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- Consolidating national authority in the Nordic states
- Health system reform in Cyprus
- Welsh Dignity in Care Programme

Volume 18 | Number 3 | 2012



EUROHEALTH

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Published by the European Observatory on Health Systems and Policies

Eurohealth is a quarterly publication that provides a forum for researchers, experts and policymakers to express their views on health policy issues and so contribute to a constructive debate in Europe and beyond.

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Design and Production: Steve Still

ISSN 1356-1030



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EDITORS' COMMENT

Eurohealth Observer

WHAT IS THE SCOPE FOR HEALTH SYSTEM **EFFICIENCY GAINS** AND HOW CAN THEY BE ACHIEVED? – Peter C. Smith

EVALUATING REFORMS IN THE **NETHERLANDS**'
COMPETITIVE HEALTH INSURANCE SYSTEM – **Ilaria Mosca**

PORTUGAL'S HEALTH POLICY UNDER A FINANCIAL RESCUE PLAN – Pedro Pita Barros

HEALTH SYSTEMS **EFFICIENCY AND SUSTAINABILITY**:
A EUROPEAN PERSPECTIVE – **Federico Paoli**

Eurohealth International

SIMULATION ON THE **EU CROSS-BORDER CARE**DIRECTIVE – **Rita Baeten** and **Elisabeth Jelfs**

CONSOLIDATING NATIONAL AUTHORITY IN NORDIC HEALTH
SYSTEMS – Richard B. Saltman, Karsten Vrangbaek,
Juhani Lehto and Ulrika Winblad

Eurohealth Systems and Policies

CONTRIBUTIONS, CO-PAYS AND COMPUTERS: HEALTH SYSTEM REFORM IN CYPRUS – Mamas Theodorou and Jonathan Cylus

POLICY FACTORS UNDERPINNING THE WELSH DIGNITY IN CARE PROGRAMME, 2007–2012 – Gareth Morgan

Eurohealth Monitor

NEW PUBLICATIONS

33 NEWS

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Perhaps at no other time in the last decade has the need to extract the best potential benefits out of stretched resources been so urgent. With public sector budgets across Europe being stringently monitored and often curtailed, health care is no exception. In fact, in quite a few countries, and especially those subject to international loan agreements, the health sector is one of the areas targeted not only for more immediate cost savings but also for longer-term re-structuring and efficiency gains.

In this issue's Eurohealth Observer section Peter Smith outlines the possibilities and challenges of obtaining a workable model of efficiency in health care. He takes care to highlight the difference between expenditure control, which focuses only on health system monetary inputs, and efficiency, which is concerned with deriving the best possible desired outputs from a given set of inputs. The article also highlights five areas in the health sector where there is the most promising scope for efficiency improvements. The following two articles focus on two countries with very different economic contexts but which have both embarked on health care reforms that include the goal of improving efficiency. llaria Mosca looks at the impact of policies moving the Netherlands gradually towards a system of regulated competition since 2006, while Pedro Pita Barros discusses Portugal's implementation of a wide menu of health care reforms as part of its financial rescue programme. The final article in this section provides a European-wide perspective and outlines some of the ways in which the European Commission operates processes aimed at helping countries to achieve efficiency and sustainability in their health sectors.

The first article in the **Eurohealth International** section explores the potential implications of the EU Cross-Border Care Directive using a simulation exercise. Baeten and Jelfs discuss the responses of different stakeholder groups from six countries. Next, Saltman and colleagues identify the current policy shift in four Nordic countries. These countries, which are moving towards a consolidation of national decision-making authority, can provide lessons for other decentralised health care systems.

In our **Eurohealth Systems and Policies** section Theodorou and Cylus delineate the challenges for Cyprus's new health system that is planned for implementation in 2016. While for Wales, the Dignity in Care Programme established in 2007, has been developed and delivered. This programme centring on person-centred holistic care can provide insights on how to approach care for older people in other regions.

The **Eurohealth Monitor** section draws attention to two new publications on intersectoral governance for Health in All policies and on health policy responses to the financial crisis in Europe, while news keeps you up to date on health policy developments.

We hope that you enjoy this issue and we welcome your comments and feedback to the editors.

Sherry Merkur, Editor Anna Maresso, Editor David McDaid, Editor

Cite this as: Eurohealth 2012; 18(3).

WHAT IS THE SCOPE FOR HEALTH SYSTEM **EFFICIENCY GAINS** AND HOW CAN THEY BE ACHIEVED?

By: Peter C. Smith

Summary: Efficiency in health systems is a beneficial goal that few would argue against. If efficiency is attained, the maximum benefits are being squeezed out of the available resources. This article sets out a basic model of efficiency and indicates how it can be used to secure operational indicators of efficiency. It concludes with a short discussion on where the most promising scope for efficiency improvement in health systems might lie, namely the reconfiguration of services; information; funding mechanisms; health-related behaviour; and accountability.

Keywords: Efficiency, Efficiency Indicators, Health Systems Improvement

Few would oppose the principle of promoting an efficient health system. If efficiency is attained, the maximum benefits are being squeezed out of the available resources. In contrast, inefficiency implies either that money is being spent on the wrong activities (allocative inefficiency) or that there is slack in the system (technical inefficiency). In either case, not all the potential benefits are being secured from health services. Furthermore, the funders of services (in most cases the general public, paying in the form of taxation or insurance premiums) cannot be assured that their financial contributions are being used wisely. This could result in increased resistance of citizens to providing funding, perhaps even threatening the longer term financial sustainability of the health system.

The case for pursuing efficiency is therefore clear. However, the practical difficulties of conceptualising, measuring and improving efficiency are formidable.

Not only is it challenging to develop tractable models of efficiency, but any shortcomings in efficiency models can lead to faulty policy inferences. These may have potentially damaging consequences for health services and threaten the popular support on which the modern health system relies. Moreover, addressing efficiencies often involves confronting powerful vested interests that can mount potent opposition. Thus, although all policymakers recognise the need to pursue efficiency, implementing efficiency improvement measures can be both a risky and daunting undertaking from a policy perspective.

This article sets out a basic model of efficiency, and then indicates how it can be used to secure operational indicators of efficiency. It concludes with a short discussion on where the most promising scope for efficiency improvement might lie. Before that, it is important to underline the distinction between the pursuit of efficiency and the pursuit of expenditure

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control. The former seeks to improve the level of valued outputs secured in return for expenditure (or other inputs). In contrast, the concern with expenditure control indicates a preoccupation only with inputs. This article is concerned primarily with the concept of efficiency, in the belief that – even when the level of expenditure is the prime source of concern – it can be properly addressed only when there is full knowledge of the benefits that the expenditure is securing.

Modelling efficiency

The usual approach of economists towards efficiency has been to model the maximum attainable outcome from a health system as a 'production function', and to consider inefficiency as the extent to which the achieved outcome falls short of that idea.2 Numerous studies have sought to apply such models to the performance of health service organisations, such as general practices and hospitals. The World Health Report 2000 sought to measure the efficiency of entire health systems relative to an empirical estimate of the production function, judging that France came closest to that estimate, achieving 99.4% of its potential outcomes, given its level of spending.

In spite of their popularity, many technical challenges confront the analyst seeking to develop such models. For example, what is meant by 'outcome'? Many would agree that it should reflect some measure of the health improvement secured by the system, but what about other goals, such as user satisfaction, equity, or financial protection? And to what extent should external, uncontrollable influences be taken into account when comparing efficiency? The World Health Report 2000 sought to adjust for different levels of social capital by including an indicator of educational attainment in its model. Yet, as the WHO Commission on the Social Determinants of Health argued, there may be many other influences beyond the immediate control of the health system that contribute to health status. A convincing model of efficiency may need to adjust for factors such as tobacco and alcohol consumption, diet, and even income levels. Finally, the more prosaic difficulties of securing adequate data and

developing acceptable empirical models often present daunting practical barriers to making conceptual models operational.

difficult to develop robust measures of comparative efficiency

Figure 1 illustrates the principles underlying the traditional model of efficiency. It shows attainment of a single outcome measure (life expectancy) in relation to a single input (health services expenditure). It suggests that Mexico, South Korea and Japan form the production frontier, against which all other health systems fall short. The manifest shortcomings of this model include: only a single output is modelled; only a single year is measured (when outputs may be the result of years of health system endeavour); no adjustment is made for external influences on attainment; no estimate of uncertainty is presented; and so on. All empirical models, however refined, will be vulnerable to such criticisms.

Partial indicators

Analysts have recognised such weaknesses and therefore have adopted alternative indicators of efficiency that do not seek to capture the cost-effectiveness of the entire entity under scrutiny, but rather offer a partial reflection of some aspect of the pathway from inputs (money) to eventual outcomes (such as health). By way of illustration, Figure 2 indicates the various stages in this transformation for (say) a hospital. First, money is used to purchase inputs (for example, in the form of labour or capital). These might be reflected in estimates of unit costs. Then physical inputs are converted into a physical output, such as an episode of care, the efficiency of which is reflected in indicators such as length of inpatient stay. Finally, physical outputs are transformed into valued health outcomes, in the form of length and

quality of life. Risk-adjusted mortality rates might offer a (partial) indicator of this stage of the transformation. Notice that all the indicators shown in Figure 2 are partial in the sense that: a) they reflect only part of the production process and b) they reflect only part of the operations of the hospital under scrutiny.

Table 1 presents a broader selection of partial indicators of efficiency, which seek to offer an insight into some aspect of wasteful use of resources during the transformation process. There is a brief commentary on the limitations of each indicator. Whilst all of these partial indicators suffer from weaknesses, properly used they can offer diagnostic information on where and why inefficiency is present. Nevertheless, it is quite clear that this is a rather arbitrary collection of metrics that suffers from a lack of theoretical coherence. A systematic review of efficiency measures confirmed the lack of intellectual rigour behind most efficiency measures. The review found that it has proved difficult to develop robust measures of comparative efficiency that are feasible to collect or estimate, that offer consistent insight into comparative health system performance, and that can be usable in guiding policy reforms. Given the importance of the policy concern, addressing these weaknesses remains a high priority for future research.

Improving health system efficiency

Measuring current levels of efficiency is only the starting point in seeking to improve health system efficiency. There are three broad preconditions without which it is likely to be impossible to promote efficiency: provision of the necessary information; an appropriate system of governance (to hold relevant parties to account); and adequate will and capacity to pursue efficiency objectives. Once these are in place, the levers to promote efficiency can be considered at four levels: system-wide mechanisms; organisational actions; practitioner-level initiatives; and arrangements that affect the individual citizen or patient. Each of these is considered briefly in turn.

System level reforms are well known and widely debated by policymakers.

Figure 1: Per capita total health spending and life expectancy, 2006

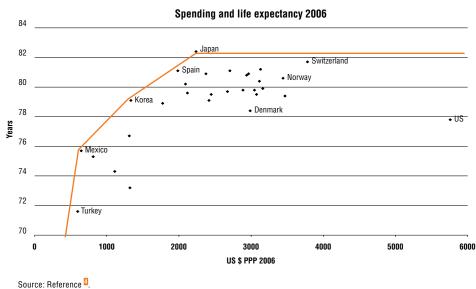
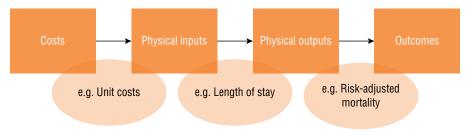


Figure 2: Representation of the transformation of hospital inputs into outcomes



Source: Author.

Examples include mandatory provision of comparative performance information; reform of provider payment mechanisms; strengthening of patient choice and provider competition; provision of guidelines on good practice; and systems of targets, audit and inspection. There is increasing evidence that such mechanisms do have an effect on system behaviour, and they are likely to be part of the armoury of any policymaker seeking to enhance efficiency. However, experience also suggests that reforms should be implemented with care, and that there should be careful monitoring of unintended side effects.

Organisational efforts to improve efficiency might include implementation of effective management accounting systems (to understand internal use of resources); use of individual and team incentive schemes; reconfiguration of

service delivery; and appropriate use of information technology. There are unresolved debates about the magnitude of economies of scale and economies of scope in health services, particularly in the hospital sector, and the extent to which integration of services can secure gains either in patient outcomes or reduced expenditure. This is an important area for further research.

Practitioners are responsible for the allocation of a large proportion of health system resources, and are therefore a key target for initiatives to improve efficiency. Much will depend on the incentive structure within which they operate, created by higher level choices such as performance reporting and practitioner payment schemes. Practitioners should be encouraged to adhere to evidence-based clinical guidelines. Finally, it is unlikely that initiatives aimed at

practitioners will be fully effective unless clinical leaders and trainers nurture a culture that recognises the importance of efficiency and the benefits it brings to the health system.

There is also increasing recognition that the actions of patients and caregivers can have a profound impact on health system efficiency. Actions such as drug compliance, missed appointments, timely presentation, and health-related behaviour can have an immense impact on the use of health service resources and their effectiveness. Most experiments are at an early stage, but there is clearly potential 6000 in initiatives such as improved provision of patient information about treatment options; information on comparative provider performance; use of user charges, exemptions and patient budgets; and aids to compliance. It is likely that these sorts of mechanisms will secure different levels of effectiveness for different types of patients, so a great deal of future research will be needed to identify the most appropriate way of using patient level mechanisms. However, the rise of telemedicine and personalised medicine are likely to make this an important area for exploring further.

Promising areas

The above discussion suggests a complex mix of potential reforms that might be useful in addressing efficiency concerns, but which also contain the potential for disappointment. Therefore, the concluding section points out five particularly promising areas where the evidence seems relatively secure, and the scope for efficiency gains is large:

Reconfiguration of services: there are immense variations in costs and use of resources between providers. Therefore, there is great scope for efficiency improvement and implementation of new service delivery models, especially for chronic disease. However, addressing the variation requires detailed diagnosis of organisational weakness and transfer of practice from efficient organisations. This can be secured only with organisational expertise and leadership.

Table 1: Selected indicators of efficiency in common use

Indicator	What is it?	What are the assumptions and what does it ignore?
Emergency department visits that could have been seen in less invasive settings.	The proportion of emergency department visits that could have been seen in a different, less costly setting.	Ignores quality of care. Depends on definitions.
Average length of stay.	The number of days per hospital inpatient stay.	Assumes cases are identical, both in terms of outcomes and in terms of intensity.
Unit costs.	Estimates of costs.	Assumes uniform treatment, uniform accounting methods, ignores quality.
Case-mix adjusted cost per episode of care.	The average costs for treating a certain type of condition.	Assumes cases are identical, both in terms of outcomes and in terms of intensity. Assumes uniform treatment, uniform accounting methods.
Duplicate medical tests.	The number of tests that are done more than once for the same patient.	Assumes any duplicate test is inefficient regardless of situation.
Share of total expenditures spent on administration.	The percentage of total health expenditures dedicated to administration.	Assumes that greater share of administrative expenditure is inefficient without accounting for scale. Highly dependent on accounting methods used.
Labour hours per episode of care.	The number of hours per case-mix adjusted episode of care.	Assumes patients require the same intensity of care; difficult to accurately measure across a large sample; affected by health system design as well as efficiency.
Share of health worker hours spent treating patients.	The percentage of health worker hours spent treating patients.	Assumes patients require the same intensity of care; difficult to accurately measure across a large sample; assumes time not spent with patients is unproductive.
Disease costs.	The average cost per case of treating a certain disease.	Can be difficult to calculate without linking patient data across providers. Assumes uniform case-mix. Highly dependent on accounting methods used.
Effective coverage.	The share of actual health gains achieved relative to maximum potential health gains for an intervention.	Difficult to measure need and quality.

Source: Reference 5.

Information: there is clear need for better clinical guidelines that, as a matter of course, should embrace principles of efficiency (for example, in the form of cost-effectiveness criteria). There is also a crucial role for national agencies in mandating the collection and dissemination of comparative information on providers and alternative treatments. The use of patient-reported outcome measures (PROMs) may prove to offer a major advance in this respect.

Funding mechanisms: provider payment has a crucial impact on the behaviour of the system and on efficiency. Traditional mechanisms are known to be inadequate, although experiments with 'pay-for-performance' to date have not been universally successful in delivering hoped-for improvements. A key unresolved

issue is the optimal level of aggregation of services into payment 'bundles' that incentivise efficient care without inducing adverse responses, such as 'dumping' of expensive patients.

Health-related behaviour: there is universal acknowledgement that lifestyle and other behavioural factors have an immense impact on health and the way that health services are used. Although blunt mechanisms such as 'sin' taxes and user charges are known to be effective, they can either be politically unattractive or have serious adverse side-effects, for example on equity. There is therefore great scope for more refined mechanisms that encourage citizens to use services efficiently.

Accountability: efforts to improve efficiency will be largely ineffective if there are no accountability mechanisms to ensure that there is proper external scrutiny of performance, and appropriate rewards and penalties. For example, funding mechanism reforms may be futile if inefficient providers continue to be 'rewarded' with additional funds to make good an end-of-year deficit. Competition and market mechanisms are attracting increased attention in both the insurance and provision of health care, and their effectiveness will be watched carefully to see if market accountability delivers efficiency gains.

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EVALUATING REFORMS IN THE NETHERLANDS'

COMPETITIVE HEALTH INSURANCE SYSTEM

By: Ilaria Mosca

Summary: The 2006 health care reform in the Netherlands attracted widespread international interest in the impact of regulated competition on key factors such as prices, quality, and volume of care. This article reviews evidence on the performance of the health care system six years after the reform: health care costs have kept growing; quality information has become readily available; hospital efficiency has improved on an annual basis; and consumers have had greater choice. The transition to regulated competition is a gradual process. The full effects may not become evident until sometime in the future. Looking forward, monitoring the health care system is an important prerequisite to better understand the effects of regulated competition in health care.

Keywords: Regulated Competition, Health Care Expenditure, Consumer Choice, Efficiency, Quality

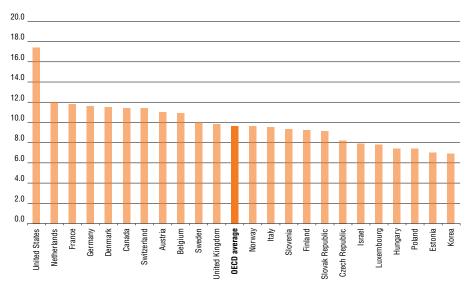
The health care reform implemented in the Netherlands in 2006 has attracted extensive international interest, particularly on how regulated competition impacts on key factors such as prices, quality, and volume of care. This reform was carried out as a response to policy concerns about accessibility to health services, quality of care, rising health care costs and waiting lists that emerged in the 1990s. Several steps were taken from 1990 that ultimately led to the 2006 reform. These included: eliminating the

regional monopolies of sickness funds (1992); developing a risk equalisation system (1992); allowing consumers to switch insurer once a year instead of once every two years (1996); introducing a bundled hospital payments system — Diagnosis Treatment Combinations (DTCs, a Dutch variant of DRGs) (2005); and partly deregulating price and capacity control (2005–2006).

In 2006, health care changed from a dual system of mandatory public insurance and

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Figure 1: Total health expenditure as a percentage of GDP in OECD countries, 2009



Source: Reference 2.

voluntary private insurance, to mandatory private insurance covering the whole population. Much emphasis was placed on individual responsibility for health and on a market-oriented model of health care based on competition and choice, though at the same time guaranteeing solidarity through earmarked subsidies to the poor.

The legal basis of the 2006 reform is the Health Insurance Act (HIA), which introduced universal coverage by individual mandate (required purchase). Insurers can set up their networks of contracted providers, i.e., they may selectively contract for discounted services from hospitals. The mandatory basic package is defined by law and premiums must be community-rated. A risk equalisation model is in place to avoid the practice of risk selection by insurers. Consumers may generally switch between insurers once a year, although some policies allow switching every month. Insurers compete on the price of the basic package - the content of which is regulated - and are responsible for buying health care services for a good price-quality ratio, i.e., value for money.

It is important to stress that the Dutch health care system does not apply the free market principle. There is strong legislation and regulation in place to counteract undesirable effects and to safeguard public objectives, such as accessibility, affordability and quality. Free market conditions apply only to supplementary voluntary insurance.

The shift to regulated competition had several goals: i) contain health care expenditure; ii) increase consumer choice; iii) improve efficiency and quality; iv) guarantee accessibility; and v) stimulate innovation in health. This article is a first attempt to briefly review the performance of the Netherlands' health care system on these five goals, six years after the reform.

Health care expenditure and volume

Total health system costs as a share of gross domestic product (GDP) have increased over the last half century. During the period 1950 to 2010, health spending as a proportion of GDP went from 3% to 12%. Until 2008, the Netherlands had an average position among OECD countries with respect to health expenditure. In 2009, however, a change in the Dutch definition of longterm care expenditure – which put it in line with the System of Health Accounts methodology – caused the Netherlands to jump up the ranking, making it only second to the United States in terms of health spending as a proportion of GDP (12% compared to 17%); much higher than the OECD average for that year (9.6%) (see Figure 1). But, if we were

to use the pre-2009 definition of health care spending, that year the Netherlands would still have ranked ninth instead of second. Thus, the relative position of the Netherlands did not really change, contrary to what is suggested by the OECD figures. Furthermore, it should be noted that long-term care expenditures are very well administered in the Netherlands compared to most other countries that rely much more heavily on informal care (for which costs are difficult to measure).

Part of this cost increase in the Netherlands was probably caused by the introduction in 2006 of mandatory private insurance covering 100% of the population. Moreover, the abolition in 2008 of lump-sum payments for medical specialists in hospitals, combined with the introduction of a fixed payment for DCTs, boosted hospital production. Hospital prices decreased in real terms over the period 2006–2009, however, the volume of care for certain treatments grew considerably. So it appears that the 2006 health care reform and payment regulation gave physicians and hospitals incentives to induce patient demand. Indeed, recent evidence shows that supplier-induced demand has played a role.

Consumer choice

One of the important preconditions of regulated competition is consumer choice. Clear and available information spurs consumers' mobility, which forces insurers to find a good balance between quality of care and price. The HIA prompted the launch of several websites (e.g., kiesbeter.nl; independer.nl; consumentenbond.nl) with price-quality information for different health care providers and insurers. On average, annual switching rates between insurers are between 4-6%. Currently, consumers have ample choice of providers and in fact, are not restricted by insurers' selective contracting practices. However, in the years to come, selective contracting between payers and hospitals is expected to increase if a proposed amendment of the HIA, put forward by the Liberal party, continues to be pushed once a new coalition government is formed following recent elections. This may result in less choice for some consumers.

Efficiency and quality

Between 2003 and 2008, hospital productivity grew yearly, on average by 2.9%. In a study by Westert et al., hospital productivity was measured by the number of admissions and financial resources spent. A point of concern was practice variation across the Netherlands. There were strong differences between hospitals in the price of care negotiated between insurers and providers. In addition, length of stay between hospitals differed considerably, although the differences have declined over the past few years.

e-health programmes on the rise

In order to spur efficiency, several initiatives were launched to substitute secondary care with primary care in order to keep costs under control. In addition, family doctors can hire nurse practitioners to deal with some physical and mental health conditions. The use of e-health programmes also has been on the rise; for example, online self-management programmes for Chronic Obstructive Pulmonary Disease (COPD) patients are available, as well as online mental health counselling; e-consultations with general practitioners; and other special apps for computers and mobile devices.

In terms of quality, health outcome indicators for the Netherlands range from about average to relatively good. Several initiatives have been set in motion to compare quality across providers, such as the Routine Outcome Measurement programme in mental health care, the Transparent Care (Zichtbare Zorg) programme, and as mentioned above, posting quality indicators on websites. Quality information is mostly available for structural and process indicators, and for patient-reported satisfaction indicators. This is an area where greater efforts could be invested in future. A good example of developing outcome indicators is the start of the Routine Outcome Measurement programme which will be used as a

benchmark between providers and will help insurers in their negotiations with mental health care organisations.

Accessibility

The Netherlands has one of the lowest levels of out-of-pocket expenditure in OECD countries, at less than 7% of total health care spending, which is comparable to France and Luxembourg, but much lower than in Greece, South Korea, Mexico and Switzerland. In terms of the number of uninsured people, there has been a decreasing trend over the years, with roughly 136,000 uninsured people in 2010 (approximately 0.8% of the population) compared to about 230,000 in 2006 (approximately 1.4%). Therefore, the 2006 reform has not had a deleterious effect on financial accessibility to health care. Essential care services are available at a short distance to almost the entire population, while waiting times for most treatments are below the agreed acceptable standard.

Innovation

Overall, the Netherlands scores well internationally with regard to investment and implementation of innovations, such as day surgery and electronic patient records. Current legislation provides additional funding for providers to conduct research and to test and implement innovations. In the years to come, much emphasis will be placed on analysing the effectiveness of these activities to ensure that the right incentives are in place and that innovation pays off for those investing in it.

Conclusion

The 2006 health care reform enhanced the transition from supply and price regulation in health care to regulated competition. This process is subject to continuous change because underlying political perspectives matter in shaping health policies. It took thirty years to introduce regulated competition with numerous committees analysing the needs of the health care system and advising governments. While typically, parties of the right support a system of negotiations between insurers and providers to regulate

price and quality, parties of the left tend to argue that competition might not offer a panacea for all unresolved issues. What is clear is that the full effects of regulated competition in health care may not become evident for some time.

However, preliminary evidence shows that over the last six years health care costs have kept growing, quality information has become readily available, hospital efficiency has improved, and consumers have had greater choice. Some key elements for improvement are ensuring that information on quality exists as a precondition to good monitoring, and establishing better payment incentives to avoid excessive volumes.

Looking forward, monitoring the health care system is an important prerequisite to better understand the effects of regulated competition in health care. A rich set of research questions and suggestions to policymakers emerge from this brief analysis. Firstly, variation in price and quality across providers must be monitored. A better understanding of the relationship between contracted prices and quality is an important step in this direction. Secondly, health care providers should be stimulated to research, innovate and measure the effectiveness of these new activities. Thirdly, consumer choice must be guaranteed for the entire population. In particular, recent signs of lock-in effects within voluntary additional insurance for specific groups, i.e., high-risk individuals, need further attention. Lastly, too often there is the misperception that better efficiency equals less total cost. However, these are two different concepts (see Smith in this issue) and policymakers should consider that higher spending may sometimes be associated with better clinical outcomes.

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PORTUGAL'S

HEALTH POLICY UNDER

A FINANCIAL RESCUE PLAN

By: Pedro Pita Barros

Summary: Under the terms of its current financial rescue plan, Portugal has launched a number of reforms in its health care sector which are a combination of cost-containment measures as well as strategies to introduce greater efficiency into the health system. The areas of intervention are wide-ranging, including the pharmaceutical market; prescription practices; fiscal credits applied to private health expenditures; health professionals and human capital; the public—private interface in health care; National Health System management; primary care; hospitals; and public health sub-systems. It will take some time to obtain a quantitative assessment of these policies' effects.

Keywords: Portugal, Memorandum of Understanding, Health Sector Measures, Health Policy Reform

Introduction

Portugal has now completed fifteen months of its financial rescue programme, following the signing of a Memorandum of Understanding (MoU) on 17 May 2011. The new government's* policies are conditioned to a considerable extent by the MoU, in particular health care policies, which make up one of the major areas in the MoU, with more than 50 measures and actions. These measures, a combination of cost-containment actions as well as strategies to introduce greater efficiency into the National Health Service (NHS) on a permanent basis, range from the very detailed to the relatively vague and

general, and a specific timetable for implementation has been set. At present, while it is relatively easy to assess formal compliance with the MoU, there is not as yet enough information to obtain a quantitative assessment of these policies' effects. This article discusses some of the main changes and their status in terms of implementation (see Table 1).

Pharmaceutical market

One of the first areas of intervention is the pharmaceutical market, which is addressed in more detail in a previous *Eurohealth* article. Briefly, the MoU sets precise targets for public expenditure on pharmaceutical products. For 2012, the

Elected on 5 June 2011 and entered office on 21 June 2011.

Table 1: Implementation status of MoU-mandated measures

Area targeted	Status
Pharmaceutical market	Implemented
User Charges	Implemented
Prescription patterns	Mostly implemented
Tax system/fiscal credits	Implemented
Public-private interface	Partially implemented, part under watch
NHS management	Mostly implemented
Primary care	Delayed
Public "health subsystems"	To have a plan by the end of Summer 2012
Human capital/health professionals	Changed to "ongoing"

Source: Author.

target will be met, as the government and an association of pharmaceutical companies signed an agreement that ensures this objective (if expenditure exceeds the target, the pharmaceutical industry will pay back the excess amount). Several regulations have been adjusted, including a new system for the wholesale distribution of pharmaceutical products and pharmacy fees, as well as the introduction of international reference pricing rules. This is an area where compliance with the MoU has occurred.

User charges

A second area that received early attention was user charges. The MoU called for an increase in the levels of user charges, although stipulating that such charges in primary care should be lower than those in hospital care. It also sought a revision of user charge exemptions. Both were implemented within the timeframe set in the MoU.

Although user charges roughly doubled in value, exemptions are now granted to a potentially larger proportion of the population (government estimates put the proportion of the population with an exemption at 70%). Currently, there is no detailed account of the impact of these increased user charges on the usage of health services. The scarce evidence so far points toward a reduction in the use of services, namely emergency room episodes but also primary care visits.

Prescription patterns

A third area of policy measures focuses on prescription patterns. There are two broad lines of action, and the MoU commitments have been translated into policy measures that were already in place. The first is the use of a monitoring system that feeds back to prescribing doctors information on individual decisions (volume and value). The second line of action is the definition of recommended prescription patterns. This includes establishing clinical guidelines, introducing prescription by international non-proprietary name (INN), and creating a general environment that is more conducive to the prescription of generic pharmaceutical products.

Prescription guidelines are being produced as a result of collaboration between the Directorate General of Health and the Portuguese Medical Association. The publication of guidelines gained momentum by the end of 2011 and as they are being defined by technical teams, they have not been publicly debated. Prescription by INN, on the other hand, has raised objections, mainly from the Portuguese Medical Association. A new law was enacted in March 2012 stipulating that regular prescriptions have to be written with the INN. However, deviations to this rule are being permitted. Firstly, while prescription by INN is mandatory, physicians also may indicate a preferred brand-name product. In such cases patients may choose either to adhere to the branded product or to buy a substitute. Secondly, doctors indicating a brand-name medicine may provide a technical justification for

dispensing only that branded product, in which case patients cannot choose substitution. In general, at the pharmacy, the patient should be informed about existing (perfect) substitutes, and the pharmacy needs to carry three out of the five lowest priced items in the market. A 'perfect substitute' refers to the same product, same dosage, and the same presentation.

Tax system

By international standards the Portuguese tax system has been relatively generous to private health expenditures. It allows a fiscal credit of 30% of the value of documented private health care expenditures, which essentially amounts to a tax rebate for out-of-pocket payments, including co-payments and user charges paid for services provided by the NHS. The equity aspects of this feature of the tax system have been debated for years, as the fiscal credit is regressive. Despite progressive tax rates, people not paying taxes due to low income do not benefit from the fiscal credit. There are also efficiency issues to be considered. The absence of any fiscal credit may lead to an increase in the informal provision of care, with no invoice being produced and therefore no income or corporate tax being paid by the provider.

The MoU contained a provision to reduce by two thirds the fiscal credit applied to private health expenditures. Subsequently, the government budget for 2012 reduced the fiscal credit from 30% to 10% of total private expenditures. In addition, in the two upper income brackets, no fiscal benefits are allowed. However, this last element raises the concern of possible tax evasion, as the absence of any formal invoices to patients has the potential to save 23% VAT and income tax payable by providers. Whether this risk materialises or not can only be assessed in 2013, after the income tax statements for the fiscal year 2012 are turned in. In this policy area, the MoU provision was translated into current tax law and by removing fiscal benefits from the higher income brackets the legislation actually goes further than that specified in the MoU.

Health professionals and human capital

A fifth area included in the MoU focuses on health professions – their distribution, training and retirement – with an emphasis on doctors and nurses. A long-standing debate in the Portuguese health sector is the scarcity versus distribution of health professionals. In particular, claims of doctor shortages contrast with a physician density that is in line with most European countries. Summarising what has been emerging as a consensus, there are areas of scarcity of physicians, while their overall numbers do not show such a pronounced scarcity. The term "areas" actually covers two different dimensions.

The first is, naturally, geography. There are locations in Portugal where we find a shortage of doctors while in others, namely the main metropolitan regions, there is probably a surplus. The other dimension is medical speciality. Some medical specialities do need to have more professionals, while others have an excess supply. The clearest case of an insufficient number of doctors is in general practice where the low number of newly trained doctors contrasts with the relatively large cohort of retiring doctors. Over recent years, policies have attempted to change these dynamics by opening up more general practice training positions.

The MoU provisions related to the distribution of health professionals set the goal of achieving a more balanced geographic distribution, a more flexible work regime, and a reduction in overtime payments. Initially, a target date to outline a human resources plan for the health sector was set (end of 2011) but subsequent revisions of the MoU moved it to "ongoing" status. At present, it is not clear what mechanisms and instruments will be used; however, opening new positions, both training and employment, seems to be the main instrument selected by the government.

Moreover, managerial expertise, as part of human capital in the (public) health sector, was not forgotten. In this area,

† This approach was revealed by the Minister of Health in a parliamentary hearing of the Health Committee on 25 July 2012.

more transparent and experience-based nominations has been urged. Compliance with this requirement can be seen in the general principle that nominations for public sector managerial positions will have to go through a screening commission that began operating in April 2012. However, only a detailed assessment of nominations can reveal whether or not a change in hiring practices has actually occurred.

the NHS imposed price reductions

So unlike other areas of intervention, the initial measures for human resources laid down in the MoU have not been completely adopted. All the same, current versions of the MoU do accept a different path to achieve a more efficient allocation of human resources in the public health sector.

Public-private interface

The Portuguese NHS is based on public provision of care. That is, the government directly runs an important number of health care facilities. Still, the NHS buys services from the private sector in several areas, including imaging services and laboratory tests. Previous governments have also resorted to private entities to build new hospitals under publicprivate partnerships (PPP). This set of relationships constitutes what we term the "public-private interface". The MoU addresses this interface by asking the government to increase competition among private providers to reduce NHS expenditures, and to have a tighter control over PPP contracts.

On the latter issue, the PPP contracts in the Portuguese health sector are a mix of build-and-operate infrastructure facilities and full-range operation (including the management of clinical activities in addition to build-and-operate facilities). The main challenges will come from technology changes and the likely contract renegotiations to accommodate such new technologies.

As to the former issue, two complementary approaches have been followed. On the one hand, the NHS imposed price reductions on some services provided by private entities (mainly imaging, laboratory tests and similar). On the other hand, it established a plan to develop procurement mechanisms to induce competition among providers of health care. A government body, the Ministry of Health Shared Services, is in charge of carrying out centralised procurement. Most of what is required in the MoU is in place, but some points are under watch and have not yet been completed.

NHS management

A broad area targeted in the MoU is the management of the NHS. Actions include general instruments like the production of a health sector strategic plan, the creation of performance assessments for hospitals, and the reorganisation of the hospital network. However, operational aspects are the more crucial points of focus. Over the years, public health care providers have accumulated a considerable volume of delayed payments and hidden debts to suppliers. These arrears amounted to €3.1 billion by the end of 2011, equal to approximately 40% of the total NHS budget for 2012 (€7.5 billion). Thus, the MoU established a twin set of goals: to recover arrears and to implement procedures to avoid the reappearance of the problem.

On the first objective, paying arrears, the government is using funds resulting from a transfer, at the end of 2011, of the banking system's pension fund assets to the public social security system[‡] as well as negotiating discounts on existing debts. The timetable set for paying the pharmaceutical industry, the largest NHS creditor, involves paying 60% of the value due by the end of 2012; payment

[‡] The Portuguese banking system operated an additional pension system on top of the general social security system, which had assets to fund future payments. These assets have now been transferred to the government, and the general social security system will pay the corresponding pensions in the future. Thus, the government receives a new injection of funds, against a future stream of payments.

of the remainder is left to subsequent years and negotiated discounts. Many of the NHS management-related measures in the MoU are vague and rely on future detailed plans. There have been several delays in producing the necessary strategic documents and detailed plans of action have not been released publicly. So in this area, to a considerable extent, the MoU measures have been postponed or moved to "ongoing" status.

Hospitals

Hospitals are required to generate cost savings of €200 million over two years (2011 and 2012) on top of the cost impact of salary freezes and reductions. Nonetheless, how to achieve the savings is left to the Ministry of Health to manage with hospitals. It may come from a mix of efficiency gains reducing the waste of resources and a better exploration of economies of scale through the reorganisation of services. As such, measures aimed at hospitals' cost savings could also be included under the broad heading of NHS management measures.

Primary care

While the hospital sector was a cause of general concern in the MoU, no detailed measures were proposed, other than those related to the arrears issue. In contrast, primary care receives less explicit attention, but more concrete measures are spelled out. There is the obvious recommendation to give primary care and general practitioners a stronger role, with a clear stipulation to create more family health units. These consist of smaller multidisciplinary teams, enjoying greater organisational flexibility. Their payment system involves a pay-per-performance component, although most remuneration comes from a fixed wage component with an associated list of patients. The creation of family health units started in 2005 but roll-out has become slower in more recent years for two reasons: one is the lack of funds for the pay-for-performance component and the other is the voluntary nature of establishing teams. The latter requires further political commitment, after early joiners, to bring in more teams. Thus, there is a clear delay in complying with the requirements of the MoU in this area.

Public "health sub-systems"

Despite the existence of an NHS, created in 1979, civil servants benefit from coverage from what are called "health subsystems". Even with the NHS, different sectors of activity within the public sector and local and central public administration have continued with their own health insurance coverage systems. These are based on a small wage-related contribution by beneficiaries, with the major part of expenditures being covered through transfers from the government budget (as an employer contribution). This double coverage system for civil servants should now be revised.

The MoU has set a transition period to self-sustainability of these health subsystems, particularly the one covering most civil servants (the ADSE), to be achieved by 2016. 2012 should see a 30% reduction in government payments. The health insurance and health care provided to armed forces personnel also needs to be resolved but due to the specific nature of their activities a different solution is to be defined. The evolution of the public health sub-systems is a matter that is still under discussion. A plan is to be set by the end of Summer 2012 which will form part of the fifth review of the MoU by the European Commission, European Central Bank and International Monetary Fund teams.

To better understand the possible ways forward, it is useful to briefly describe how the public health sub-systems operate. Joining was mandatory for civil servants until recently, with new people recruited having to decide whether or not to join. The health sub-system for civil servants does not have direct provision of health care. Rather, it relies on contracting with public and private providers, with a network of providers throughout the country.

The adjustment in the civil servants' health sub-system may involve changes in coverage, increased contribution rates for beneficiaries, both, or even some other settlement. In theory, we can envisage

solutions ranging from the extreme of closing down the health sub-system altogether, transition to some sort of (double coverage) private health insurance with expenditures fully funded by beneficiaries' contributions, or even to an opting-out agreement for the health subsystem. In this latter case, it would receive an NHS capitation for each beneficiary to assume full financial responsibility for health insurance coverage of its beneficiaries. Any deficit would be funded by direct contributions by the beneficiaries or revision of coverage. In the former option of closing down the health subsystem, civil servants would, of course, keep the first layer of coverage, the NHS.

The decisions on this matter should incorporate available evidence on the role of health sub-systems. According to their own rules, they provide speedier access to providers, namely specialists, as no referral from a general practitioner is required. Despite this, there is no evidence that beneficiaries of public health sub-systems have, on average, better health, once other factors like education, income, etc., are accounted for. On the other hand, the role of the main public health sub-system, ADSE, as a purchaser of health services for its beneficiaries, has improved in terms of efficiency (prices and availability) over time. This experience should not be lost, whatever the final solution. At this point in time, it is not clear what path will be chosen. The next review of the MoU should clarify this issue and until then, we can consider it under watch.

Final remarks

Overall, the MoU has established a large set of measures, with most having to be implemented up front. The measures containing enough detail and which essentially required the publication of laws and regulations were implemented quickly. In contrast, the production of strategic documents has progressed at a slower pace than expected. In particular, most of the long-term measures associated with the management of the NHS (broadly interpreted) have been postponed. Notably, private suppliers to the NHS (creditors such as pharmaceutical companies, pharmacies, imaging providers

and laboratories) have been easier to deal with than issues related to NHS human resources.

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HEALTH SYSTEMS

EFFICIENCY AND SUSTAINABILITY:

A EUROPEAN PERSPECTIVE

By: Federico Paoli

Summary: While health systems are clearly under the responsibility of Member States, the European Union also operates to help them achieve efficiency and sustainability. The EU endeavours to do this in several ways and via different processes. For example, the reform of health systems may be part of country-specific economic assistance programmes. Furthermore, more recently health systems are assuming a growing importance within the strategies of the EU, including the framework of *Europe 2020* and in particular in the activities of the European Semester. Finally, the EU recently started a reflection process on the sustainability of health systems, which explores effective ways of investing in health.

Keywords: European Union, Health Systems, Efficiency, Sustainability

Institutional and legal framework

It is often stated that the European Union (EU) does not have a mandate to deal with health systems. In fact, this is true, but not entirely. Article 168 of the Lisbon Treaty affirms that the management of health services and medical care, and the allocation of the resources assigned to them, are responsibilities of Member States (MS). The same article also states that the Commission may, in close contact with the MS, take any useful initiative to promote coordination on policies and programmes; such coordination is particularly suggested for initiatives aimed

at the establishment of guidelines and indicators, the exchange of best practice and periodic monitoring and evaluation.

In 2007, on the basis of this mandate to complement national policies on health, the EU adopted its first Health Strategy, aimed at delivering concrete results in improving health. The Health Strategy covers the period from 2007 to 2013, and focuses on three strategic objectives, one of which is: "Supporting dynamic health systems and new technologies". Among the actions related to this objective, the Commission was explicitly asked to develop a Community framework for safe, high quality and efficient health services.

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Note: This article expresses the personal views of the author, and does not represent the official position of the European Commission.

Background data and analysis

The Commission, through Eurostat and in close collaboration with the World Health Organization (WHO) and the Organisation of Economic Co-operation and Development (OECD), collects data to monitor health systems' performance. These data are presented both in the Eurostat database and more specifically in the Heidi data tool whose core set is constituted by the European Community Health Indicators (ECHI).

In 2010, the publication of two major reports helped to build more systematic knowledge on health systems in the EU. The first is the *Health at a glance, Europe 2010* report, based on collaboration between the OECD and the Commission. It presents statistics and analysis on health and health systems across European countries, adopting a model similar to the original Health at a glance reports on OECD countries, but tailored to the peculiarities of the EU.

In the same year the Commission, together with the Economic Policy Committee, also published a joint report on health systems. This report explicitly aims to understand the drivers of health expenditure and therefore expenditure differences across MS. It does so by also looking at the organisational features of health systems, which are presented in detail in a section dedicated to country-specific analysis. The final goal of the report is to identify good practices that may lead to greater cost-effectiveness of health systems, independently of the possible future burden of demographic developments.

The joint report highlights the need to ensure efficiency and effectiveness of health care, especially in these times of economic crisis, which places additional burdens on MS and to their capacity to finance their health systems in the short to medium term. In its conclusions the report identifies the main challenges ahead, and presents a list of ten measures to contain costs and make the system more efficient. These measures, analysed in detail in the report, cover a wide spectrum of actions, from ensuring a sustainable financing basis for the system (taking into account equity principles), to balancing

the skill mix of health professionals, and improving life styles, health promotion and disease prevention.

Country assistance programmes

In the last few years the EU's intervention in the internal affairs of some MS, including in their health systems, has been at the core of many debates. The most famous cases have probably been those of Greece and Portugal, although they are not the only ones.

a Community framework for safe, high quality and efficient health services

This is clearly not a business-as-usual situation. Here the EU was called upon, either individually or with other international institutions, to intervene with programmes of economic assistance for countries which experienced severe financial problems. Other examples, apart from Portugal and Greece, are Ireland and Romania (and in the past also Latvia and Hungary). In order to receive assistance, the country involved will usually commit to implementing adjustment programmes in order to achieve a healthy macroeconomic situation. These adjustment programmes are normally very comprehensive and may imply structural reforms in the health system, as in Greece and Portugal. In both cases the countries signed a Memorandum of Understanding with the EU (and with the International Monetary Fund) that listed several measures to be taken, including in the health care sector (see Pita Barros article in this issue).

As we will see below, although intended as emergency interventions, these reforms have a strong link with the activities of *Europe 2020*.

Europe 2020

In March 2010, the Commission adopted Europe 2020, a strategy for smart, sustainable and inclusive growth. Europe 2020 presents five targets for the EU in 2020; and as the international health community immediately noticed, none of these directly refers to health. However, in spite of this, health and health systems play an important role in the implementation of Europe 2020, for two reasons.

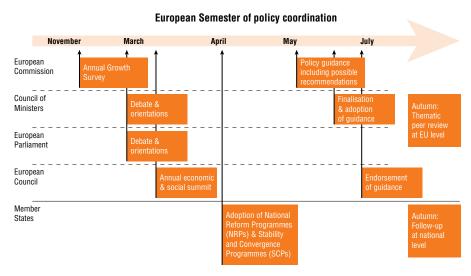
The first lies in the role of one of the main tools to implement *Europe 2020*: the Flagship initiatives, which were presented as new engines to boost jobs and growth. The first pilot development of a Flagship initiative has been the launch of the European Innovation Partnership on Active and Healthy Ageing, whose final goal is to add, by 2020, two healthy life years to the average healthy life span of European citizens. Supporting the long-term sustainability and efficiency of health and social care systems is one of the three founding pillars of the Partnership.

However, health contributes even more directly to *Europe 2020* targets. To better understand the second reason we will take a closer look at how this strategy is implemented in practical terms. Here is where the European Semester enters in the game. In fact, all MS have committed to achieving *Europe 2020* targets and have consequently translated them into national targets and policies. Accordingly, in order to harmonise MS efforts, the European Commission has set up a yearly cycle of economic policy coordination: the European Semester.

The structure of the Semester is schematically presented in Figure 1*. Each year the European Commission publishes an Annual Growth Survey, in which the overall targets of *Europe 2020* are translated into operational priorities for the year to come. Subsequently, each MS submits to the Commission its National Reform Programme (NRP), in which the priorities of the Annual Growth Survey are integrated into national policies and reform plans. Eventually, the European Council,

^{*} For a more detailed and rigorous description of the European Semester activities, please consult: http://ec.europa.eu/europe2020/making-it-happen/index_en.htm.

Figure 1: the European Semester



Source: Author adaptation of European Commission diagram.

on the basis of a Commission's analysis of NRPs, adopts a full set of Country-Specific Recommendations (in fact the set is composed of 28 recommendations, one of which is addressed to the Euro area as a whole). In the second half of the year, MS implement their reforms, while the Commission monitors their developments; the findings of this monitoring exercise will feed the next Annual Growth Survey, which is the start of a new European Semester's cycle.

health systems play an important role in Europe 2020

The first European Semester took place in 2011. Interestingly, this first Annual Growth Survey did not mention health at all. However, several countries presented their plans to carry out reforms of their health systems, mainly in order to improve efficiency and ensure long-term fiscal sustainability. Eventually, the Council recommended that four countries should intervene specifically in their health care and long-term care systems, namely, Austria, Cyprus, Germany and the Netherlands (the latter only with regard

to long-term care). In all cases, the recommendations were aimed at ensuring fiscal sustainability in the long run.

In the second Semester exercise the picture is quite different. The Annual Growth Survey 2012 refers to health on three different occasions. Firstly, the section dealing with growth-friendly fiscal consolidation highlights the need to improve the "cost-efficiency and sustainability" of health systems through reforms. Secondly, the health sector is recognised as a contributor to a real internal market for services. And finally, the survey proposes to tackle unemployment by developing initiatives in the health sector, which is described as one of the sectors with the highest employment potential.

In line with this new trend, the number of MS that were recommended to intervene in their health systems increased, albeit slightly, to six (with the addition of Belgium and Bulgaria). However, it should be pointed out that for countries that are engaged in an economic assistance programme, such as Greece, Portugal, Ireland and Romania, the sole recommendation from the Council is to implement the programme itself. And the programmes, as briefly stated above, often mention specific measures to improve the efficiency and sustainability of these countries' health systems. On the other

hand, what is probably more interesting is that in its recommendations to all of the Euro area, the Council acknowledges that reforms of long-term entitlements – "notably health" – are urgently needed, to underpin the long-term sustainability of public finances. In fact, in making such a statement the Council reaffirms the concerns already expressed in its recently adopted Conclusions on the sustainability of public finances, which are based on the projections of its 2012 report on population ageing.

Reflection process

Besides the European Semester, another important step is enriching the European debate on health systems: in June 2011, the Council invited MS and the Commission to initiate a reflection process aimed at identifying effective ways of investing in health, so as to pursue modern, responsive and sustainable health systems. The reflection process is intended to bring together MS, with the support of the Commission, with the goal to prepare their health systems to meet future challenges due to ageing populations, changing population needs, increasing patient expectations, rapid diffusion of technology and MS fiscal constraints.

The reflection process is meant to be an occasion for sharing experiences, best practices and expertise, with the final objective of proposing concrete solutions and models that policy makers can take into consideration. In order to carry out this reflection process, MS and the Commission established five working groups, each one with a different focus, namely:

- 1) Enhancing the adequate representation of health in the framework of the *Europe 2020* strategy and in the process of the European Semester (the Commission is coordinating this group);
- 2) Defining success factors for the effective use of Structural Funds for health investments (Hungary);
- 3) Cost-effective use of medicines (the Netherlands);
- 4) Integrated care models and better hospital management (Poland);

 Measuring and monitoring the effectiveness of health investments (Sweden).

The links with *Europe 2020* are quite evident; in fact they are extremely explicit in the scope of the first group, but the outcomes of any of them are expected to bring valuable contributions to the European agenda for growth, and to the development of efficient, effective and sustainable health systems in Europe. The first results, in terms of concrete proposals to be delivered by the working groups, are expected by Autumn 2013.

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Observatory publication

Migration and Health in the European Union

Edited by: Bernd Rechel, Philipa Mladovsky, Walter Devillé, Barbara Rijks, Roumyana Petrova-Benedict and Martin McKee

European Observatory on Health Systems and Policies; Netherlands Institute for Health Services Research; International Organization for Migration; London School of Hygiene & Tropical Medicine, UK

Maidenhead: Open University Press, 2011

Number of pages: 216

eBook ISBN: 9780335245680; Paperback £29.99

ISBN: 9780335245673



Written by a collaboration of authors from three key international organisations, as well as leading researchers from across Europe, the book thoroughly explores the different aspects of migration and health in the European Union and how they can be addressed by health systems.

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- · Contributions from experts from across Europe
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"This book provides an ample orientation to the field in the European context. Among other important raised issues, it underlines an all too often neglected fact; health is a human right.

By involving broad issues and problem areas from a variety of perspectives, the volume illustrates that migration and health is a field that cannot be allocated to a single discipline."

> Carin Björngren Cuadra, Senior Lecturer, Malmö University, Sweden.



18 Eurohealth INTERNATIONAL

SIMULATION ON THE EU CROSS-BORDER CARE DIRECTIVE

By: Rita Baeten and Elisabeth Jelfs

Summary: The adoption in 2011 of the EU Directive on the application of Patients' Rights in Cross-Border Health Care raises important questions about how the legislation will be implemented in practice. In order to build a stronger understanding of the likely future impact of the Directive, different stakeholder groups from six countries participated in a simulation, discussing how they would respond in reality to key issues raised by the Directive. If the simulation is right, the Directive will bring legal certainty on important issues. However, the potential burden for patients is high, as they will bear the responsibility for many of the elements involved in accessing planned treatment across borders.

Keywords: Cross-Border Health Care, EU Law, Patient Mobility, Simulation, Patients' Rights

Introduction

In March 2011, the Directive on the application of Patients' Rights in Crossborder Health Care (hereafter the Directive) was signed into EU law. The Directive marked the provisional end of a lengthy policy process responding to rulings in which the Court of Justice of the European Union (CJEU) made clear that health care, when it is provided for remuneration, is an economic activity to which the Treaty provisions on the freedom to provide services are applicable.* The Court ruled that making the reimbursement for care received in another Member State (MS) subject to

the requirement that patients must first receive authorisation from their domestic social protection system is an obstacle to freedom of movement, which can be justified for hospital care but not for ambulatory care. Up until then, planned treatment abroad could only be reimbursed based on Regulation 883/2004 (formerly Regulation 1408/71) on the coordination of social security schemes, provided that patients first received prior authorisation from the financing institution to which they are affiliated.

In a context of legal uncertainty on the responsibilities of Member States in response to these rulings, the Directive aims to codify the case law by clarifying the rights of patients to seek health care in another EU MS and to ensure the proper conditions for receiving that care. It is structured around three main areas. First, it provides a specific framework for reimbursement of care

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Acknowledgments:

The simulation was organised by the EHMA, AIM and OSE, with financial support from the Belgian National Institute of Health and Disability Insurance (NIHDI). The authors would like to thank Christian Horemans, Chris Segaert, Magdalena Machalska and Henri Lewalle for their support in the design and organisation of the simulation.

^{*} The main cases are: CJEU, Case C-120/95 Decker v.

Caisse de Maladie des Employés Privés [1998] ECR I-1831;

CJEU, Case C-158/96 Kohll v. Union des Caisses de Maladie

[1998] ECR I-1931; CJEU, Case C-157/99 Geraets-Smits and

Peerbooms [2001] ECR I-5473; CJEU, Case C-385/99 Müller
Fauré and Van Riet [2003] ECR I-4509; CJEU, Case C-372/04

Watts [2006] ECR I-4325; CJEU, Case C-444/05 Stamatelaki

[2007] ECR I-3185

received abroad; secondly, it addresses the question as to which MS, in the case of cross-border care, should be responsible for ensuring quality and safety standards, information, redress and liability as well as privacy protection; and thirdly, it aims to encourage European cooperation on health care in specific areas. Countries have until October 2013 to transpose the Directive into national legislation.

Although the ratification of the Directive marked the end of the formal policy process at EU level, important questions on the Directive's implementation remain. In order to build a stronger understanding of the likely future impact and forecast potential issues as the Directive is put into practice, 37 stakeholders from six countries (Belgium, France, Germany, The Netherlands, Luxembourg and Spain) convened in November 2011 for a simulation on the Directive. The stakeholders were divided into five groups: public authorities; health care payers (mainly insurers) (two groups); health care providers; and patients (organisations).

Three cases were drafted specifically for the event, addressing some of the difficult questions in the implementation of the Directive, such as rare diseases, patient information and the relationship between the Directive and Regulation 883/04. Each case had a number of questions specific to each stakeholder group. The groups discussed how they would respond in reality to the described cases.

Legal certainty

In the simulation there was a striking consensus in some areas, which suggests that the Directive will bring substantial legal certainty. Perhaps surprisingly this includes areas where tensions in implementation may have been predicted, such as on the articulation between the Directive and Regulation 883/04. For other issues there were divergent views, in particular between stakeholder groups. However, the simulation suggests that, as long as the number of cross border patients remains low, this potential clash between stakeholders will be solved pragmatically on a case-by-case basis.

Conditions for reimbursement

For instance, stakeholders disagreed on the extent to which care abroad should conform to domestic conditions for reimbursement. Payers and public authorities made clear that for the care abroad to be reimbursed, it should comply with the conditions and criteria of eligibility as defined by the MS where the patient is socially insured for care provided domestically. This is in conformity with the Directive (Art. 7,7°). However, health care providers were unanimous in stating that they would not adapt treatment procedures to the requirements of the foreign payer of the patient. As a result, patients risk not being reimbursed for the provided care.

Directive will bring substantial legal certainty

Controlling inflows and outflows

One of the most striking findings of the simulation related to prior authorisation. This issue was heavily debated as the Directive made its way through the Council of the EU, as most MSs wished to retain control over outflows of patients. The Directive states the general principle that countries are not permitted to make the reimbursement of costs of cross-border health care subject to prior authorisation (Art. 7), whilst defining some important exceptions, in particular for hospital inpatient care (Art. 8). The simulation suggests that in practice patients will request prior authorisation, including for ambulatory care, "to be on the safe side". Some insurers also argued that they advised patients to talk with them prior to receiving care abroad and suggested using prior authorisation as a tool to specify reimbursement conditions (e.g., requirements with regard to the treatment and the invoice).

Upon the insistence of MS, the Directive provides that they can, in exceptional cases, adopt measures to ensure sufficient

and permanent access to health care within their territory when inflows of patients may create a demand exceeding the capacities for a given treatment (Art. 4.3°). It was therefore rather surprising that public authorities in the simulation stated that they did not have mechanisms to track the number of foreign patients using health care in their country, let alone a system for regulating that flow. Health authorities mentioned that health care providers were responsible for ensuring that domestic patients were not disadvantaged by foreign patients. However, health care providers suggested that the solution would be to increase capacity or to reallocate patients to other hospitals when flows exceed their capacity. Given this, we can perhaps assume that this provision of the Directive will not be applied in practice.

Tariffs and invoicing

The simulation also raised questions on which domestic tariffs were being applied – i.e., whether the agreed tariffs between health insurers and providers were being used or those for private patients, which are applied by providers who do not adhere to the (collectively) agreed tariffs. According to the Directive, the MS of treatment has to ensure that the health care providers in its territory apply the same scale of fees for health care for patients from other MSs and for domestic patients (Art. 4,4°). Health care providers suggested that private tariffs would most often be used for foreign patients travelling under the Directive. Whilst most authorities and insurers would reimburse these private tariffs up to the level of the applicable reimbursement tariff in the MS of affiliation, some health insurers would not pay for these supplements.

Important issues were raised on invoicing, for example, and in particular on how insurers can know exactly what care has been provided. The Directive states that the MS of treatment has to ensure that health care providers supply clear invoices (Art. 4,2°,b) and that MSs shall provide mutual assistance to clarify the content of invoices (Art. 10,1°). Interestingly, statutory providers argued that they would not make major efforts to adapt invoices, but for-profit providers were willing to adapt invoices to the requirements of

insurers from abroad and would bill the patient for this. However, although the public authorities were clear that they would assist patients in securing accurate information and that it is the obligation of the health insurers to help patients if they cannot obtain all the necessary information themselves, both public authorities and payers argued strongly that the final responsibility for accurate invoices lies with the patient, who will be asked to provide proof of the care that has been provided and the content of the invoice.

Information

The question of information in a crossborder setting was a consistent theme throughout the simulation.

Whereas the patients in the simulation put doctors (treating and referring) at the top of the list of sources of information on the treatment options in cross-border care, health care providers saw national contact points as having the duty of informing patients from abroad on alternative options. The Directive requires the MS of treatment to ensure that health care providers supply relevant information to help individual patients to make an informed choice, including on treatment options (Art. 4,2°,b). It is arguable, however, whether national authorities will be able to make health providers comply with this duty and how they would be able to monitor whether providers assume this responsibility.

According to the Directive, it is the responsibility of the MS of affiliation to ensure that patients receive information on their rights and entitlements to crossborder care (Art. 5,b). Patients stressed that this information should be impartial. They recognised health insurers as the "most knowledgeable" party on cross-border health care, and the insurers themselves assumed throughout the discussions that they would be a crucial port of call for patients looking for neutral information. However, there was concern among patients that the information provided by health insurers, in particular when they have financial incentives, is not neutral. Patients also highlighted that some choices on administrative options for cross-border care were too complex for them and should be decided by the competent authorities.

language is one of the major barriers to cross-border care

Language was a theme running through the simulation, whether of the patient file, invoice, or information on quality and safety. It was highlighted by patients as one of the major barriers to cross-border care and health care providers argued that without translation the medical file would have no use. Strikingly, the Directive does not address this issue at all. The simulation also raised major questions of accountability for the correctness of translated documents, in particular with regard to medical records. As to the costs for necessary translations, stakeholders argued consistently that the patient should bear these.

Domestic impact

Finally, the simulation highlighted the potential for the Directive to become a lever to change domestic policy and practice beyond the strict legal scope of the Directive. Firstly, some participants, in particular health insurers, argued that it is difficult to see how in practice a MS could refuse to reimburse treatment provided in a centre of expertise integrated in a European Reference Network, once they will have an EU "label" established by the Directive. Secondly, health care providers argued that the Directive might provide an opportunity to clarify invoices and cost calculation mechanisms also at national level. Thirdly, the provisions on information on quality and prices might also benefit domestic patients and provoke a culture shift on information. Finally, as suggested by providers, the

Directive might also push initiatives for accreditation of health care services, such as hospitals.

Conclusions

The simulation paints a picture of the Directive that differs from the discussions that dominated in the run up to its adoption into European law. It is expected that the Directive will bring legal certainty on important issues and that a number of the most heavily debated questions, such as the interaction between the Directive and Regulation 883/04, will not in practice turn out to be significant problems.

However, the most striking set of conclusions relates to the potential burden for patients. Patients who go abroad for treatment under the Directive with public cover, in many ways are treated as if they are not part of the social system. National contact points and other institutions seem unable to bridge this gap. If the simulation is right, patients will bear the responsibility for many of the elements involved in accessing planned treatment across borders. This includes finding information on potential treatments, the burden of proof in demonstrating to insurers that the treatment has been carried out and the responsibility to submit the correct documentation.

Given the size of the burden for patients, it is likely that the Directive will be used only when there is no other option to receive treatment, or by patients who do not understand the risks they take. The Directive will bring much-needed legal clarity, but the jury is still out on whether it will really be a Patients' Rights Directive.

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Eurohealth INTERNATIONAL 21

CONSOLIDATING NATIONAL AUTHORITY IN **NORDIC HEALTH**

By: Richard B. Saltman, Karsten Vrangbaek, Juhani Lehto and Ulrika Winblad

SYSTEMS

Summary: Although formally decentralised in structure, four Nordic health systems are currently shifting policy and finance related decision-making upward and, in many cases, directly to the national level of government. This shift occurred initially in Norway and Denmark, and it now appears that a similar if somewhat slower process is underway in Sweden and Finland. This emerging consolidation of national decision-making authority reflects heightened concerns about quality, safety, and efficiency issues. While deeply rooted in ongoing dilemmas within Nordic systems, this shift upward in governance carries important implications for other decentralised health systems elsewhere in Europe and beyond.

Keywords: Nordic Health Systems, Health Care Reform, Recentralisation in Health Systems, Decentralisation in Health Systems

Introduction

Decentralisation has long been seen as an attractive health sector strategy in Europe. Whether in the tax-funded systems of Northern and Southern Europe, or in social health insurance countries such as Germany and the Netherlands since the inception of their subscriber-based sickness fund systems, the notion that locally based decision-making would be both more effective in its policies and more efficient in its day-to-day management is ingrained into national political thinking.

Proponents of decentralised health care systems have turned in particular to the Nordic countries for support of their key arguments. These have included the superiority of local political control over most policy and administrative decisions, as well as the ability of these

locally elected representatives to set their own tax rate in order to finance those decisions. In the Nordic region, this decentralised model has been viewed as an important mechanism to ensure broad popular participation, responsiveness to patient and citizen needs, and efficient care production, all while still preserving equity among the different groups in the citizenry. Moreover, these health care systems built on decentralised models have wide acceptance among their citizenry, regularly garnering high levels of support in national opinion surveys.

This article focuses on four of the five Nordic Countries – Norway, Denmark, Sweden and Finland. It does not discuss the situation in Iceland. It is notable to find that all four of these Nordic countries now appear to be in the process of changing

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the balance of decision-making capacity at different levels (local, regional, national) in favour of the higher levels in the health care arena. This shift occurred initially in Norway and Denmark, and it now appears that a similar, if somewhat slower, process is underway in Sweden and Finland as well. While this shift is deeply rooted in ongoing dilemmas within Nordic health systems, the emergence of this new pattern of consolidating national authority carries important implications for other decentralised health systems elsewhere in Europe and beyond.

Earlier structural changes in Nordic health systems

During the previous decade, Norway (in 2002) and Denmark (in 2006–07) radically restructured their health care systems, in both cases abolishing the prior elected county council system of local control and replacing, respectively, nineteen and fourteen counties with four (Norway) and five (Denmark) new regional governments. In both countries, these regional governments could no longer raise taxes, but were directly financed by the central government, eliminating a key lever of power and credibility for the regional administrations, and making these new actors directly dependent on national government decisions for their funding.

Interestingly, both Denmark and Norway at the same time strengthened the role of the municipal authorities in delivering long-term care, prevention and rehabilitation services. This is backed by economic incentives in the form of introducing municipal copayments upon hospitalisation of their citizens. The idea has been to encourage municipalities to develop services and strengthen their efforts to prevent unnecessary hospitalisation.

The simultaneous strengthening of the state and the municipal authorities within health care has changed the balance of power within the Danish and Norwegian health systems. Regions are still important for making operational decisions and for developing strategic plans, but now within a more constrained environment. While directly elected politicians

remain in power in the Danish regions, the Norwegian regions are now run by regional councils with members appointed from Oslo (a combination of local level politicians and bureaucrats or business people), largely eliminating the democratic participation and legitimacy that had previously accompanied having these local councils directly elected.

A shifting pattern

These Nordic differences in the early 2000s should not be overemphasised, however. During the initial period when these new centralising reforms were being introduced in Norway and Denmark, there seemed little interest in making similar changes in either Sweden or Finland. As a result, there appeared to be a type of structural split in the Nordic region, with some countries moving toward a strengthened national role that reduced the power and authority of the traditionally decentralised local actors, while other governments continued with the traditional decentralised structures that have long since been in place.

While the formal administrative structures gave certain powers to different levels of government, power over many essential elements of health care governance has been, and continues to be, centralised and uniform in all four countries examined. This includes macro-economic policy regulations that set tight frameworks for local/regional government taxation; bargaining and contracts for health care employee wages; setting the rules for inhabitants' entitlements for health services; as well as preparing and adopting clinical guidelines and a number of other standards.

What appears to be changing now is that Finland and Sweden, although somewhat indirectly, are also beginning to restructure their local and regional governments in a way that may be expected to lead to a consolidation of more health sector authority in national political hands. For instance, the Swedish government recently introduced several new laws that increase patients' rights, implying a weakening of regional self-governance. In both countries, it appears that the national decisions behind this

strategic shift are driven not by immediate economic constraints generated by the post-2008 European economic and financial crisis, but rather by long-term concerns about quality of care and equal access to health care services regardless of where one lives in the county. There is also concern about the growing need to re-structure health services delivery in the face of new technologies and rapid population ageing, with an accompanying wish to achieve all these objectives more efficiently and effectively.

Recent recentralising reforms

Denmark, Finland, and Sweden have all adopted recent health sector changes that reflect a pattern of consolidating greater national influence over health sector decision-making. Norway's existing structure may yet experience greater national control in the future.

Denmark

A new financial stability law in Denmark will require regions and municipalities to keep within 1.5% of their budgets — budgets which are agreed with the national government. This reinforced budgeting supervision creates a *de facto* national veto on the ability of Danish municipalities to set their own tax rates, dramatically reducing their level of authority downward such that, in practice, the national government is now making the essential fiscal decisions for both regional and municipal levels of local government.

A second arena in which the Danish national government has exerted new authority is in the design and building of new public hospitals. Traditionally in Denmark (before 2006), the county councils were relatively autonomous in managing new building, not always with good results. In Copenhagen County in the early 1980s, for example, decisions were taken to build a large new fifteen-story hospital in Herley, which turned out to be too expensive to fully build for many years. In the current building process, however, the five regional governments are being required to obtain approval for their hospital plans, including the siting of new hospitals and the closure of existing facilities, from the national government before building.

current process unconnected to the 2008 economic crisis

Moreover, since now the majority of the capital funds come directly from the national government (as the regional governments have lost their right to tax), the national government has placed tight requirements on these new "super hospitals" regarding the specialised services that they must include, to the point of dictating that at least 20-25% of the total hospital expenditure must be devoted to new technologies. The goal appears to be to continue the ongoing centralisation of hospital services into much larger units in order to increase the quality of the technical services offered, and to thereby respond to citizen demands for more modernised and effective services.

A key prerequisite for the ongoing centralisation and specialisation of hospital services is to create more efficient interaction between primary care, municipal health and social care, and hospital care. Therefore, the Danish state has mandated that the municipalities and regions must enter into comprehensive health agreements to this effect, and is currently establishing a set of indicators to monitor their progress in developing these collaborative arrangements. These new lower level obligations again illustrate the stronger steering ambitions of the state level in Denmark.

Finland

In Finland, the national government began, in the mid-2000s, a process of consolidating municipal governments (which are the owners and operators of the Finnish health system, typically through federations with neighbouring districts) into fewer, larger, more administratively and financially capable units. Originally 454 municipalities a few years ago, Finland now has 339 local governments for its five million people, and there is an aim that the

ongoing consolidation process will result in perhaps 70 municipalities – or less – at its end (in comparison, Denmark re-structured its municipalities from 271 to 98 as part of its structural reforms in 2006–07). This process of municipal consolidation could well be a preview to consolidating the twenty hospital districts (made up of federations of municipalities) and the existing public hospital structure into five regional hospital consortiums built around the five university hospitals.

Finland also is debating again the potential consolidation of its two different sources of public funding for health care, which would involve folding parts of the national health insurance fund (KELA) into the existing publicly financed, municipally operated health system structure. If it occurs, this would remove a source of funding that has been used to provide partial public funding for Finns to use private medical services, in effect further consolidating the position of the public authorities in the health care system. It may not reduce private health care provision; however, as the public authority run system is itself increasingly outsourcing the provision of health services that it funds.

Sweden

In Sweden, since its election in 2006 the national Conservative-led government has sought to exert more strategic authority over the officially independent 21 county councils. Initially, this effort was largely limited to offering financial incentives to the counties to raise the quality and lower the cost on a negotiated number of service indicators. Since 2007, the Ministry of Health has required permits from the National Board of Health for certain advanced specialisations, and is seeking to consolidate them in only a few locations in the country – a process that initially included organ transplantation, eye cancer, paediatric surgery and treatment of severe burns.8

There are also several examples of increasing state monitoring and supervision. For instance, starting in 2006, the national government began publishing yearly comparative data showing the quality of key clinical

services provided by each county – enabling the Swedish media to make interesting, sometimes invidious comparisons and thereby giving poorer performing counties an incentive to improve.

Another example of increased state monitoring has been the National Guidelines, developed by the National Board and Welfare in order to govern clinical prioritisation as well as resource allocation within the counties. In addition to being a channel for professional guidance, the National Guidelines are also used as an instrument for the national government to exercise control over local political decision-making. Similar developments of monitoring systems and national guidelines also have been introduced in Denmark in recent years, although Denmark has chosen to back this with mandatory accreditation of all health care providers (including municipal and primary care) at regular threeyear intervals.

These efforts at service consolidation in Sweden are being made in the context of a 2007 national commission which proposed that the existing 21 counties be combined into six to eight regional governments to run health services. While the commission's recommendations were not adopted, efforts to encourage voluntary mergers between counties have been intensified lately (the three large metropolitan areas already are large merged counties). In Sweden, too, then, the overall direction appears to be toward consolidation, especially of hospital services, moving in a similar direction toward the "super hospitals" process currently underway in Denmark. A recent example is the so-called Nya Karolinska Solna, a large university hospital that is currently being built in Stockholm.

Norway

This general pattern of increased national authority also can be observed in Norway. The five regional state enterprise councils initially envisioned in the 2002 reform were reduced to four in 2007, when the two Southeastern regions were amalgamated into one large administrative structure. Further, the general expectation among policy analysts is that ongoing

inadequacies in the performance of the existing structure will likely lead to future changes in the direction of yet greater national control.

Minimal impact of post-2008 economic crisis

The current process of increasing national authority in the Nordic region appears to be mostly unconnected to concerns generated by the 2008 economic crisis. Many of the reforms either started or had been discussed prior to 2008. More importantly, both Finland and Sweden had suffered severe economic contractions in the early 1990s, complete with collapsing real estate prices and nationalisation of major banks, and had had to re-engineer their financial systems more than a decade before the 2008 wave broke. As a result, neither country was particularly vulnerable in this latest downturn.

Norway, buoyed by oil revenues and relatively tight national economic management, suffered little economically either in the early 1990s or in the post-2008 period.

Denmark had a strong economy going in to the financial crisis and has maintained relatively strong exports of diverse manufacturing, pharmaceuticals, and consumer goods. This has sheltered the country from severe effects of the crisis in spite of a drop in the housing market of 22% since 2007.

Finland also had strengthened its economy since the deep recession it experienced in 1991–93 and has reduced its public debt to one of the lowest within the Eurozone. Thus, despite an 8% drop in gross domestic product (GDP) in 2009, it was able to go through that short recession without major cuts in health expenditure.

In Sweden, the health care sector went through tough years after the economic crisis in the 1990s. It was not until 2004 that the county councils reported positive net incomes. However, the recent economic recession did not hit Swedish health care especially hard. After a substantial dip of GDP in 2009, Gross National Product (GNP) growth was already 5.6% in 2010. High crisis

awareness, in combination with almost unchanged tax-incomes, led to good results in almost all counties in the years after the 2008 crisis.

stronger national authority over fiscal and policy issues should cause a stir in Europe

To be certain, concerns about the potential economic slowdown among other European trading countries (only Finland is a member of the Eurozone) have intensified health sector cost and efficiency pressures in all four countries. However, public sector budgets have thus far been relatively well protected.

Drawing conclusions

In the debate over the relative benefit of decentralised versus centralised health system strategies, the Nordic countries traditionally have been strongly supportive of decentralised approaches. This has been backed by social values about local control, as well as financial mechanisms that included only a small national government apparatus to steer health system decision-making, emphasising so-called "framework legislation."

Based on recent experience as detailed above, it would appear that this Nordic commitment to a reduced role for their national governments in the health sector may be weakening. On the contrary, in Nordic countries and elsewhere in Europe, it would seem that a combination of rapidly changing technology, growing pressure from patients, and stark, if as yet unrealised, fears about the cost consequences of an ageing population with a higher prevalence of chronic care needs have led Nordic countries to increase considerably the steering and supervisory

role of their national governments. The degree to which this shift appears to be relatively independent of ongoing economic problems in Europe can only serve to strengthen the implications of the structural shift that appears to be underway.

From the perspective of other countries seeking solutions to their health sector challenges, it is never easy to draw comparisons with the Nordic region. The four countries under discussion here are relatively distinct in the size of their population (small), in their relative wealth (considerable), and their long tradition of strong public control. That said, despite these contextual differences, this emerging new pattern amongst these Nordic countries of stronger national authority over fiscal and policy issues in their health sectors should cause a stir elsewhere in Europe and beyond. If the Nordics feel compelled by current pressures to reconfigure their traditionally regionally/ locally run health systems, the message to larger, more complex countries like Italy and Spain, where regionally run, publicly funded health systems have encountered serious fiscal and performance difficulties, may be hard to miss. If these new consolidated measures are indeed successful in changing health sector behaviour and outcomes, the long-running debate about the superiority of decentralised as against centralised functions in health care systems may well take a new turn.

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Eurohealth SYSTEMS AND POLICIES 25

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Note: Cyprus has been a divided island since 1974; in depth discussion of this still-contentious issue is not appropriate for this article. In general, the government of the Republic of Cyprus has no access to information concerning the northern part of the island. Consequently, unless otherwise stated, all figures and discussions in this article refer to those areas of the Republic of Cyprus in which the government of the Republic of Cyprus exercises effective control.

CONTRIBUTIONS, CO-PAYS AND COMPUTERS HEALTH SYSTEM

REFORM IN CYPRUS

By: Mamas Theodorou and Jonathan Cylus

Summary: Cyprus' new health system, which has been in the planning stages for well over a decade, is expected to come into effect in 2016. While discussions are still ongoing regarding important elements of the reform, the new health system will lead to sweeping changes in areas such as coverage, financing, co-payments, provider payments, and data collection. In this article, we review some of these and discuss challenges for implementation.

Keywords: Cyprus, Health Reform, Financing, User Charges

Introduction

Cyprus is the only country in the European Union that does not claim to have universal health care coverage. The legal basis for entitlement to public services is citizenship and proof of having earned below a certain level of annual income. It is estimated that 83% of the population has free-of-charge access to the public health care system, while the rest of the population has coverage either through voluntary health insurance or must pay to use public services according to fee schedules set by the Ministry of Health (MoH). As a result of gaps in coverage and public sector inefficiencies that drive some Cypriots to seek care in the private sector, approximately half (47.6% in 2010) of total health expenditures are out-of-pocket.

The current system is thus divided into two parallel, uncoordinated delivery systems – one public and the other private. This leads to poor continuity of care, duplication of services and other wasteful practices. The public system is highly centralised with almost everything determined by the MoH, and is plagued by a lack of efficient payment mechanisms and monitoring systems, which contribute to inequalities in financing and access to care, as well as to inefficient allocation and utilisation of resources. For example, few resources are allocated to disease prevention. On the other hand, the private sector is poorly regulated and suffers from an oversupply of clinical laboratories, radiology and expensive technology imaging services, as well as poor organisation and management. For the last ten years, the public system has dealt with long waiting lists for several types of surgery and diagnostic tests, while the private sector has experienced low utilisation of high cost medical technology, which has worsened due to the ongoing economic crisis.

Interestingly, despite low levels of health expenditure as a percentage of gross

domestic product (GDP) (second only to Romania in the EU) and as a percentage of government expenditure (lowest in the EU), high out-of-pocket payments, and inefficiencies such as long waiting lists, Cypriots report in surveys that they are largely satisfied with their health system and the quality of services. Indeed, Cypriots do enjoy levels of health similar to other developed countries.

the new system has not been implemented

However, to address the deficiencies in the system, in 2001 the Parliament passed the General Health Insurance Scheme (GHIS) Act, (alternatively known as the National Health Insurance Scheme or NHIS) to establish a new and modern public health care system offering universal coverage, embracing the goals, direction and strategy recommended by an international team of health policy experts in 1992. Yet to date the new system has not been implemented.

In light of Cyprus' EU Presidency, the recent Cypriot application for accession to the EU support mechanism due to the economic crisis, the European Commission's recommendation for "completion and implementation of the national healthcare system without delay" and finally the announcement by the government of a step by step implementation of the GHIS beginning in 2016, this article discusses some of the main health system reforms, the new proposed changes to the implementation plan, and challenges for the implementation process.

Structure of the new General Health Insurance Scheme

Though many specific elements of the GHIS have yet to be determined, the reform is expected to lead to important changes in financing, coverage, provider payments, administration and data collection, creating a completely different

health sector in which public and private providers will offer services in a quasi-competitive environment. These changes are anticipated to improve quality of care, equity of access, and efficiency. The main features of the new GHIS are: universal and equal coverage for all Cypriots; the creation of an internal market with elements of competitiveness among providers; a single-payer system; and a new provider payment system with a balanced incentive structure across the public and private sectors. The new payment system will use a mix of payment mechanisms for different types of care.

Contrary to the current system which is financed exclusively by the state budget, the new GHIS will be funded mainly by contributions paid by employees (2% of their annual income), private and state employers (2.55% of annual employee income), pensioners (2% of their annual pension), freelancers and self-employed (3.55% of their annual income) and the state (4.55% of the level of total annual income received by all employees, pensioners, freelancers, and self-employed). This money will be collected and transferred to the Health Insurance Organisation (HIO), which is responsible for pooling as well as for implementing and organising the system, contracting, monitoring, remunerating providers in both public and private sectors, determining the list of approved pharmaceuticals, setting medical protocols and guidelines, health technology assessment, medical ethics, fair competition, complaints management and for keeping beneficiary and provider registries. The HIO expects that the new system, with universal coverage and higher levels of funding, will lead to lower out-of-pocket payments. However, co-payments, which are now negligible and only for certain types of care, may increase to comprise up to 9% of the total health budget, and be required from a larger segment of the population according to the most recent strategic plan prepared by HIO.

New payment methods will require high quality data from providers. Inpatient care will be remunerated using activity based payment under hard global budgeting based on Diagnostic Related Groups (DRGs). Specialists will be paid on a points-per-service basis, whereby the monetary value of points collected from patient visits will be assessed monthly in relation to the total quantity of services delivered that month. The compensation of clinical laboratories will also be based on a similar point-based system and the HIO will reimburse the cost or part of the cost of pharmaceutical products included in the list of approved drugs by reference price. Finally, General Practitioners (GPs) will be paid through capitation and receive bonuses for selected performance indicators.

Because the proposed payment systems require reliable data on health activity and quality of care, a tender is anticipated for the installation and operation of an integrated information system, where data collection and other operational functions will be outsourced to a third-party and expanded to cover all hospitals/clinics and other health providers. According to the MoH, the information system will be financed through the Build Operate Transfer (BOT) method.

Other relevant issues regarding providers include how to encourage interaction between providers, specifically between GPs and specialists, the minimum criteria to be met by providers to be able to contract with the HIO, the reorganisation and autonomy of public hospitals in order to compete with the private hospitals, and the amount of global budget by specialty. For these matters there is ongoing discussion between key stakeholders including the Cyprus Medical Association, HIO, MoH, and the Ministry of Finance.

Analysis of the reforms in light of the new implementation plan

The GHIS is a comprehensive plan and an ambitious effort to provide universal coverage and access to health care services, tackling the existing imbalance between the public and private sectors. According to the implementation plan prepared by the HIO the most important challenges related to the GHIS are the cost containment and economic sustainability of the system, the quality control of provided services and the harmonious collaboration between

public and private sectors in a completive environment. Necessary requirements are the installation and operation of the information system and the reorganisation and autonomy of public hospitals. A brief discussion below presents the changes to contributions, co-payments, and data collection.

Contributions

In regards to the financing of the GHIS, the updated implementation plan estimates the total annual cost at €975 million. This will require a significant increase in the level of contributions paid by employees, pensioners, employers and the state relative to that laid out in the 2001 law. According to different scenarios, the increase is estimated to range between 27–50% more from employees, pensioners and employers, and 8-10% more from the state. According to the Household Survey of 2009, even with these increases, the household burden of health expenses is expected to be lower than the current level of out-of-pocket payments, assuming that the new health system manages to reduce out-of-pocket payments by at least 50% of the current level. However, the ongoing economic recession is expected to reduce household income and therefore, any increase of contributions may have negative consequences for household consumption and savings, as well as macroeconomic fundamentals. The HIO, MoH and Ministry of Finance should carefully consider what impact this is likely to have on spending, employment and growth before implementing such a policy.

Co-payments

It is estimated that €90 million will be raised annually through co-payments, which is about 9% of the total amount of the health budget. While patients will have universal access under the new scheme, increases in co-payments are a regressive way to raise revenues, which will limit demand for care, and should not be expected to lead to savings. Especially in times of crisis, user charges may have large adverse consequences for equity. In order to mitigate this effect it is important to apply exemptions for groups such as older people, the chronically ill, and the poorest members of society.

HIO expects the new system will lead to lower out-of-pocket payments

Computerisation

To ensure that the new health system is properly managed, a comprehensive data collection system is needed to be put in place within a realistic timeframe. This system should be established within public and private facilities, before the reform is implemented in order to enable policymakers to collect the relevant data necessary to make certain that new policies are effective. Further to that, successful implementation of the GHIS requires a rigorous and transparent evaluation and contracting process with providers, adherence to the contract terms, and strict monitoring and control systems against phenomena such as supplier induced demand, moral hazard, overprescribing and fraud. Without reliable data, it will be difficult for the HIO to successfully carry out the GHIS.

Conclusions

Currently, there appears to be government commitment to a timetable for implementation of the GHIS, complete with milestones and deliverables. Positive factors towards this decision were the recommendation of the European Commission for the "completion and implementation of the NHIS without delay, on the basis of a roadmap, which should ensure its financial sustainability while providing universal coverage" and the potential for more willingness on the part of the private sector to accept change due to decreases in revenues attributed to the economic crisis, which has allowed for increased negotiating power of the HIO to achieve lower reimbursement prices in the new system. Yet there are concerns, including that the ongoing economic crisis might limit the ability of the HIO to

generate sufficient revenues, with negative consequences for investment, employment and competitiveness of Cyprus' economy.

27

The new implementation proposal and the commitment of the government may be signs of a new beginning, but much more is needed beyond political showboating. As the saying goes, the devil is in the detail. There are important issues that remain unaddressed, including whether fair competition can exist between the public and private sectors, which are currently remunerated differently; any competition would also require autonomy of public hospitals as a prerequisite, though whether this will occur remains uncertain. Giving public hospitals autonomy may facilitate better data collection, because hospital managers will have greater incentives to track their performance so that they can better oversee their facilities. There are additional fears that, as the private sector already has excess capacity, it may become difficult to control costs once there are fewer barriers for patients who want to access private services.

Perhaps most importantly, the government must ensure that in implementing its new health system, Cypriots are sufficiently protected from the financial burden of health care costs. This means not only ensuring that vulnerable groups are exempt from co-payments, but also that contribution rates are set at a level that does not compromise household consumption. The current financial crisis provides an opportunity for the government to implement its long-awaited reform but Cyprus must proceed carefully and set realistic milestones for its execution.

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POLICY FACTORS UNDERPINNING THE

WELSH DIGNITY IN CARE PROGRAMME,

2007-2012

By: Gareth Morgan

Summary: The Welsh Dignity in Care Programme was launched on 1 October 2007. This paper offers a summary of the programme and evaluates the implementation against six evidence-based policy factors.

Keywords: National Service Framework, Older People, Health and Social Care Services Dignity, Wales

Introduction

Launched in March 2006, the National Service Framework (NSF) for Older People in Wales is a ten-year programme concerned with the provision of evidencebased health and social care services in Wales for individuals over the age of 50. Dignity in care is one of the key cross cutting themes of the NSF. Dignity in care is a difficult term to define objectively because it has subjective elements associated with it. What is dignity to one person may be different to another person. In Wales, however, some of the key principles underpinning dignity were set out in the NSF and included personcentred approaches and holistic care based on individual needs.

The Dignity in Care Programme for Wales was launched on 1 October 2007, United Nations Older Person's Day, by the Welsh Deputy Minister for Social Services, Mrs Gwenda Thomas, Assembly Member (AM). Shortly after this launch, a Dignity

in Care National Co-ordinating Group (DCNCG) for Wales was established in 2008.

The way that the DCNCG was constituted drew, at least in part, from the prior experience of the Welsh Aspirin Group.² Indeed, the author was Secretary for both of these Groups and the objectives set were very similar. Furthermore, although the issues that these respective groups were addressing were different, skills of relationship building, leading to collaborative working, were crucial elements. The role of Secretary, as a reflective practitioner⁸, also was crucial to support the national implementation of the Dignity in Care Programme. At all stages, efforts were made to publish work so as to ensure good communication and peer-review.

Box 1 presents the DCNCG objectives and an internal evaluation of the programme against these has been undertaken.
This internal evaluation shows that

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Box 1: Objectives of the Welsh Dignity in Care National Co-ordinating Group

- to collect, critique and organise dignity in care literature
- to debate and discuss dignity in care research and policy
- to stimulate or co-ordinate pragmatic research projects on dignity in care
- to disseminate information on dignity in care using the NSF web site
- to influence dignity in care policy and practice in Wales
- to correspond with interested partners from outside Wales

the objectives have all been completed through a number of work streams. This includes the delivery of six training events for health and social care staff across Wales, three listening events including older people, financial support to over twenty small grants as well as several other commissioned projects. The focus of this article, however, is to consider the policy factors underpinning the delivery of the Welsh Dignity in Care Programme.

A review of the literature has suggested that six factors are important to underpin the delivery of evidence-based health policy. It follows that an absence of these factors might compromise implementation of policies. The six factors are: i) the importance and value of having multidisciplinary teams; ii) the need to have a broad evidence base to draw upon; iii) the circular relationship between research and policy; iv) the need for policy implementation to be locally sensitive; v) the benefit of stakeholder involvement; and vi) support by the national government. An evaluation of these factors with respect to programme delivery in Wales has been undertaken on the NSF for Older People and also on one of the specific standards, namely the provision of health promotion for older people. In both situations, the

six factors provided a useful evaluative framework. No claim is made that the framework offers a universal template for all circumstances but it certainly promotes critical thinking, ensuring that all pertinent factors are given explicit consideration.

Evaluation of the programme

Given that the Dignity in Care Programme for Wales has delivered on the objectives originally set, which is acknowledged as only one measure for the success of the DCNCG work, a different test is offered against the six factors. These are presented below and offer a retrospective view of work, as well as some commentary on the legacy the programme has offered to date, including active initiatives.

Support by the national government

The Welsh Deputy Minister for Social Services was involved closely in all aspects of the programme. Between 2007 and 2011, the Minister was able to set aside a budget of over £300,000 (€380,000) for a number of work streams to be taken forward. In addition, the interest of the Minister and frequent press releases to the Welsh media gave this a profile in Wales that encouraged engagement at all levels. The Minister also published into the wider domain some details on the ongoing Dignity in Care Programme; for example, on the British Gerontology Society website.

The importance and value of having multi-disciplinary teams

The DCNCG was chaired by Dr Win Tadd, a recognised authority on dignity in care issues. This authority helped give the programme a high profile and in addition, the DCNCG drew upon wide representation from across Wales. This included representatives from health and social care statutory organisations, private and voluntary groups, policy officials from the Welsh Assembly Government, academic partners and older people. Each representative themselves had a key role within their particular sector with networks. Furthermore, the Vice-Chair, Angela Roberts, represented an umbrella organisation for voluntary groups, namely Age Alliance Wales.

The need to have a broad evidence base to draw upon

One important source of evidence was prior research on the dignity in care agenda[®], which included Welsh participants. This research considered a wide range of issues, including the subjective elements to dignity in care and barriers to dignity in care being delivered. There were also other sources of evidence that were available to the DCNCG. For example, practices that were worth sharing in Wales were collected and published on the Social Services Improvement Agency website. Also, evidence from projects within Wales was used; for example, a virtual family was developed and used to support training and reflective practice. Given the Welsh focus of the dignity programme, evidence and experience that was derived from within Wales was largely used.

personcentred approaches and holistic care

The need for policy implementation to be locally sensitive

The six training events engaged with over 500 front line health and social care staff in Wales. Each participant was provided with a resource pack and equipped with a change management tool, the 'Plan, Do, Study, Act' model. The rational to this approach was to allow implementation to be locally sensitive in a diverse range of settings and also indirectly lead to wider improvements through influencing organisational culture. Another way in which policy implementation was locally sensitive was through the small grants programme, allowing innovative projects to be progressed. Each of the projects funded had the potential to be shared across Wales and impact on the provision of care services, leading to real improvements for older people. This 'real time real world' impact was one of the key underpinning philosophies to the work.

The benefit of stakeholder involvement

The three listening events were established to empower older people to share their experience or otherwise of dignity in care. Other aims included raising awareness in relation to dignity in care amongst frontline staff and exploring the facilitators and barriers to providing dignified care. Two questions were posed, namely: What will make a difference in service delivery? How can this be achieved? Another separate development involved commissioning the Patients Association, a national organisation, to prepare a report on some of the negative experiences of individuals receiving care in the Welsh National Health Service. This report was in turn picked up by the Welsh media¹⁰, leading to wider coverage of the issues. In turn, this generated further discussions helping to ensure dignity in care in Wales is culturally significant. Ultimately, the key stakeholders are EVERY resident living in Wales.

proactive approach to improving care for older people

The circular relationship between research and policy

The experience of the programme has already been used to influence policy. For example, in Wales, a website titled 'e-governance', targeted to NHS Wales staff but open to all sectors, has introduced a section on dignity in care. This section has been populated with resources developed within the programme. Independently, the Welsh Commissioner for Older People has undertaken a review of dignity in care within Welsh hospitals and this also has important policy implications.

NHS Wales organisations have developed action plans and the Welsh Assembly Government has also included dignity in care as a key target for NHS Wales to deliver and be performance managed against. Furthermore, an independent

evaluation of the impact of the programme to date was commissioned and this has reported. It found that the dignity in care programme has made a positive impact in Wales and consideration is now being given as to the next steps. As part of this, a national conference has been organised for 1 October 2012 and further work has been undertaken to identify current activities in Wales. This will be published as a compendium of practice worth sharing, with a view to generating further interest and work.

Closing remarks

The Dignity in Care Programme in Wales is a systematic, coordinated and pro-active approach to improving care for older people. Whilst other countries may be developing their respective dignity in care agendas, the formal programme approach that is being taken forward in Wales is believed to be unique. The programme uniquely has had engagement and support from the Welsh Assembly Government, health and social care professionals 2. older people and their carers. 15 Other countries might consider the experience from Wales as a model to implement similar initiatives in their respective health and social care systems.

In Wales, the strong networks associated with this geographically small country of about three million residents was important in developing the programme. The antecedent events and subsequent delivery of the programme are thought to be the first in the world specifically at a country level on the dignity in care agenda. Developments are still progressing, for example a poster awareness raising campaign was implemented in all care settings. The impact of this work may be difficult to measure directly, but the poster campaign may help influence organisational culture and expectations from those individuals who access services. Work is also active on the bilingual aspects of Wales, in accordance with the Welsh Language Act.

Wales has the opportunity to progress the dignity in care agenda further and build on experience to date. This programme also satisfies the six factors that underpin evidence-based health policy. Should other

countries seek to develop a dignity in care programme, these factors may offer a framework that could help appropriate initiatives to be progressed elsewhere. The relevance of this to other countries, specifically those in Europe, is that Wales has demonstrated 'proof of concept' that a dignity in care programme can be developed and delivered, with clear benefit achieved for a budget over three years of less than 10 pence (12 euro cents), per head of population. Surely this modest sum is not too high a price to pay for a dignity in care programme?

So what next for Wales? The next October conference, held on UN Older Person's day, gives an opportunity to critically consider progress to date and next steps. It is clear, however, that Wales is set on a course of strong integration between health and social care services. The ultimate impact of the dignity in care programme must be to mainstream a culture in which person-centred holistic care is routine. When the dignity in care programme is decommissioned because of the cumulative effects of a range of national and local initiatives, then Wales really will have been successful.

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HiT on Bulgaria

By: A Dimova , M Rohova, E Moutafova, E Atanasova, S Koeva, D Panteli, E van Ginneken

Freely available to download at: www.healthobservatory.eu

This new HiT outlines the latest developments in the Bulgarian health system, which is characterised by limited statism: the Ministry of Health is responsible for national health policy and the overall functioning of the health system and key players in the insurance system include the National Health Insurance Fund, voluntary health insurance companies, insured individuals and health care providers.



Health care reforms after 1989 focused predominantly on ambulatory care and the restructuring of the hospital sector is still pending. With a health system that is economically unstable and health care establishments, most notably hospitals, suffering from underfunding, future reforms are imperative. Moreover, citizens as well as medical professionals are dissatisfied with the health care system and equity is a challenge, not only because of differences in health needs, but also because of socioeconomic disparities and territorial imbalances.

New Observatory publication

Governing Public HospitalsReform strategies and the movement towards institutional autonomy

Edited by: Richard B Saltman, Antonio Durán, Hans FW Dubois

European Observatory Study Series No. 25

Copenhagen: World Health Organization, 2011

Number of pages: 259

Freely available to download at:

www.healthobservatory.eu

The governance of public hospitals in Europe is changing. Individual hospitals have been given varying degrees of semi-autonomy within the public sector and empowered to make key strategic, financial and clinical decisions. This study explores the major developments and their implications for national and European health policy.

The study focuses on hospital-level decision-making and draws together both theoretical and practical evidence. It

includes an in-depth assessment of eight different country models of semi-autonomy. The evidence that emerges throws light on the shifting relationships between public sector decision-making and hospital-level organisational behaviour and will be of real and practical value to those working with this increasingly important and complex mix of approaches.

Part I of the volume

analyses the key issues that have emerged from developments in public-sector hospital governance models and summarises the general findings. Part II looks in detail at hospital governance in eight countries. 32 Eurohealth MONITOR

NEW PUBLICATIONS

Intersectoral Governance for Health in All Policies. Structures, actions and experiences

Edited By: DV McQueen, M Wismar, V Lin, CM Jones, M Davies

Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies. Observatory Studies Series No. 26, 2012

Number of pages: xix + 206

ISBN: 978 92 890 0281 3

Available online at: http://www.euro.who.int/en/who-we-are/ partners/observatory/studies/intersectoral-governance-for-health-in-all-policies.-structures,-actions-and-experiences

Many of the policies and programmes that affect health originate outside the health sector. Governments therefore need to address

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population health using a strategy or policy principle that fosters intersectoral action. Health in all policies (HiAP) does just that, encouraging intersectoral approaches to management, coordination and action. This publication captures the research on how intersectoral governance structures operate, showing how governments and ministries can initiate action, and how intersectoral governance structures can be successfully established,

used and sustained.

Contents:

Forewords; Acknowledgements; List of case studies; List of tables, figures and boxes; Abbreviations; List of Contributors; Part I: Policy Issues and Research Results; 1) Introduction: Health in All Policies, the social determinants of health and governance; 2) Synthesising the evidence: how governance structures can trigger governance actions to support Health in All Policies; Part II: Analysing Intersectoral Governance for HiAP; 3) Cabinet committees and cabinet secretariats; 4) The role of parliaments: the case of a parliamentary scrutiny; 5) Interdepartmental units and committees; 6) Mergers and mega-ministries; 7) Joint budgeting: can it facilitate intersectoral action? 8) Delegated financing; 9) Involving the public to facilitate or trigger governance actions contributing to HiAP; 10) Collaborative governance: the example of health conferences; 11) Industry engagement.

Policy Summary: Health policy responses to the financial crisis in Europe

By: P Mladovsky, D Srivastava, J Cylus, M Karanikolos, T Evetovits, S Thomson, M McKee

Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies. Policy Summary No. 5, 2012

Number of pages: 119

ISSN: 2077-1584

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0009/170865/e96643.pdf

The global financial crisis that began in 2007 can be classified as a health system shock – that is, an unexpected occurrence



originating outside the health system that has a large negative effect on the availability of health system resources or a large positive effect on the demand for health services. Economic shocks present policy-makers with three main challenges. Firstly, health systems require predictable sources of revenue. Sudden interruptions to public revenue streams can make it difficult to maintain necessary levels of health care. Secondly, cuts to public spending on health made in

response to an economic shock typically

come at a time when health systems may require more, not fewer, resources. And thirdly, arbitrary cuts to essential services may further destabilise the health system if they erode financial protection, equitable access to care and the quality of care provided, increasing costs in the longer term.

This Policy Summary analyses the background and government responses to this economic shock, and presents key findings.

Contents:

Acknowledgements; Executive summary; Key messages; 1) Introduction; 2) Understanding health policy responses to the financial crisis; 3) Methods; 4) Results; 5) Conclusions; References; Annexes.

NEWS

International

Health ministers adopt Health 2020 – the new European policy for health and well-being

On 12 September the World Health Organization (WHO) European Region adopted a new policy to protect and promote the health of its 900 million citizens, particularly the most vulnerable. This new policy, called Health 2020, was endorsed by the WHO Regional Committee for Europe, WHO's governing body for the Region, during its meeting in Malta. It aims to "significantly improve the health and well-being of populations, reduce health inequalities, strengthen public health and ensure people-centred health systems that are universal, equitable, sustainable and of high quality".

This is a critical issue given that while the Region as a whole has seen important improvements in people's health over the last few decades, these improvements have not been experienced everywhere and equally by all. There is, for example, a sixteen year difference in life expectancy at birth between countries with the lowest and highest levels, a 42-fold difference in maternal mortality between countries, and major differences in life expectancy between social groups within all countries in the Region.

Acknowledging the interconnectedness of local, national, regional and global health actors, actions and challenges, the Health 2020 process will work to create unity in the European public health community through the active promotion and adoption of a common values - and evidence-based, outcome-focused, Region-wide policy framework. The policy targets the main health challenges in the 53 countries in the Region, such as increasing health inequities within and between countries, shrinking public service expenditures due to the financial crisis, and a growing burden of ill health from non-communicable diseases, including obesity, cancer and heart disease. Its implementation should help mobilise

decision-makers everywhere, within and beyond the boundaries of the health sector.

"There is a lot of action in different countries, by governments, donors, the private sector, nongovernmental organisations and other groups," said Zsuzsanna Jakab, WHO Regional Director for Europe, "but we need these different players to pool their knowledge and work together. That is the only way we are going to reduce death and suffering. A European policy could be the beginning of a new united fight to save not just the lives of the citizens of today's Europe, but also those of generations to come."

"So many factors affect health, and health has an impact on so many areas of our lives that progress on public health can only come from whole-of-society and whole-of-government efforts," said Ms Jakab. "That is why there is a role for everyone to play in implementing Health 2020, from prime ministers, to civil society, to citizens."

Objectives and priorities

Health 2020 identifies two strategic objectives and four priority areas for action to guide policy approaches. They are drawn from an extensive review of public health evidence, a comprehensive peer-review process and the experience of Member States and the WHO Regional Office for Europe working together.

The first strategic objective is concerned with improving health for all and reducing health inequalities. This focuses on implementing whole of government and whole of society approaches to these issues and bringing together new European evidence on effective interventions that address inequalities in the distribution of power, influence, goods and services, as well as in early life, living and working conditions, and access to good quality health care, schools and education, all of which underpin the health divide between and within countries.

The second strategic objective is concerned with improving leadership and participatory governance for health. Health 2020 identifies ways in which new

collaborative leadership can bring many partners together and mobilise broadbased political and cultural support for equitable, sustainable and accountable approaches to health development, and effectively challenge groups whose activities are detrimental to the public's health. It also identifies citizens' and patients' empowerment as key elements for improving health outcomes, health systems' performance and satisfaction. These elements can advocate for healthier policies in all sectors, reduce the use of health services and health care costs, bring better communication between patient and health professionals as well as a better adherence to treatment regimens, and eventually lead to better life expectancy, more control over disease, increased selfesteem, greater inclusion in society and improved quality of life.

The four priority action areas are firstly to invest in a life-course approach and empower people. This includes giving children a good start in life, empowering adults to maintain control over their lives and promoting active and healthy ageing. Another priority action area is to tackle Europe's major health challenges from both non-communicable and communicable diseases. Evidence points to the need to underpin these interventions with actions on equity, social determinants of health, empowerment and supportive environments. Strengthening peoplecentred health systems, public health capacity and emergency preparedness, surveillance and response is another priority. Finally there is also a focus on creating supportive environments and resilient communities. This recognises that health chances are closely linked to the conditions in which they are born, grow, work and age. Resilient and empowered communities respond proactively to new or adverse situations, prepare for economic, social and environmental change and cope better with crisis and hardship. Communities that remain disadvantaged and disempowered have disproportionately poor outcomes, in terms of both health and other social determinants. There is a need for a systematic assessment of the health

effects of a rapidly changing environment, especially in the areas of technology, work, energy production and urbanisation. This can then be followed by action to ensure positive benefits to health.

More information on Health 2020 is available

at: http://www.euro.who.int/en/what-we-do/health-topics/health-policy/health-2020

European Commission proposes to revamp rules on trials with medicines

The Commission have announced plans intended to boost clinical research. in Europe by simplifying the rules for conducting clinical trials. Clinical trials are tests of medicines in humans and give patients access to most innovative treatments. At the same time, clinical research with over €20 billion of investment per year in the EU makes a significant contribution to the growth policy of the Europe 2020 agenda. Clinical trials are vital to develop medicines and to improve and compare the use of already authorised medicines. The data generated in clinical trials are used by researchers in publications and by pharmaceutical companies applying for marketing authorisations. Once implemented, the measures proposed should speed up and simplify the authorisation and reporting procedures, while maintaining the highest standards of patient safety and robustness and reliability of data. The Commission also state they will better differentiate obligations according to the risk-profile of the trial, and improve transparency including on trials done in third countries.

The new proposed legislation will take the form of a Regulation. This will ensure that the rules for conducting clinical trials are identical throughout the EU. In particular, it will make it easier to conduct multinational clinical trials in Europe. Some concrete proposals are:

 An authorisation procedure for clinical trials which will allow for a fast and thorough assessment of the application by all Member States concerned and which will ensure one single assessment outcome.

- Simplified reporting procedures which will spare researchers from submitting largely identical information on the clinical trial separately to various bodies and Member States.
- More transparency on whether recruitment for participating in a clinical trial is still ongoing and on the results of the clinical trial.
- The possibility for the Commission to conduct controls in Member States and other countries to make sure the rules are being properly supervised and enforced.

John Dalli, European Commissioner for Health and Consumer Policy, said: "patients in Europe should have access to the most innovative clinical research. Clinical trials are crucial for developing new medicines and improving existing treatments. This is why today's proposal significantly facilitates the management of clinical trials, while maintaining the highest standards of patient safety and the robustness and reliability of trial data. €800 million per year could be saved in regulatory costs and boost research and development in the EU, thus contributing to economic growth."

The proposed Regulation, once adopted, will replace the 'Clinical Trials Directive' of 2001. According to the Commission it has ensured a high level of patient safety, but its divergent transposition and application led to an unfavourable regulatory framework for clinical research, thus contributing to a decrease of 25% in clinical trials conducted in the period between 2007 and 2011: in 2007, more than 5000 clinical trials were applied for in the EU while by 2011 the number had dropped to 3,800.

The legislative proposal will now be discussed in the European Parliament and in the Council. It is expected to come into effect in 2016.

For more information on clinical trials: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

Reducing health inequalities in small countries: WHO Europe signs agreement with San Marino

San Marino is providing €1.25 million for a five-year project to support European countries with small populations address the social determinants of health and reduce health inequities. The project will establish a strategic platform for investment for health and development for small-population countries, which will bring together WHO, countries, academic institutions and regional development organisations with a shared interest in developing policy and governance responses that advance health equity as part of a fair and sustainable society.

In signing the agreement Claudio Podeschi, San Marino Minister of Health and Social Security, National Insurance and Gender Equality, stated that he hoped that "San Marino can act as a catalyst for identifying and testing new scientific evidence and policy solutions to reduce health inequities in small-population countries."

The effects of social and economic shifts often emerge more quickly in small-population countries, and thus offer early warning signs and opportunities to identify and test policy solutions to mitigate these effects on health. Member States of the WHO European Region with a population of under two million include Andorra, Cyprus, Estonia, Iceland, Luxembourg, Malta, Monaco, Montenegro and San Marino.

Specifically, the project and new platform will consolidate policy innovations, applying emerging evidence and tools to the key policy challenges of small countries and identifying promising solutions that can be applied at the European level and beyond. It will promote active collaboration between small countries and document progress to disseminate to a wider audience, for instance through policy dialogues and capacity building events. It will also foster alliances for fair and sustainable health and development through learning exchanges and partnerships at local, national and European levels.

Eurohealth MONITOR 35

Country news

Iceland: study published on impact of the economic crisis

A recent study published by the US National Bureau for Economic Research and conducted by the University of Iceland, Rider University and the Robert Wood Johnson Medical Centre has found that Icelanders reduced high health risk behaviours following the country's economic crisis. They also increased some health-promoting activities. Survey data for the period between 2007 and 2009 indicate that the population cut back on heavy drinking, artificial sun tans, smoking, sugary drinks and fast foods. At the same time, individuals were more likely to get healthy amounts of sleep and consume more fish oil, although fruit and vegetables consumption declined. The effects were most visible amongst the working age population. Changes in hours of work, real household income, wealth and mental health explained some of the effects on health-compromising behaviours, ranging from 9% for smoking to 42% for heavy drinking. For health-promoting behaviours, these factors reduced the effects of the crisis only for fish oil and vitamins/ supplements by about one third. The study authors concluded broad factors, including prices, which increased over 27%, played a major role in the effects of the crisis on health behaviours.

The report is available at:

http://papers.nber.org/papers/w18233

Ireland: additional cost reduction measures announced

On 30 August the Health Service Executive (HSE) in Ireland announced additional budget reductions in order to contain costs and remain within clearly defined budget target set by both the Troika and Government. In 2010 and 2011 the health services saw unprecedented budget reductions of approximately €1.75 billion. This was followed in 2012 with additional reductions of €750 million. These reductions have occurred at a time when demand for health services continues to grow. Currently the HSE is running a significant budget deficit. This deficit is due to several factors, including

the need to issue 33,000 medical cards entitling individuals to most health services without charge, over and above service plan projections. The deficit as of 31 August 2012 was €259 million, but the HSE has a statutory obligation to remain within its allocated budget of €13.2 billion for 2012.

In order to deal with the existing deficit and to remain within budget, the HSE has been obliged to introduce a range of additional cost reduction measures to be implemented throughout the remainder of 2012 and into 2013. These measures amount to €130 million. These measures include €35 million through reductions in the usage of agency and overtime, €10.8 million in home help hours and €10 million through the reduction of Personal Assistant hours. This is in addition to other non-operational measures to be undertaken that have been submitted to the Troika.

$\label{thm:model} \mbox{More information on the measures taken at:} \\$

http://www.hse.ie/eng/services/News/finances.html

Ireland: starting salaries for hospital consultants to fall by 30%; new rostering agreements

The Health Service Executive (HSE) has confirmed there will be a 30% reduction in the starting salaries for new consultants. It follows the conclusion of talks involving the Irish Hospital Consultants Association, the Irish Medical Organisation and the HSE at the Labour Relations Commission. Speaking to national broadcaster RTE, HSE National Director of Human Resources Barry O'Brien said the new salary rate for consultants would be between €116,000 and €121,000. Mr O'Brien said consultants did not agree with the new rate but they were aware of the HSE's decision to proceed with it and implement it. He said new consultant posts would be advertised at this rate, which represented a €50,000 saving per consultant post. The Department of Health and Children have also commented that this move will pave the way for the appointment of more consultants which will directly enhance the care of patients in the health services and the greater provision of consultantprovided services.

The Minister for Health Dr James Reilly also welcomed the agreement reached with hospital consultants and health service management for 24/7 rostering where consultants will be available for rostering for any five days out of seven as opposed to weekdays only, as is currently the case. It should help in the organisation of day to day work in hospitals and provide greater capacity for efficient forward planning. The agreement also puts on a formal basis, a range of productivity flexibilities, which allows for considerable advancements in the use of hospital beds. These flexibilities should reach in the region of €200 million annually.

More information at: http://www.dohc.ie/press/releases/2012/20120917.html

Sweden: proposals for reorganisation of government agencies

The Swedish Government's Health Care and Social Services Inquiry (the Inquiry) has put forward proposals for the reorganisation of government agencies, which if enacted would lead to a 20% reduction in costs as ten agencies, one non-profit association and a state-owned company will be replaced by four new agencies. The Inquiry's remit had been to "... review how central government, through its agencies, can promote a longterm sustainable system of health care and social services focused on healthpromoting and disease-preventing efforts with the aim of promoting health and reducing ill-health and future care needs and bring about equal health care and social services throughout the country."

The focus in the Inquiry's terms of reference was on bringing about a clearer distribution of responsibilities and improved efficiency in the central-government parts of the system of health care and social services, both between the agencies and for national government as a whole.

The new proposed institutional structure in the areas of public health, health care, social services is based on four main tasks:

1. Knowledge that supports successive improvement efforts in the mentioned areas.

2. Regulation and supervision to ensure an acceptable quality to all providers.

3. Infrastructure for information

technology (IT) and communication.
4. Long-term strategic management.

The Inquiry proposes that the current ten government agencies (The National Board of Health and Welfare, the Medical Products Agency, the Dental and Pharmaceutical Benefits Agency, the Swedish Council on Technology Assessment in Health Care, the Swedish National Institute of Public Health, the Swedish Institute for Infectious Disease Control, the Swedish Agency for Health and Care Services Analysis, the Swedish Agency for Disability Policy Coordination, the Swedish Intercountry Adoptions Authority and the Swedish National Council on Medical Ethics), a non-profit association (Apotekens Service AB, provider of infrastructure services for operators on the re-regulated pharmacy market), and a state-owned company (the Swedish Institute of Assistive Technology) be replaced by the following four new agencies:

- The Knowledge Agency for Public Health, Health Care and Social Services.
- 2. The Inspectorate of Public Health, Health Care and Social Services.
- 3. The Infrastructure Agency for Public Health, Health Care and Social Services.
- 4. The Agency for Welfare Strategy.

The Knowledge Agency and the Inspectorate will work with groups within health care and social services such as the professions, responsible authorities, patients and services users. The Infrastructure Agency will support the development of IT and communications structures of the whole sector and assist the other agencies in the health care and social services sector. Finally, the Agency for Welfare Strategy will support strategic overview and policy. The proposals are currently out to consultation and it is proposed that a special Bill be presented to the Swedish Parliament for consideration at the beginning of 2013. If approved the new agencies would then begin work on 1 January 2014.

A summary in English and full report in Swedish available at:

http://www.regeringen.se/content/1/c6/19/28/99/2eaebcbd.pdf

Germany: Calls for stricter controls on organ transplants

German Health Minister Daniel Bahr has called for stricter controls over Germany's organ transplant system. The minister presented his plan for tighter independent control over Germany's transplant centres during an emergency meeting of leading health professionals on 27 August in Berlin. The minister met with representatives from all sixteen German states, health insurance providers, hospitals and medical associations to devise a plan to reform Germany's scandal-hit organ transplant system.

Of more than 50,000 transplants in recent years, only 31 were found to be in violation of the organ allocation system, according to the German Medical Association.

However, there are allegations currently being investigated that some surgeons have falsified medical files to speed up the supply of donor organs for paying patients. The adverse publicity has contributed to a marked drop in the number of organ donations. In the last year around 1,100 patients have died while waiting to receive organs and the rate of organ donation lags behind Spain, the US and France.

Hospital associations, health insurers and doctors are currently responsible for the system of organ donation and distribution. A key outcome from the August talks is the so-called 'six-eye' principle. It was decided that at least three people should be responsible for admitting patients onto the transplant waiting list. The result of this joint decision must then be thoroughly and clearly documented. All specialist transplant clinics will be examined by independent investigators to ensure there have been no irregularities and in future there will be regular unannounced inspections across the country.

The news comes just months after legislation was passed to try and increase the number of organ donations in the country. Health insurance companies now have to ask all adults over 16 at regular intervals whether they want to donate organs after their death.

A recent interview that Minister Bahr gave to the newspaper BILD am Sonntag where he responds among other issues to the organ transplantation crisis is available in English at: http://www.bmg.bund.de/ministerium/english-version/interview-bild.

Spain: 150,000 immigrants lose rights to public health services

On 1 September approximately 150,000 immigrants who do not have legal residency in Spain lost most of their rights to the public health care system, leaving them only with access to treatment in accident and emergency hospital departments, as well as care for pregnancy and child birth. As reported by the BBC in a recent speech, Health Minister Ana Mato has argued that the new measures relating to illegal immigrants' access to free public health care were "not driven by a desire to save money". She argued it was a question of Spain complying with European health regulations and ensuring that Spanish people received the same treatment abroad as those from abroad received in Spain. She also said that provisions would be made to ensure that certain diseases were controlled, including "chronic illnesses for foreign people without legal residency [in Spain]."

Some commentators have however suggested that the move is a cost cutting exercise as the government seeks to reduce its budget deficit and maintain membership in the Eurozone. Six of Spain's 17 autonomous regional governments, including Andalucia, Catalonia and Galicia, have pledged to ignore the legislation and will continue to provide health care to immigrants.

Speaking to the BBC, Professor Nuria Mas from Spain's IESE business school at the University of Navarra said that she believes the new law could increase the amount Spain spends on health care each year, because some illegal immigrants might avoid preventative or early treatments, which they would have to pay for. Emergency care can be more expensive. The new law will, she argues, make it "more difficult" for those people and may reduce the "pull effect" now and beyond Spain's financial crisis.

There has also been a tightening up of access to services for EU citizens living in Spain. As reported recently in the British newspaper *The Guardian*, authorities in Valencia have begun making British residents apply for new health cards. One British woman who spoke to the paper said that when she went to see her doctor to get a regular prescription for insulin she was told that she had been removed from the list. She needed to apply for health care again; it took three here three days of queuing for the necessary papers.

More information at: http://www.bbc.co.uk/news/world-europe-19487321

Norway: tobacco display ban law upheld by court

On 14 September the Oslo District Court ruled that a tobacco display ban does not constitute a barrier to trade, and even so, it can be justified for public health reasons. The Norwegian tobacco display ban came into effect 1 January 2010. Norway was sued by Phillip Morris Norway in March 2010, who claimed that the ban was incompatible with European Economic Area law (freedom of trade).

The Norwegian government argued that the display ban constitutes an important measure in order to further reduce tobacco use in general and smoking in particular. It is in line with the WHO Framework Convention on Tobacco Control, with new legislation in other EU and European Economic Area states, and it is substantiated by extensive research. The case was tried in the Oslo District court in June 2012.

Norwegian Minister of Health Anne-Grete Strøm-Erichsen said that she was "very pleased that the court agreed that a tobacco display ban is a legitimate and appropriate tobacco control measure", adding that "the Norwegian government will not let the tobacco industry influence our public health policy. It is a given that the tobacco industry are opposed to tobacco control measures that are effective in reducing tobacco use."

More information and access to the judgement in Norwegian and English at:

http://tinyurl.com/8fzk8ma

England: New suicide strategy and £1.5 million into prevention research

On 10 September, World Suicide Prevention Day, a new Suicide Prevention Strategy for England was launched. It will focus on supporting bereaved families and preventing suicide amongst at risk groups and is backed by a call to action led by the Samaritans and up to £1.5 million for new research. Six key areas for action have been identified:

- A better understanding of why people take their own life and how it can be prevented – supported by new suicide prevention research funding.
- Working with the media, and with the internet industry through members of the UK Council for Child Internet Safety (UKCCIS) to help parents ensure their children are not accessing harmful suicide-related websites, and to increase the availability and take-up of effective parental controls to reduce access to harmful websites.
- Reducing opportunities for suicide, by making sure prisons and mental health facilities keep people safer – for example by redesigning buildings to take away ligature – and by safer prescribing of potentially lethal drugs.
- Better support for high-risk groups such as those with mental health problems and people who self-harm – by making sure the health service effectively manages the mental health aspects as well as any physical injuries when people who have self-harmed present themselves.
- Improving services for groups like children and young people or ensuring the mental health needs of those with long-term conditions are being met through the Government's mental health strategy.
- Providing better information and support to those bereaved or affected by suicide

 making sure families are included in the recovery and treatment of a patient and giving support to families affected by suicide.

More information on the new strategy at:

http://www.dh.gov.uk/health/2012/09/suicide-prevention/

Russian Federation: New measures proposed to tackle smoking.

The Russian Federation has the second largest market for tobacco products after China, with almost 40% of Russians smoking in 2009. Deputy Health Minister Sergei Velmyaikin has estimated that the country loses almost 1.5 trillion roubles (\$46 billion) per year from tobacco-related deaths among people of working age. This is 2.5% of Gross Domestic Product (GDP), but is still conservative; it does not include the costs of treating people with tobacco-related diseases.

A number of new measures to tackle smoking are being developed.

On 3 September the Ministry of Health unveiled 12 graphic images which have been approved for printing on cigarette packaging from May 2013. They include a blue-tinted image of a dead baby and a graphic image of a blackened gangrenous foot. They will be displayed alongside words such as "Emphysema", "Cancer", "Misery", "Self-destruction", "Amputation", "Ageing" and "Stillbirth".

Four years ago Russia ratified the WHO Framework Convention on Tobacco Control. Two years later the country introduced large written health warnings on packaging. Most recently a draft law published on 31 August is calling for an immediate total ban on all cigarette advertising, ending retail sales at kiosks, and banning smoking in public buildings such as bars and restaurants by 1 January 2015. The draft bill will be submitted to Parliament in November.

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