Framework Convention on Tobacco Control (FCTC), which was adopted in 2003 and signed by more than 150 countries, aims to help national governments curb smoking that kills five million people across the world annually. The signatories to the Convention are also encouraged to raise taxes for tobacco producers, eliminate the illicit trade in tobacco products, ban tobacco sales to and by children, and promote agricultural diversification and alternative livelihoods for tobacco producers. The death toll from smoking-related diseases could increase up to ten million people a year by 2020, according to World Health Organization forecasts.

In recent years, tobacco producers have shifted their focus to the developing world, where about 70% of all tobacco products are now sold. Russia is a major exporter of cheap cigarettes, with its domestic production from multi-national tobacco giants outstripping even Russia's heavy consumer demand by some one hundred billion cigarettes a year.

Tobacco use has contributed greatly to Russia's demographic crisis. Although Russia's population of 143 million is roughly half that of the United States, Russian tobacco use kills almost as many people, some 400,000 per year. More than 60% of Russian men and up to 30% of Russian women smoke. According to Euromonitor International, Russia ranks fifth worldwide in annual per-capita consumption, with

some 2,665 cigarettes smoked, behind only Serbia, Montenegro, Greece and Bulgaria.

The head of the State Duma health committee, Olga Borzova, earlier said Russia could pass a national anti-smoking strategy this year which would comply with the WHO Convention requirements. In a report on global tobacco control efforts in February, the WHO urged greater commitment from countries in implementing key tobacco control measures, saying among other things that national governments collect five hundred times more money in tobacco taxes each year than they spend on anti-tobacco advertising.

With the addition of Russia, 154 nations have now ratified the tobacco control treaty. The United States and Indonesia, both of which are large manufacturers and consumers of tobacco products, remain the two most populous nations that have not ratified the treaty.

More information at <http://en.rian.ru/russia/20080425/105915892.html>

Hungary: Parliament repeals controversial health insurance law

On 27 May, the Hungarian parliament repealed the Health Insurance Act, with only Free Democrat MPs voting against the motion. 347 MPs voted in favour of repeal with only nineteen against and no abstentions. The for-profit twenty-two regional health insurance funds established under the Act, which can have minority (up to 49%) private shareholdings, will also be phased out. Several parts of the Act will remain in force, including hospital waiting list regulations and measures designed to make pharmacies more profitable.

Health spokesman for the main opposition party, Alliance of Young Democrats–Hungarian Civic Party (Fiatl Demokraták Szövetsége–Magyar Polgári Szövetség, or Fidesz), István Mikola, said the government should account for the ‘dark era’ of eighteen months of health care reform, the Hungarian daily *Népszabadság* reported. The planned health care reforms led to a crisis in the governing coalition and in part caused the split between the ruling Socialists (MSZP) and their Liberal coalition partners (SZDSZ).

The health care reform act had been part of a series of government measures that aim to reduce the budget deficit by

attempting to create more customer-oriented but also cost-effective public services. The proposed new system was based on the Dutch health insurance system, which allowed private insurance companies to compete within a strictly regulated framework. Hungary even employed former Dutch health minister Hans Hoogervorst as an advisor on the project.

The reforms attracted widespread resistance across many sections of society. The opposition parties, led by the Alliance of Young Democrats–Hungarian Civic Party (Fiatl Demokraták Szövetsége–Magyar Polgári Szövetség, FIDESZ-MPSZ), were also heavily critical. The opposition highlighted the widespread fear that the reform would eventually lead to the break-up of the universal social insurance system and the introduction of a health insurance system based on competing insurance funds, similar to those found in the United States.

A large number of doctors also protested against the planned reform. As a result, the government received virtually no support for the proposed reform, with the exception of the support of the employer organisations. A day of national protest against the reforms had been held in November 2007. Despite this action, the Hungarian parliament passed the health insurance bill with minor changes on 11 February 2008.

However, in a referendum on 16 March voters rejected fees for medical treatment and higher education. Inevitably this led to a reduction in the levels of investor confidence that would be necessary to raise the private capital needed for the new health insurance system. Moreover, investor confidence was further dented by the knowledge that the main opposition party, Fidesz, which has promised to scrap the system if it comes to power in 2010, is well ahead in the opinion polls.

UN in Russia warns of demographic crisis

In Moscow on 28 April, Karl Kulessa, UN Population Fund chief in Russia, in launching the new UN in Russia joint publication *Demographic Policy in Russia: From Reflection to Action* said that the population could fall from 142 million to 100 million by 2050. The report, prepared by a group of independent national experts, suggests that,

even though the birth rate rose 8.3 % and the mortality rate decreased by 4% in 2007, this favourable trend is unlikely to continue beyond another five or six years. Then population decline will set in again.

Outgoing President Vladimir Putin had made fighting the falling population a priority. The new report, while praising recent government efforts to increase the birth rate and extend lives, argues that not enough is being done to counter stark demographic forces: an impending decrease in the number of women of child-bearing age, poor health care, rampant road vehicle and industrial accidents, widespread alcoholism and social conditions that discourage family formation.

The UN Report suggests that by 2025 the population will already have shrunk to 125 million. While children constituted 24.5 % of the Russian population in 1989, this had decreased to 16% by 2007. By year 2023 the number of children born per year is expected to drop to less than one million from its current level of one and a half million. With the shrinking population it is estimated that the Russian labour market will then be in need of twenty-two million more workers.

Valeri Elizarov, principal author and Head of the Centre for Population Studies at Moscow State University Economics Department, offered a set of concrete recommendations, which, in his opinion, could have an immediate positive effect to counter the declining trend. He listed among low-cost measures the necessity to restore the distorted information collection system and to improve the knowledge of demographic issues among civil servants and parliamentarians. Other measures could include tax benefits for those who have more children, development of family and child care infrastructure, and an increase of family allowances to the level of developed countries (2–3% of Gross Domestic Product).

More encouragingly, at the launch of the report, Olga Sharapova, Director of the Department for Medical and Social Issues of Families, Maternity and Childhood of the Ministry of Health and Social Development of the Russian Federation, cited preliminary results of recent measures undertaken by the government. Several programmes have

been adopted, including those targeted at decreasing mortality from cardiovascular diseases and traffic accidents. The state has allocated ten billion roubles (€269 million) for these programmes, which will be transferred to Russia's regions. Maternity allowances are also to be increased and measures are being taken to improve the health services for pregnant women and children. The construction of twenty-three specialised prenatal centres has also started. However, as Sharapova put it, "the discussion of the report will give a strong impetus in identifying, which aspects we should still work on."

The report can be freely downloaded at <http://www.undp.ru/index.phtml?iso=RU&lid=1&cmd=publications1&id=73>

Czech Republic: court rules in favour of patient charges

On 28 May in Brno, the Czech Constitutional Court ruled that the government has the right to charge fees for patients using the health care system. The government began charging 30 koruny (€1.19) per doctor's visit or prescribed drug and 60 koruny (€2.28) for a day in hospital in January 2008.

The upfront payments, for which local opinion polls show a high level of public opposition, were intended to reduce unnecessary visits to the doctor and use of medications. The Organisation for Economic Cooperation and Development (OECD) says Czechs see a doctor more than anyone else in Europe at 13.2 visits per year, compared to the OECD average of 6.8 visits a year.

The Czech Constitution states that Czechs have the right "to free medical care," but "under the conditions defined by law." The court's decision was a victory for Prime Minister Mirek Topolánek's government, which instituted the payments at the start of the year as part of a broader reform of public finances. The court said that it did not want to play a political role. If the court intervened, it could "close the door on any reform efforts," said Judge Stanislav Balík, reading an explanation of the court's decision. Health Minister Tomáš Julínek said the decision was 'good news for patients'

The court said that the fees could still be rolled back in Parliament. The leading opposition party has promised to abolish them. Topolánek's junior

coalition partners have also put pressure on his governing Civic Democrats to exempt children and older people. The payments are very unpopular in the region: similar fees were overturned by a court in Slovakia and in Hungary by popular referendum. However the Ministry of Health says the measure has been effective, noting that the number of prescriptions fell 40% in the first quarter of 2008 compared to the same period last year. The Ministry estimate that it has avoided 1.75 billion koruny (€70 million) on medicine costs in the first three months of this year.

Germany: Federal Administrative Court permits mail order businesses to cooperate with pharmacies

The Federal Administrative Court in Leipzig (Bundesverwaltungsgericht – BVerwG) ruled on 13 March 2008 that cooperation between mail order businesses and pharmacies for the purpose of ordering and supplying medicinal products to consumers is permitted under the provisions of the German Act on Medicinal Products (Arzneimittelgesetz – AMG) and the German Pharmacy Act (Apothekengesetz – ApoG).

The AMG has permitted medicinal products to be supplied by mail order businesses since 1 January 2004. Based on this, the Dutch mail order pharmacy, Europa Apotheek Venlo, concluded an agreement to cooperate with the German pharmacy chain, dm-drogerie. Under this cooperation, orders from consumers for medicinal products can be deposited at a pharmacy operated by dm-drogerie and then collected after three days. However, the municipal government in Düsseldorf prohibited this practice in 2004. dm-drogerie successfully appealed against this prohibition at the Administrative Court of Appeal in Münster in 2006. This appeal has now been upheld by the Federal Administrative Court in Leipzig.

The Federal Administrative Court justified its decision on the basis that the distribution of medicinal products by collection from a designated pick-up point is a common business method for mail order companies. Thus, this form of distribution comes within the term 'mail order business' under section 43(1) of the AMG and section 11a no. 1 of the ApoG. The court held that the 'order-and-collect' form of mail order did not

involve any higher safety risks when compared to a classical mail order business where the products are delivered directly to the consumer. Therefore, the AMG and the ApoG did not prohibit this form of distribution. However, the court also stated that, in an 'order-and-collect' form of mail order, the role of the pharmacy should be limited to a logistical service only. Consequently the pharmacy should not give the impression that it is dispensing the relevant medicinal products or that the consumer is entering into a contract with the relevant pharmacy. Furthermore, any advertisements conveying these impressions should not be used.

Spain: New court ruling on the pharmaceutical patent system

A ruling of the Provincial Court of Barcelona has confirmed that pharmaceutical companies in Spain are not permitted to manufacture generic versions of pharmaceutical products manufactured by other pharmaceutical companies. Whilst this ruling does not create new legal rights, it does widen the scope of the existing law.

When Spain joined the EU it enacted legislation creating a patent system. This did not, however, offer patent protection for pharmaceutical products. As a result, European patents for pharmaceutical products were also unenforceable in Spain. Subsequently, Spain became part of the World Trade Organisation and ratified the TRIPS/ADPIC Agreement which provided minimum standards of industrial protection between the ratifying states. The TRIPS/ADPIC Agreement entered into force in Spain on 1 January 1996.

The pharmaceutical industry in Spain had argued that the TRIPS/ADPIC Agreement altered the Spanish patent system and, thus, revoked the restriction on patentability of pharmaceutical products. This argument was supported by the Barcelona court which ruled that product patents will be enforceable in Spain even if they had been requested prior to October 1992 (i.e. prior to the end of the restriction on patentability of pharmaceutical products). Furthermore, the court established that patents that had been granted before the TRIPS/ADPIC Agreement entered into force will also be enforceable. The court stated that, "we consider that the TRIPS/

ADPIC Agreement cannot be ignored in Spain". The ruling also established a "supervised patentability" for those patents that fall under the protection of the TRIPS/ADPIC Agreement.

Greece: Government to ban smoking in public places by 2010

The Health Ministry has announced that it will gradually ban smoking in public places, such as cafes and restaurants, by 2010. Although 46% of men and 31% of women are regular smokers, the stricter measures, aimed at protecting smokers and non-smokers, have the backing of most Greeks. According to a recent survey, eight in ten Greeks believe that banning the habit from all public places is not an infringement on personal rights. Additionally, 73% agreed that the reduction of smoking should be a target in national government policy. The authorities are also planning to launch a marketing campaign aimed at preventing young people from taking up smoking.

Those who flout the new laws can expect to incur sizable fines and other penalties.

Offending smokers may earn proprietors fines as high as €3,000. The non-smoking act will further prohibit tobacco sales to minors. Tobacco products will be on sale in specialist shops, while the sales of cigarettes by the piece will be banned, as well as that of packets containing less than 20 cigarettes.

Ukraine: National measles and rubella vaccination campaign suspended

Measles and rubella are highly contagious infections and can lead to severe complications, birth defects and death. In 2005–2006, Ukraine experienced large outbreaks of measles, infecting over 50,000 young people that accounted for 80% of measles cases in Europe. Over 20,000 young Ukrainians contract rubella annually and a large outbreak of over 100,000 cases occurred in 2002, resulting in serious birth defects.

However, following the death on 13 May of a 17-year-old boy after use of a measles vaccination in the Donetsk Region, and the subsequent hospitalisation of over sixty people in eastern Ukraine, the Ministry of Health has called a moratorium on mandatory vaccination against measles and rubella. The President of Ukraine, Viktor Yushchenko, has insisted that vaccination is carried out on a voluntary basis only.

Anton Tishchenko died in intensive care in a hospital in the city of Kramatorsk in Donetsk Region after he had been given the vaccine. Although a special commission of the Ministry of Health is still investigating the case, the Minister of Health stated that preliminary results provide no evidence of vaccination causing this tragic death.

The WHO, the United Nations Children's Fund (UNICEF) and the Centers for Disease Control and Prevention (CDC) in a statement said that they regret the suspension of the national measles and rubella vaccination campaign. They argued that the decision will have long-term implications not only for the campaign but for other routine immunisation coverage, resulting in the potential for outbreaks of other infectious diseases. They also regretted the decision to suspend vaccination prior to the outcome of the investigation into Mr Tishchenko's death. They called on the government to complete its full investigation into this death in order to restore public trust in immunisation.

The three organisations reiterated that the measles and rubella vaccine used in Ukraine is pre-qualified by WHO and produced in accordance with the highest international standards by the Serum Institute of India, the largest producer of measles and rubella vaccine globally. Two out of three children in the world are immunised against measles with vaccine from this manufacturer. They stated that this measles–rubella vaccine has an excellent track record and has been successfully used in countries across Europe and the Commonwealth of Independent States (CIS), immunising over thirty-four million young people. The rubella vaccine from the same manufacturer has been used in Ukraine since 2002, successfully vaccinating over 1.3 million people.

More information at
http://www.euro.who.int/mediacentre/PR/2008/20080521_1

France: Happy hour ban to curb youth drinking considered

On 19 May it was reported that France is planning to ban 'happy hours' in bars in a bid to stem the rise of binge drinking. The leaked government proposals follow calls from doctors and politicians to tackle excessive alcohol consumption. The cross-ministry report also calls for a ban on the sale in night-

clubs of bottles of strong alcohol, including spirits, and raising tax levels on strong beer. 'Le open bar' – where patrons pay a fixed fee to drink all night – would also be banned. The legal age at which people can buy alcoholic drinks might also be raised: currently teenagers aged between 16 and 18 are allowed to buy beer and wine.

The tougher measures were necessary, the report said, after preventative and educational action had not been "sufficient in altering trends" in binge drinking in France. Research indicates that the number of French people indulging in frequent bouts of heavy drinking has risen steadily in recent years. Half of all seventeen year olds admitted getting excessively drunk at least once in the last month, while a small minority confessed to binge drinking more than twice a week. The university town of Nantes banned happy hours in October, following the drowning of two students in the Loire River after leaving a night club drunk.

Many bar owners object to the bans, however, especially in the wake of a new law prohibiting smoking in bars and restaurants. Speaking to French daily, *Le Parisien*, Patrick Malvaës, President of the Union of Discos and Places of Leisure said "I don't see how these measures will resolve the problem of alcoholism. To get rid of happy hours is ridiculous."

While the health ministry said that the measures were "proposals at this stage", the government is reportedly keen to see them through. "Alcoholism is a scourge and all available means are welcome to fight it," said one doctor consulted in drawing up the planned rules. According to Etienne Apaire, head of a government body in charge of the fight against addiction to drugs or alcohol, the proposed measures are being discussed with producers and distributors of alcoholic drinks and some decisions are expected within weeks. The move is the latest action against excess drinking: in February Prime Minister Francois Fillon indicated that new laws would be introduced to confiscate the vehicles of drunk drivers. He also promised the prohibition of the alcohol sales in service stations and the automatic confiscation of the license in the event of vehicular homicide.

News in Brief

WHO European Ministerial Conference on Health Systems

Organised by WHO Regional Office for Europe and hosted by the Government of the Republic of Estonia, *Health Systems, Health and Wealth* will take place in Tallinn on 25–27 June 2008. Ministers of health from the 53 Member States in the WHO European Region and up to 500 participants are expected to attend the event. High-level delegations will be invited, as well as health systems partners, experts, observers and representatives of international and civil society organisations and the media. The conference aims to improve understanding of how health systems not only impact on health but also on economic growth. It also takes stock of recent evidence on effective strategies to improve the performance of health systems, given the increasing pressure on them to ensure sustainability and solidarity.

More information at <http://www.euro.who.int/healthsystems2008>

Physical activity affected by social status

Move for Health Day 2008 on 10 May put an emphasis on physical activity is for all. Its primary aims were to increase public awareness of the benefits of physical activity in the prevention of non-communicable diseases and to draw attention to good practice. One in five people in the WHO European Region is now inactive and socioeconomic status influences our level of physical activity. People with lower incomes have disproportionately higher rates of the chronic diseases and obesity associated with less physical activity and unhealthy eating patterns. Although poorer people are more likely to walk or cycle to shops or work than those with higher incomes, they are less likely to be active in their leisure time. The mechanisation of labour has brought about a general homogenisation of levels of work-related physical activity among social groups. Thus, socioeconomic differences in overall physical activity are more likely to result from variations in leisure-time pursuits than in activities related to other areas of life.

More information available at <http://www.euro.who.int/moveforhealth>

Launch of Trencin Statement on prisons and mental health

On 24 June 2008, at the London-based Sainsbury Centre for Mental Health, the Trencin Statement on Prisons and Mental Health will be launched. It aims to draw the attention of all countries in Europe to the essential need for a greater focus on mental health problems among people in custodial settings. Of the nine million prisoners world-wide, at least one million suffer from a significant mental disorder, and even more suffer from common mental health problems such as depression and anxiety. There is often co-morbidity with conditions such as personality disorder, alcoholism and drug dependence.

The statement highlights that without urgent and comprehensive action, prisons will move closer to becoming twenty-first century asylums for the mentally ill, full of those who most require treatment and care but who are held in unsuitable places with limited help and treatment available. The event is organised by the WHO Health in Prisons Project, in collaboration with its Collaborating Centre, the UK Department of Health and the Sainsbury Centre for Mental Health. Previously the statement was adopted by twenty-eight European Member States present at a mental health conference held in Trencin, Slovakia in October 2007.

More information at http://www.euro.who.int/prisons/20080428_4

Netherlands: Government to publish vision on drug policy

On 19 March, during a parliamentary debate, Health Minister Ab Klink announced the development of an integrated policy document on the future of drug policy. The document will include an evaluation of the results of the Dutch government's policy of tolerance (*gedoogbeleid*), as well as making a comparison between Dutch drug policy and that of other countries. The Minister also plans to commission research into the damaging impact of various types of drugs, including alcohol and tobacco. There will also be a risk analysis of the damaging effect of cannabis. The new drugs policy document, including details of research, is expected to be published in spring 2009.

Injury statistics in the EU

The report, *Injuries in the European Union – Statistics Summary 2003–2005*, launched on 3 April 2008, clearly shows that injury remains one of the biggest health threats facing Europe today. Published by Eurosafe, the European Association for Injury Prevention and Safety Promotion, it indicates that there are approximately 250,000 fatalities each year in the EU, the fourth major cause of death. Only cardiovascular diseases, cancer and diseases of the respiratory system claim more lives. Sixty million people in the EU receive medical treatment each year as a result of an accident or injury. Making use of current injury data at EU27 level, the new report provides a statistical overview on different sectors of injury prevention such as traffic, work place, and home and leisure.

For the report and other injury statistics see <https://webgate.ec.europa.eu/idb>

Better outcomes through health reforms in the Russian Federation

A new discussion paper *Better Outcomes through Health Reforms in the Russian Federation: The Challenge in 2008 and Beyond* has been published by the World Bank. Written by Patricio Marquez it looks at selected health challenges in the Russian Federation, focusing on outcomes, expenditures and options for policy and institutional reforms in the health care system. The areas covered in the paper draw on recent studies and reports, and take into account lessons derived from the World Bank-funded Health Reform Implementation Project (HRIP) at the federal level and in the Chuvash Republic and the Voronezh Oblast – the pilot regions of the project, over the 2005–2007 period.

The paper is freely available at <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/MarquezRussianHealthReforms.pdf>

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