Quarterly of the European Observatory on Health Systems and Policies

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Measuring efficiency in health care

- Identifying the causes of inefficiencies in health systems
- The challenges of using cross-national comparisons of efficiency
- Big data for public health
- SELFIE Framework: Integrated care for multi-morbidity
- Proportionality test for regulation of health professions?
- Investing in health literacy
- Increasing the health budget in Romania

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EUROHEALTH

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EDITORS' CORNER

Being able to measure efficiency is one of the cornerstones of assessing the performance of health systems, and can help to achieve several objectives, such as allocating resources in the best possible way to meet population needs and health system goals; maximising value for money in terms of the resources spent; contributing to improving quality of care for health services users; and improving population health outcomes.

Opening the Summer issue, our **Observer** section features two articles that explore central issues related to measuring the performance of health systems. First, Cylus et al. discuss the challenges of identifying the causes of inefficiencies in health systems, which entail not only defining but also interpreting health system efficiency metrics. Outlining the main aspects of some of these metrics, the authors propose an analytical framework that can operationalise the assessment process; they also apply it to an example to illustrate what particular metrics can and cannot tell us. In a complementary article, Papanicolas and Cylus look at the significant challenges involved in attempting to use international comparisons of various aspects of efficiency. Noting the scarcity of such comparative studies, the authors discuss different types of efficiency data, the availability of cross-country databases and some of the cross-country studies that have attempted to gauge aspects of efficiency at the health system level.

In a bumper **International** section, we begin with an article looking at how big data may have some potential to change the ways in which we receive treatment and transform health systems. Giedrojc and Lim discuss how our increasing understanding of the broad determinants of health, coupled with the daily use of digital technology, has generated big data that could ultimately be used to improve wellbeing. However, they argue that despite some good case examples, the use of big data in health is a new science with many obstacles yet to overcome.

Partners on the European Commission funded project, 'Sustainable integrated chronic care models for multi-morbidity: delivery, financing, and performance', so called SELFIE, present their framework. They assert that by better understanding integrated care programmes and facilitating a dialogue around continuation, implementation and financing – this type of care can benefit patients with multi-morbidity.

Turning to Health in All policies, an article by one of our editors, David McDaid, addresses the challenge of implementing effective health promotion and protection actions beyond the health sector. Using the example of health literacy, he explains how focusing on the benefits to the education sector, rather than health outcomes per se, can go a long way in promoting investment by other crucial sectors to public health goals.

Rounding off the section, Baeten provides some perspective on the new draft EU Directive which proposes imposing a proportionality test to the regulation of professions, including health professions. She argues that legal uncertainty on regulations may result from the lack of clarity as to what measure can withstand the test and proposes a different approach.

With a spotlight on Romania, the **Health Systems and Policies** section highlights some of the latest health system strategies being employed under the country's recently enhanced health budget.

We round off with the **Monitor** section which features new publications as well as some of the latest health policy news around Europe.

We hope you enjoy the issue and the summer!

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

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IDENTIFYING THE **CAUSES OF INEFFICIENCIES** IN HEALTH SYSTEMS

By: Jonathan Cylus, Irene Papanicolas and Peter C Smith

Summary: Persistent growth in health expenditures coupled with fiscal pressures have led to widespread calls for efficiency improvements. However, identifying the sources of inefficiencies in health systems remains challenging. In this article, we provide an analytic framework to facilitate better understanding and interpretation of common health system efficiency metrics.
To demonstrate its potential, we apply the framework to a simple efficiency metric comparing per capita health care expenditure to amenable mortality rates in the EU-28 Member States. This exercise highlights the information each metric can and cannot tell analysts and decision-makers. Going forward, more refined metrics should be developed based on more standardised and detailed cost accounting data and linked datasets and registries.

Keywords: *Efficiency, Health System, Efficiency Indicators, Outcomes, Performance*

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Why is health system efficiency important?

The concept of health system efficiency – as well as the related topics of cost-effectiveness and value for money – seeks to capture the extent to which the inputs to the health system, in the form of expenditures, labour, and capital, are used to secure valued health system goals. It is one of the most commonly debated dimensions of health system performance.

Inefficiency in any part of the health system leads to a number of undesirable consequences, including comparatively poorer outcomes for patients. If finite health system resources are not used efficiently it will also mean that some individuals are denied access to care. Taking a broader perspective, health system inefficiencies may divert resources from other sectors of the economy where the resources could be put to good use. In addition, not only does increased efficiency allow money to be spent more effectively, but the ability to eliminate waste also demonstrates good stewardship of the health system, which can persuade governments and citizens to finance universal health coverage.

The pursuit of efficiency is therefore one of the central preoccupations of health policy-makers and managers, and there is considerable evidence to suggest that inefficiencies exist in all health systems.

Figure 1: The simplistic view of health system production

Source: Authors

The World Health Report 2000 pointed to very large apparent worldwide variations in efficiency at the system level, a finding replicated by both the Organisation for Economic Cooperation and Development (OECD) as well as the European Commission.[1,2,3,4] In this article, we review the concept of efficiency and focus on interpretation of metrics, making use of a framework to facilitate analysis. For more detail please see our full volume on measuring health system efficiency produced by the European Observatory on Health Systems and Policies.[5]

Understanding production processes in the health system

Efficiency indicators are useful to compare and evaluate production processes. Taking a simplistic view, efficiency is represented by the ratio of the inputs an organisation consumes in relation to the valued outputs it produces (**see Figure 1**). An organisation consumes a set of physical resources, referred to as inputs, often measured in terms of total expenditures or physical inputs like health care personnel or beds; it then transforms those inputs into a series of valued outputs, such as an episode of care, through a set of discrete health care activities.

Any specific indicator of efficiency may seek to aggregate all inputs into a single measure of costs, or it may consider only a partial measure of inputs. For example, labour productivity measures such as 'patient consultations per physician' ignore the many other inputs into the consultation, and the many outputs other than patient consultations produced by the physician. In effect, such partial measures create efficiency ratios using only a subset of the inputs and outputs represented by the arrows in Figure 1. In short, the indicator shows only a fragment of the complete transformation of resources into desired outcomes (improved health).

Numerous other issues arise when seeking to develop operational models of efficiency in health care, reflecting the complexity of the health care production process. The production of the majority of health care outputs rarely conforms to a production-line type technology, in which a set of clearly identifiable inputs is used to produce a standard type of output. Instead, the majority of health care is tailor-made to the specific needs of an individual patient, with consequent variations in clinical needs, social circumstances and personal preferences. This means that there is often considerable variation amongst patients in how inputs are consumed and outputs or outcomes are produced. For example, contributions to the care process may be made by multiple organisations and caregivers, an 'episode' of care may occur over an extended period of time, and in different settings, and the responsibilities for delivery may vary from place to place and over time.

> although the core idea of efficiency is easy to understand it often becomes difficult to operationalise

Therefore, although the core idea of efficiency is easy to understand in principle – maximising valued outputs relative to inputs – it often becomes difficult to operationalise it when applied to real-life situations, particularly at the system level.

An analytic framework to facilitate interpretation of efficiency indicators

In light of the challenges in measuring efficiency and interpreting analysis, we have developed a simple framework to assist analysts seeking to understand and respond to efficiency concerns. Using this framework, five aspects of any efficiency indicator can be explicitly considered to clarify what precisely is being measured and to determine subsequent analysis or action (**see Figure 2**):

- the **entity** to be assessed;
- the **outputs** (or outcomes) under consideration;
- the **inputs** under consideration;
- the **external influences** on attainment;
- the **links with the rest of the health system**.

In the following sections we briefly discuss each aspect.

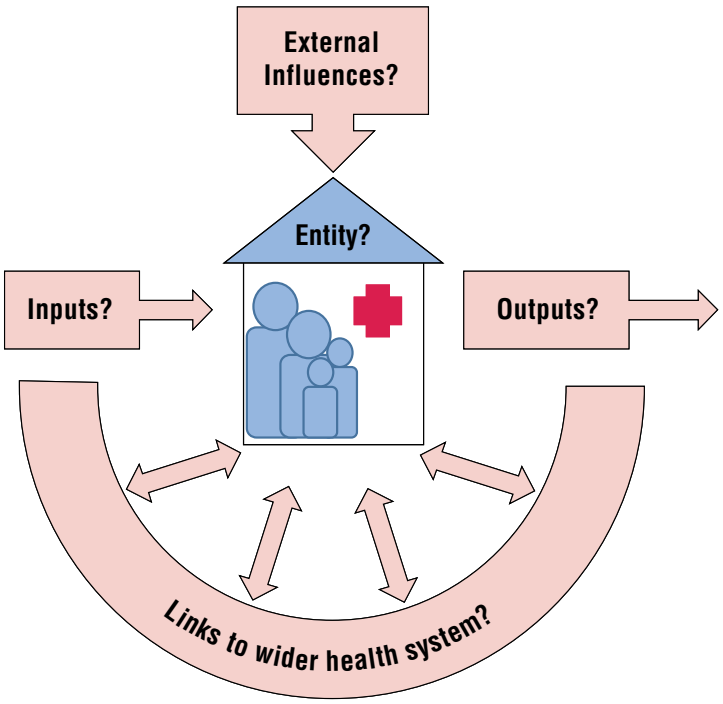
Identifying the accountable entity: who is being evaluated?

An assessment of efficiency first depends on understanding the boundaries of the entity under scrutiny. At the finest level, an entity could be a single treatment, where the goal is to assess its cost relative to its expected benefit. At the other extreme, the entity could be the entire health system. Most often, efficiency measurement takes place at an intermediate level, where the actions of individuals or groups of practitioners, teams, hospitals or other organisations within the health system are assessed. Whatever the chosen level, as a general principle it is important that any analysis reflects an entity for which clear accountability can be determined. It is also important that entities being compared are genuinely comparable and producing outputs under similar conditions.

What are the outputs under consideration?

Two fundamental issues need to be considered with regards to outputs: how should the outputs of the health care sector be defined and what value should be attached to them? In principle health care outputs should usually be defined in terms of the health gains produced. However, the concept of health gain has

Figure 2: Visualisation of analytic framework



Source: Authors

proved challenging to make operational. Recent progress in the use of patient reported outcome measures (PROMs) offers some prospect of making more secure comparisons, at least of providers delivering a specific treatment[6] and a number of well-established measurement instruments have been developed that could be used to collect before/after measures of treatment effects, such as the EQ-5D and SF-36.[7,8]

In practice, however, analysts are often limited to examining efficiency by measuring the volume of activities, for example in the form of patients treated, operations undertaken, or outpatients seen. Such measures are manifestly inadequate, as they fail to capture variations in the effectiveness (or quality) of the health care delivered. Yet there is often in practice no alternative to using such incomplete measures of activity in lieu of health care outcomes.

What are the inputs under consideration?

The input side is usually considered less problematic than the output side. Physical inputs can often be measured more accurately than outputs, or can be summarised in the form of a measure of costs. However, when considering costs as the input the implication is that the organisations under scrutiny are free to deploy inputs efficiently, taking account of relative prices. In practice, some aspects of the input mix are often beyond the control of the organisation, such as capital stock, at least in the short term.

Labour inputs can usually be measured with some degree of accuracy, often disaggregated by skill level. An important issue is therefore how much aggregation of labour inputs to use before pursuing an efficiency analysis. Unless there is a specific interest in the deployment of different labour types, it may be appropriate to aggregate into a single measure of labour input, weighting the various labour inputs by their relative wages. Additionally, with regard to labour inputs, problems may arise if the interest is in examining the efficiency of sub-units within organisations, such as, for example, operating theatres within hospitals. As the unit of observation within the hospital becomes smaller (department, team, surgeon, and patient), it becomes increasingly difficult to attribute labour inputs to that specific unit.

What are the external influences?

In many contexts, a separate class of factors affects production – the external or 'environmental' determinants of performance. These are influences on the entity, beyond its control, that reflect the external environment within which it must operate. For example, population mortality rates are heavily dependent on the demographic structure of the population under consideration and the broader social determinants of health. Likewise, a community nurse practicing in a remote rural area may appear inefficient when assessed using a metric such as 'patient encounters per month' if local geography limits the number of patients that can be visited.

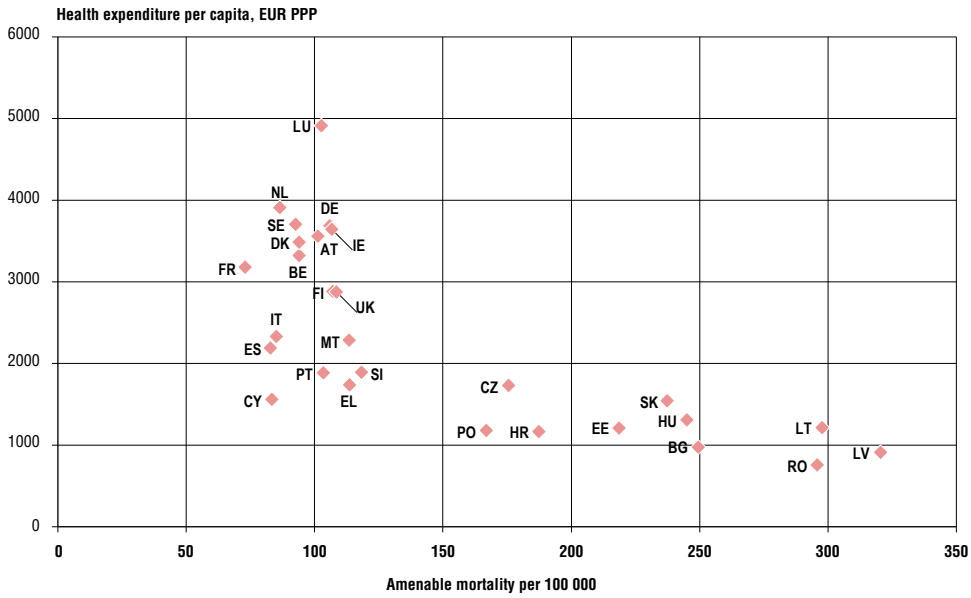
There is often considerable debate as to what environmental factors are considered 'controllable'. This will be a key issue for any scrutiny of efficiency and holding relevant management to account. The choice of whether to adjust for such external influences is likely to be heavily dependent on the degree of autonomy enjoyed by management, and whether the purpose of the analysis is short run and tactical, or longer run and strategic. In the short run, almost all input factors and external constraints may be fixed. In the long run, depending on the level of autonomy, many may be changeable. In many circumstances it will be appropriate to consider efficiency metrics both with and without adjustment for external factors.

Broadly speaking, environmental factors can be taken into account by restricting comparison only to entities operating within a similarly constrained environment; by modelling the constraints explicitly, using statistical methods such as regression analysis;[9] or by undertaking risk adjustment to adjust the outcomes achieved to reflect the external constraints.[10]

Links with the rest of the health system

No outputs from a health service practitioner or organisation can be considered in isolation from the rest of the health system in which they operate. Scrutiny of a health system entity in isolation, be it a team of surgeons or a hospital, may ignore the important implications of its impact on whole system efficiency. For example, if a primary

Figure 3: Amenable mortality and health expenditure per capita, 2013



Source: OECD Health Statistics 2016 and Eurostat.

care practice is held to account only by metrics of costs per patient, it might secure apparently good levels of efficiency by inappropriately shifting certain costs (such as emergency cover) onto other agencies, such as hospitals or ambulance services. The chosen metric may create perverse incentives for the practice, and may fail to capture its serious negative impact on other parts of the health system. That consequence should in principle be accounted for in any assessment of that practice's efficiency.

> No outputs can be considered in isolation from the rest of the health system

Applying the framework to compare health system efficiency in the European Union

To illustrate, we apply the framework to a crude metric that compares per capita health care expenditure to amenable mortality rates in the EU-28 Member States (**see Figure 3**). Countries towards the bottom right of the figure are spending low levels on health care but have very high rates of amenable mortality. Countries towards the top left have very low levels of amenable mortality but high levels of spending. Countries in the bottom left are low spenders that secure low levels of amenable mortality, and thus appear most efficient.

The framework demonstrates that this conclusion is not so straightforward. The *accountable entity* in this instance is an entire health system. One important consideration is that it is not clear that all of the countries included in the analysis are comparable to such an extent that their health systems have the same potential to produce health care outputs. In all likelihood the countries are not sufficiently comparable to be considered together given the multitude of differences, including how they organise health services and inherent differences in their populations' health needs. Some countries towards the bottom right of the Figure may be operating efficiently given their low levels of expenditure. It would be sensible to restrict the set of countries to those that are most comparable, or to only construct the figure for a single country using multiple years of data.

Moreover, the *output* considered is amenable mortality, which captures deaths that are considered avoidable in the presence of timely and effective care. This measure is attractive in the sense that it captures a valued health outcome and it is directly influenced by the quality and availability of health care. However the *input* is health care expenditure, which serves as an imperfect proxy for the health system's many inputs and especially for the inputs to amenable mortality. Additionally, health care expenditures go towards other outcomes besides amenable deaths; it is not possible to disentangle expenditure on conditions amenable to health care from expenditure on other minor conditions, such as glue ear. Amenable mortality rates are also affected by current health expenditure but are also affected by factors such as the prevalence of disease, which occur as a result of things like genetics, current and long-term health behaviours, and health care in previous years. No efforts are made to control for these and other *external influences* that undoubtedly play an important role in determining amenable mortality rates; this is something that should be done prior to drawing any conclusions about which system is most efficient.

Nevertheless, aggregate analyses like this can provide interesting information about how well systems are performing overall and can highlight unexpected variations that might not be observed by focusing on specific health care processes alone. Yet at the same time, these metrics are useful only as a starting point before conducting further analysis, since they cannot give any clear indication about where problems might be occurring *within the health system* and are susceptible to missing information. The location (e.g. provider) where an efficiency issue becomes apparent is not necessarily the area where policy-makers should take action if they want to make improvements.

Potential for health system efficiency evaluations in the future

The interest in health system efficiency has been heightened by the perception of high growth in health system expenditure in most countries and the widespread

belief that efficiency gains can be made. However, despite being one of the most fundamental health system performance concerns for researchers and policy-makers, the measurement of health system efficiency in practice is difficult to realise. It has proved challenging 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.

> A challenge to better information on efficiency is the lack of agreement on information standards and protocols

There is enormous scope for improvement in measuring efficiency. Conceptually, there is much work still to be done in creating indicators that conform to the usual requirements of specificity, validity, reliability, timeliness, comparability, and avoidance of perverse incentives. On the input side, there is a need for more consistent and more detailed costing of the care given to individual patients. Management accountants have a key role to play in this respect. On the output side, the use of PROMs might offer great scope for improved quality measurement. Furthermore, most indicators reflect only part of the patient pathway. The increased use of electronic health records, linked datasets and registries, capturing entire patient treatments, offers considerable scope for developing more complete efficiency metrics, capable of assessing the relative merits of alternative approaches to care.

A general challenge to better information on efficiency is the lack of agreement on information standards and protocols. Even within countries, there is considerable variation in interpretation of accountancy rules and the use of patient level information systems. International comparison is even more problematic, and there would be major gains if there could be international agreement on basic reporting and information standards, building on achievements such as EuroDRG[11] and the System of Health Accounts.[12]

Measuring the efficiency of health systems is therefore a challenging but worthwhile undertaking. Decision-makers who rely on inadequate analysis or interpretation of efficiency metrics to implement reforms may inappropriately target apparently inefficient practices. For example, an initiative to reduce the length of hospital inpatient stay may in some circumstances yield gains in terms of more intensive use of hospital resources. Yet in other circumstances this may be at the expense of serious additional costs for ambulatory health services, or even future readmissions to hospitals. Decision-makers therefore need to assess the balance of such risks when seeking to tackle inefficiency, and make informed judgements about how to reform their system. We believe the analytic framework presented here helps to facilitate the appropriate interpretation of the relevant efficiency metrics.

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THE CHALLENGES OF USING CROSS-NATIONAL COMPARISONS OF EFFICIENCY TO INFORM HEALTH POLICY

By: Irene Papanicolas and Jonathan Cylus

Summary: Many comparative efficiency metrics focus on scrutinising the operation of specific parts of a single health system. This article reviews the key issues involved in international comparisons of various aspects of efficiency. It examines data sources and analytic techniques used to create comparative indicators, and discusses approaches to interpreting variations. It also highlights key challenges and promising new initiatives, such as the consistent use of international definitions and technical developments, such as data linkages, which hold the potential to enhance work in this area.

Keywords: *Efficiency, Indicators, International Comparisons, Health Systems*

Introduction

As spending, demographic and technological pressures on health care continue to rise across health systems, the resources to meet these challenges are limited. This issue has produced a drive for policy-makers to identify and correct for inefficiencies in every aspect of health care – its delivery to patients, its technology, its business models and its policies. To monitor and pinpoint the causes of variability, it can be helpful to compare efficiency within, as well as across countries. Looking abroad, to comparative data on health systems which are designed differently, can be useful both for benchmarking as well as to try to gauge whether different types of health care delivery or policies may be successful at realising efficiency gains or improving health. As a result, for some time many policy-makers and researchers have been interested in developing metrics that are able to compare health system efficiency across countries.[1,2,3] However, despite the interest surrounding them, internationally comparable efficiency indicators are among the most elusive of health system comparative performance metrics; with a 2008 review noting that of all health care efficiency studies, only 4% were cross-country analyses.[4]

In this article we consider the availability of internationally comparative health system efficiency data, focusing primarily on measures of technical efficiency – i.e. the effectiveness of a given set of inputs to produce a given set of outputs or outcomes.[5]

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Types of efficiency data

We have already noted our interest in indicators that relate to a given set of inputs to produce a given set of outputs or outcomes. We do not consider allocative efficiency or dynamic efficiency as very few studies and datasets exist that collect or compare data on these types of efficiency across countries.

While our cross-country review includes both indicators that relate health system *inputs* (including but not limited to expenditures, personnel and beds) to a given set of health system *outputs* (including but not limited to physician visits and discharges), or health *outcomes*, we note that the distinction between health outcome-based and health care output-based indicators is important. Outcome-based approaches tend to be more policy relevant, given that what matters to patients and policy-makers is to obtain quality health services that will improve their health; however in practice, output-based indicators are easier to collect and more widely available and thus more commonly used.

Cross-country databases

There are few longitudinal, regularly updated databases that compare health system efficiency across countries. Key resources of comparable cross-country data are collected and regularly updated by intergovernmental organisations, such as the World Health Organization (WHO), Eurostat, and the Organisation for Economic Cooperation and Development (OECD). Member countries typically supply these organisations with their own national data, which are then reviewed and harmonised to ensure comparability across countries and time (OECD/WHO/Eurostat). Some resources such as the System of Health Accounts (SHA), for example, have made important advances on the input side to ensure that health care expenditure data are collected under a common framework and are comparable across countries.

Each of these databases is updated annually and covers a wide range of health care inputs (e.g. health care expenditure, physician density or hospital beds), outputs (e.g. hospital discharges) and outcomes (e.g. life expectancy or infant mortality) that can be used to compute efficiency metrics. In some cases, such as the OECD health data, the database contains only a few indicators that capture ratios of outputs and inputs, and which might allow efficiency comparison, such as average length of hospital stay or curative care occupancy rates.

> “policy makers need to consider the assumptions being made

While such indicators are often used to make direct efficiency comparisons across countries, they should be used with caution as the data will also include information on both potential inefficiencies, as well as differences reflecting case-mix of patients across countries, as well organisational differences reflecting different treatment patterns or settings (for example, definitions of an acute care bed differ across countries). As the data are not adjusted for these confounding factors, one would not be able to make an informed statement of whether differences in length-of-stay are due to more efficient practices or other factors. The case-mix issue can be partially accounted for by focusing on the length-of-stay for specific diagnostic categories, though this still cannot adjust for variations in case-severity within a diagnostic category.

Occasionally, some expenditure-based data, such as total health spending as a share of GDP, are used to compare efficiency across countries. These too should be interpreted with caution as they assume that health outcomes are identical across countries, so that using fewer resources implies greater efficiency. Despite the existence of few comparable efficiency metrics in most international databases, the large number of input and output/outcome information allows researchers and policy-makers to manually calculate simple efficiency indicators, such as metrics that relate health expenditure data to health outcome data, such as life expectancy or amenable mortality rates. Some studies even relate such ratios to manually constructed production possibilities frontiers*, to better assess efficiency.[6]

While these measures can illustrate variations across countries, policy-makers and researchers need to consider the assumptions being made when constructing such ratio measures, to best inform their correct interpretation. Outcomes such as life expectancy or avoidable mortality will be influenced by a host of factors outside of the health care system, making it difficult to conclusively attribute these ratios to differences in health system efficiency. While better quality data on health care quality and health outcomes is becoming available (through datasets such as the OECD Health Care Quality Indicators Project), it is still a challenge to find input data that can be directly attributable to the quality indicators collected.

Cross-country studies of efficiency at the system level

Although efficiency indicators are scarce in international health databases, there are a number of studies that compare health care efficiency across countries. These studies are often cross-sectional and not regularly reproduced. One characteristic that sets these studies apart from the databases discussed above is that these studies frequently employ analytic frontier methods to calculate efficiency scores. These methodological approaches can address some of the issues that otherwise inhibit comparisons, for example by accounting for multiple inputs to health production and adjusting for differences in production capabilities at various scales. However, while many analytic approaches have been taken, there is no consensus on the “correct” methodological approach. Many system-level studies have taken advantage of access to international harmonised

* A curve depicting all maximum output possibilities for two goods, given a set of inputs consisting of resources and other factors.

Box 1: Critiques of WHO World Health Report

Some critiques of the WHO study have illustrated that the choice of parametric and non-parametric approaches, such as Data Envelopment Analysis (DEA) or Stochastic Frontier Analysis (SFA) will influence the results of such an exercise,[3,8] as well as noting that such models will be sensitive to the assumptions made about how efficiency changes over time, and the data and methods available to model this.

datasets to compare efficiency, with their added value generally being the use of analytic techniques.

One of the first large studies to compare the efficiency of health systems was conducted by WHO to compare health expenditure per capita to life expectancy (adjusted to account for disability), after controlling for educational attainment [7] for 191 countries. The models use country-fixed effects, which take advantage of variations within each country over time to estimate parameters. An efficiency index was constructed, where the expected level of health, if there was no health care expenditure, is compared to the expected level of health if all health systems were as efficient as the best performer. Based on this analysis, only one country, Oman, is deemed to be efficient while Zimbabwe the least efficient.

The WHO efficiency study and related study of overall performance in the 2000 *World Health Report* [3] have been heavily criticised both on methodological and data quality grounds (**see Box 1**). Similar research using DEA methods and panel data regression have also been carried out by the OECD [9] and the European Commission [10] as well as by independent authors using available international data.[11] Yet despite the efforts to account for other inputs that have an effect on health outcomes, such as lifestyle, education or institutional characteristics, much of the variability in efficiency scores appears to be unexplained by health system characteristics or other factors. It is unclear how successfully confounders can be controlled for. Additionally, most studies take a very narrow perspective on the outputs of the health system, with the main products of the health system being life expectancy and infant mortality. It is noteworthy that there seems to be little consistency across studies in the countries that are found to perform most efficiently, despite studies frequently relying on the same datasets.

Cross-country studies of efficiency at the sector and/or disease level

Cross-country studies also compare sub-sectors (often hospitals) using available data, or utilise comparative instruments such as vignettes or diagnosis related groups (DRGs) to analyse similar patients and similar types of care using micro-level data. At this less aggregated level, because patient characteristics are often more homogenous than population characteristics, variations in outcomes are likely due to unobserved confounding factors to a lesser degree. There are also a number of outputs, such as hospital discharges or physician visits, which can be assessed that are not possible at the health system level. Common frontier-based analytic techniques, DEA and SFA, are also employed.

Studies in this area also vary in terms of what they compare, and which data they use. Some studies look at efficiency in hospitals, adjusting for differences in case severity and environmental factors.[12] Researchers have also compared efficiency for specific types of care provided within a hospital, often using DEA models, and performing specific analysis amongst countries with similar institutional arrangements [13] or access to similar high quality patient data such as registries.[14]

Health system efficiency has also been explored by examining the costs, resources, outputs and outcomes associated with treating specific diseases, the advantage being that patients treated for certain diseases are likely to be more homogeneous. Additionally, it may be possible to more accurately observe the processes that lead to differences in efficiency if the data are detailed enough. For example, the McKinsey Health Care Productivity study examined variations in inputs and outcomes for treating breast cancer, lung cancer, gall stones, and diabetes in the US, UK and Germany.[15]

Other European projects such as the HealthBASKET project reviewed the costs of care for nine European countries.[16] Using 'case vignettes' which describe particular types of patients (i.e. based on age, gender and co-morbidities), the study compared and attempted to explain variations in costs within and between countries. The advantage of this approach is that specific services for comparable patients could be costed and compared across countries. The more recent EuroDRG used an episode of care approach to compare costs across countries [17] based on the fact that most analyses of efficiency are unable to properly control for differences in case-mix. This study investigated the classification variables used by different country DRG systems, such as diagnosis, procedure, patient age, length-of-stay, death and the level of reimbursement for a selection of similarly defined patients based on episodes of care.

> "few regularly updated databases compare health system efficiency across countries"

Another recent project, the European Health Care Outcomes, Performance and Efficiency project (EuroHOPE) has made important advances in disease-based efficiency comparisons across countries.[18] This study uses linkable patient-level data, which allows for measurement of both outcomes (including follow up) and the use of health care resources (costs, days of care, procedures, and drugs) for comparable patient groups.

Key progress and remaining challenges

We find that while there are many different ways to conceptualise and calculate efficiency metrics, estimates do not generally lead to definitive conclusions regarding efficient health systems, providers or practices. Frequently collected metrics are simple, compare entire health systems, and are readily available in international databases, but because of their high level of aggregation, these metrics are not particularly useful for identifying determinants of inefficiency or developing appropriate policy responses. Advanced analytical tools are often used to construct more sophisticated system-level metrics based on data from these same international databases; however, their use of the same, limited datasets raises potential questions of their external validity.

Overall, there are few longitudinal, regularly updated databases that compare health system efficiency across countries. Available data is at an aggregated level, making it difficult to directly attribute output or outcome data to input data, or to properly adjust for confounding factors that might influence efficiency. Despite the common use of analytic methods such as DEA or SFA in multi-country efficiency studies we were not able to identify any regularly-updated longitudinal databases that employ these tools themselves in an effort to report efficiency scores that account for multiple inputs and outputs, or that control for factors exogenous to the health system. Current international databases are therefore limited to simple measures, primarily unadjusted ratios of outputs to inputs, to gauge cross-country differences in health care efficiency.

Cross-country comparisons of providers or sub-sectors allow for more detailed analysis and are a promising way forward, but are primarily focused on hospitals, with limited analysis of other types of care settings. Some of the most important gains have been made by disease-based efficiency studies; these studies capture variations in the costs, processes, and outcomes associated with treating particular diseases, and can often be linked to registry data containing non-health based characteristics (e.g. income, education, occupation). Longitudinal disease-based studies that take advantage of high quality patient-level data allow numerous observable non-health-related confounders to be controlled for when comparing the treatment of specific diseases across countries, providing important insight into health production processes.

Conclusions

While there has been considerable progress, much work remains before internationally comparable efficiency metrics should play a formal role in informing health policy. To ensure that international health system efficiency metrics do not misinform policy decisions, it is essential for continued efforts to enhance data quality, availability and comparability.

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BIG DATA FOR PUBLIC HEALTH: DOES THE DATA PROMISE A BETTER QUALITY OF LIFE?

By: Martyna Giedrojc and Roger Lim

Summary: Public health in the 21st century brings all stakeholders together in an organised effort to ensure the safe use of their data in a digital world. Big data holds the potential to transform and benefit public health and could lead to improved quality of life. It could open the door for more research and bring effective and tailored treatments for patients. It is no longer only about providing access to health care services and medication, but also about assuring a whole range of other factors, such as a stable social and economic situation, climate, as well as good housing and workplace conditions.

Keywords: *Big Data, Public Health, Quality of Life, Privacy, Digital Future*

Europe's digital challenges and public health transformation

The notion of what is considered public health has been changing. Previously, it primarily focused on addressing the need for sanitary conditions and the fight against infectious diseases. The next public health revolution was focused on changing individual behaviours contributing to non-communicable diseases and premature death. At present, public health is emphasising health as a key factor of quality of life. It means that future health moves beyond a focus on individual behaviour towards recognising the influence of a very broad range of determinants on health such as climate, social and economic development, culture, housing and workplace conditions.[1]

In line with that, European society has embraced new technology by transforming the ways in which we pay, shop, dine and travel. The use of digital technology in our daily lives has led us to generate massive amounts of data, which in the majority of cases are unstructured. Only recently have we been able to understand and have the means to use this data for health purposes. The current "big data revolution" has the potential to transform our health systems and change the way in which we receive treatment. Big data could lead to improved quality of life for people by providing them with crucial information about their future health and enabling them to take the necessary steps to prevent the onset of illness and thus stimulate behavioural change. As global society is becoming more digital, there are many challenges that need to be solved to ensure that Europe does not lag behind. Digital technology can enrich public health and care provision, thus allowing citizens to live longer and enjoy more healthy life years.

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What kind of data is desirable?

On the other hand, the notion of sharing personal data between people, facilities and companies for purposes other than treating the patient has raised many concerns regarding data privacy. Personal health data has become of great value for organisations and institutions which use it for research purposes. The list of companies interested in big data includes major pharmaceutical and medical devices players who use these data to tailor their health care products to the needs and demands of patients. In recent years, technology giants have been showing greater interest in providing health care solutions and have become large actors in the health care sector. These companies offer solutions for storing data in their clouds and they invest heavily in the development of artificial intelligence (AI) for health care. But the digital footprints of every click leave traces on the Internet: every piece of information has a value and by extension it also has a price on the health care market.

The health care sector is a data-intensive industry collecting information, such as clinical, genetic, behavioural and environmental data from an array of devices including electronic health records (EHRs), genome sequencing machines, patient registries, social networks and smartphone applications that monitor health. Gathering this wealth of information by tapping into different data repositories and being able to analyse it provides immense potential for improving the effectiveness and quality of health care for patients, possibilities for disease prevention, by identifying risk factors at population, subpopulation and individual level and improve medicine monitoring and patient safety. Big data for public health purposes could also encompass information from Internet clicks, queries in search engines, social media information, home monitoring, mobile transactions and socioeconomic indicators.[2] Such data can be analysed and linked with health data to create new datasets for analytical purposes. On the one hand, this can foster innovation and create patterns for new insights, but on the other hand it can be an assumption based only on data comparison. This assumption can be wrong as it does not take into account the behavioural aspect of collected data. The major concerns of big data for society are a decline of universal access to health care, growing inequalities and patients and health professionals' exclusion from the product development process, for the benefit of business development.

The people behind big data

The term big data is already well known and frequently used in scientific, political and corporate discussions at the European level. For example, its importance has been acknowledged by the European Commission in the "Study on Big Data in Public Health, Telemedicine and Health care":

"Big Data in Health refers to large routinely or automatically collected datasets, which are electronically captured and stored. It is reusable in the sense of multipurpose data and comprises the fusion and connection of existing databases for the purpose of improving health and health systems performance. It does not refer to data collected for specific study."[3]

The study, prepared by Gesundheit Osterreich Forschungs – und Planungs GmbH and commissioned by Directorate General Health and Food Safety (DG SANTE), highlights the need to communicate a positive picture of big data in health and to encourage people to get involved in the discussion. The Commission has also outlined the next steps towards a data-driven economy, by making sure that all citizens have a sufficient level of digital skills. This includes not only patients, health professionals, academics and medical industries, but the whole of society.

The use of big data in health is a new science full of promising case examples, but arguably there are still many obstacles that need to be overcome. While the use of big data for public health holds enormous promise, there are numbers of practical and legal hurdles that need to be worked out, such as data privacy and citizen's awareness of its ownership. The lack of transparency, uneven access to information and, unfair and discriminatory conclusions based on comparisons of data blocks with no specific questions in mind, feature among the key concerns, which could led to social and cultural segregation.[4]

Better use of data for health systems

The needs of our society are growing and citizens are becoming more demanding, therefore European health systems need to start adjusting to the new situation. Concerns about deteriorating health access are well-founded and the quality of health care affects public health in general. In practice, public health expenditure has been decreasing steadily since the onset of the financial crisis and patients' out of pocket expenditure has increased.

> Big data could lead to improved quality of life

Some countries monitor and measure their health systems by using the Health System Performance Assessment (HSPA), a tool to collect information and data to identify areas where health systems need improvements. The assessment captures and takes into account all aspects of health systems, especially indicators on workforce, health information systems, health determinants and, socio-economic and environmental factors in order to have a complete picture of health systems performance. The feasibility and effectiveness of HSPA depends on the existence of extensive comparable and reliable data sources, collected on a consistent basis in each country and the ability to compare the results amongst as many other countries as possible. The EU could focus on improving availability of indicators and making better use of those data that could be translated into comparable knowledge.

The advent of big data has important implications on further measuring the accessibility, effectiveness, efficiency and safety of health systems. Healthy life years and access to high-quality health care for those in need should be

the principles of every HSPA process. One of the difficulties is that national governments have the liberty to determine their own way of applying HSPA, for which there is no single accepted template at the European level yet.[5] This creates challenges for the comparability of indicators between EU Member States.

Outbreak control in favour of epidemiology

The process of providing an overview of the national legislation on electronic health records within the EU Member States and the introduction of the legal requirements for electronic health records implementation remains one of the most important priorities of DG SANTE.[6]

> “ensure safe use of data in a digital world

Furthermore, on 9 March 2017 the European Commission launched 24 European Reference Networks (ERN) covering more than 950 highly specialised health care units in 313 hospitals within 25 Member States and Norway. Its implementation is one of the most important and innovative pan-European cooperation initiatives in health care. These ERNs will help facilitate access to diagnosis and treatment by centralising knowledge and experience, medical research and training and resources in the area of rare or low prevalence complex diseases or conditions. The possibility to analyse data in medical research plays an important role in many other disease areas such as cancer or Alzheimers.

The secondary use of data has an enormous potential to better understand the human genome and allow researchers to sequence and analyse the latter in order to find out individuals' possible predisposition to certain conditions–for instance, cancer or other genetic diseases; to follow the course of infectious diseases; and to better grasp the overall resistance of the human body. To better understand the course of a disease, researchers need to track interactions between multiple genes. Big data use in the area of genetics might lead to a better understanding to predict specific health outcomes of populations in the future.[7]

The information for epidemiological purposes could be used to plan and evaluate future strategies to prevent illness and study the distribution of diseases among populations. As can be expected, only through access to reliable information can epidemiologists predict actions and create guidelines for the management of patients who already have existing health conditions.[8] With high quality data sources, tracking disease outbreaks can be simpler and faster, but a closer look at the source of the data is needed.[9]

Business innovation result in better treatment

Big data could open the door for more effective and tailored treatments for patients. That brings an opportunity for the development of new pharmaceuticals that respond to different patients individually, albeit coming at great financial cost. For example, innovation in the pharmaceutical field in view of the digital agenda and eHealth could be a key driver to safeguard the health, well being and lives of European citizens. It is likely to uncover unknown links between diseases, which can lead to medical recommendations based on new information. Big data can accelerate the development of new drugs and repurpose existing ones in order to tailor them to the needs of patients. It also fosters the creation of new data-focused businesses and health analytics.

While it brings a lot of opportunities, big data also raises some important concerns about its impact on the rights and freedoms of people, including their right to privacy. There is not enough transparency about the risk of constant monitoring of people's daily activities and about the logic of profiling, which could be used for marketing unhealthy products and behaviours, or even abused by unauthorised persons.

Data translated into quality of life

Big data presents a formidable opportunity and sizeable challenge to the development of digital health. The EU bolsters data-driven innovation and growth and in 2014, the European Commission launched its strategy on big data, which, according to the Vice President for the Digital Single Market will bring opportunities to more traditional sectors such as health care.[10]

To obtain a complete picture of data-driven health care, it is crucial to have a regulated and safe free flow of data between countries. Reliable data flow also involves cross-border health care, where information can be collected, exchanged or shared. The European Commission DG SANTE has been working closely with the eHealth Network, established under Article 14 of the Directive on the application of patients' rights in cross-border health care. It has created a voluntary network of national authorities responsible for eHealth, whose main activity is to improve eHealth interoperability, allowing data to travel smoothly between health systems. eHealth interoperability creates added value by linking up various data repositories in the EU, which could be tapped into for the purpose of research.

In the next few years, the eHealth Network's work on big data will focus on the real importance of public health and how data could contribute to the quality of life for all people living in Europe. For example, it could be used to create a better understanding of the causes of people's bad eating and drinking habits, lifestyle factors and stress, all of which exert a negative effect on physical and mental health.

Health in the 21st century ensures public health in a digital world

People tend to forget that technology is only a means to an end on the path to success in achieving better public health. In order to make the best use of digital technology for health we need to guarantee a whole range of factors.[1] It will not be possible to create effective, accessible and resilient health systems

and sustainable economies whilst dealing with a population that is increasingly unhealthy. Health, as one of the key preconditions for economic growth, has to be strengthened using many measures including healthy housing and workplace conditions and improving lifestyles, as well as maintaining good air quality.[11]

> “health systems need to start adjusting to the new situation

In the end, public health policy as such is not something that needs to be implemented only by public health authorities. To advance on health in the 21st century, all stakeholders should be aware and involved in an organised effort to ensure safe use of data in a digital world. Big data holds the potential to transform and benefit public health in the future, but it will be no longer only about providing access to health care services, institutions and medication, but about the bigger picture in which society understands digital technology, also taking into account the socio-behavioural aspects that influence quality of life.

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Portugal: health system review

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While overall health indicators for Portugal have notably improved in recent years, they still hide significant health inequalities, which are mostly related to health determinants, such as child poverty, mental health and quality of life.

Even though the Portuguese National Health Service (NHS) is universal, comprehensive and almost free at point of delivery, there are also inequities in access to health care, mostly related to geography, income and health literacy. The so-called health subsystems, the special health insurance schemes for particular professions or companies that exist next to the NHS, as well as private voluntary health insurance, provide easier access for certain groups.

Since the financial crisis, health sector reforms in Portugal have been guided by the Memorandum of Understanding that was signed between the Portuguese Government and three international institutions (the European Commission, the European Central Bank and the International Monetary Fund) in exchange for a €78 billion loan. Measures were implemented to contain costs, improve efficiency and increase regulation. Still, financial sustainability of the Portuguese health system remains a challenge. Due to cuts in public workers' salaries the increasing migration of health care workers risks to negatively affect the quality and accessibility of care. While several reforms are aimed at improving coordinated care and developing the use of Health Technology Assessment, there is still scope for increasing efficiency in the health system.

THE SELFIE FRAMEWORK FOR INTEGRATED CARE FOR MULTI-MORBIDITY

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Summary: There is an increasing prevalence of multi-morbidity, which is associated with lower quality of life and higher expenditures, and constitutes a challenge to current, often fragmented, care provision. Integrated care programmes appear to be a promising solution. However, the dialogue on such programmes needs to be streamlined to ensure continuation, wider implementation and sustainable financing. The SELFIE framework provides a means to ensure such a dialogue by structuring relevant concepts of integrated care for multi-morbidity. The framework can be used to describe, develop, implement and evaluate integrated care programmes for multi-morbidity.

Keywords: *Multi-morbidity, Integrated Care, Sustainable Financing, SELFIE Framework*

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Introduction

With the rapid increase in the prevalence of multi-morbidity there is a need for appropriate care provisions. People with multi-morbidity are often confronted with care providers from different disciplines, organisations, or even sectors.[1] Subsequently, individuals with multi-morbidity have been found to have a lower quality of life and greater health care utilisation.[2,3] Multi-morbidity has also become a serious challenge for policy makers responsible for the organisation, financing and provision of care. Integrated care, defined as coordinated, pro-active, person-centred, multidisciplinary care provided by well-communicating and collaborating providers, can offer the solution to providing multi-morbidity care.

SELFIE (**S**ustainable int**E**grated chronic care mode**L**s for multi-morbidity: delivery, **FI**nancing, and performanc**E**) is a Horizon2020 funded EU project that aims to contribute to the improvement of person-centred care for people with multi-morbidity by proposing evidence-based, economically sustainable, integrated care programmes that stimulate cooperation across health and social care and are supported by appropriate financing and payment schemes. More specifically, SELFIE aims to:

- Develop a taxonomy of promising integrated care programmes for persons with multi-morbidity;
- Provide evidence-based advice on matching financing/payment schemes with adequate incentives to implement integrated care;
- Provide empirical evidence of the impact of promising integrated care on a wide range of outcomes using Multi-Criteria Decision Analysis;
- Develop implementation and change strategies tailored to different care settings and contexts in Europe, especially Central and Eastern Europe.

The SELFIE consortium includes eight organisations in the following countries: the Netherlands (coordinator), Austria, Croatia, Germany, Hungary, Norway, Spain, and the UK. www.selfie2020.eu [Grant Agreement No 634288]

Increasingly, integrated care programmes for multi-morbidity are being implemented across Europe. A basic and essential starting point, however, is to understand these programmes, e.g., what does such a programme consist of, how does it work, how has it been implemented, is it effective, what can others learn from it? In order to have a successful dialogue on these programmes it is important to use a consistent framework that aids the description, development, implementation and evaluation thereof. Such a framework has been developed within the Horizon2020 EU-funded project SELFIE: Sustainable Integrated Chronic Care Models for Multi-Morbidity: Delivery, Financing and Performance. The SELFIE framework for integrated care for multi-morbidity was developed through a scoping review of scientific and grey literature and expert discussions in eight European countries. Specifically five types of experts were involved in these discussions: Patients (individuals with multi-morbidity), Partners (informal caregivers), Professionals, Payers and Policy makers (the 5Ps).

The SELFIE framework structures relevant concepts to consider in integrated care for multi-morbidity into a 'core' and micro-, meso-, and macro-levels of the six slightly adapted WHO health system components (**see Figure 1**).[4] Each is described below. The framework has been extensively described elsewhere.[5]

The core: the individual with multi-morbidity

At the core of integrated care for people with multi-morbidity is the holistic understanding of this individual in his or her environment. Attention to the individual's health, well being, capabilities and self-management abilities is needed. The basis for ensuring person-centred and tailored care is a focus on his or her needs and preferences. There is also a focus on several 'environmental' factors that interplay with the aforementioned factors: their social network, financial and housing situation, their community and the transport and welfare services available to them. A holistic understanding is something that is often made concrete through a formal assessment at multiple points in an integrated care trajectory.

Service delivery

At the micro level, service delivery pertains to person-centred, pro-active and tailored care provision, with attention for all that comes out of the holistic understanding/assessment. It is especially relevant in the case of multi-morbidity that continuity is ensured, which includes smooth and monitored transitions between professionals and organisations and attention to potential treatment interactions.

At the meso level there should be recognition for continuous quality improvement systems, which are a challenge in the case of multiple chronic diseases – appropriate indicators still need to be developed. Furthermore, to increase the sustainability of integrated care programmes, organisational and structural integration across sectors is beneficial. This can be realised not only through formal alliances or mergers but also through informal cooperative agreements.

> holistic understanding of the individual in his or her environment

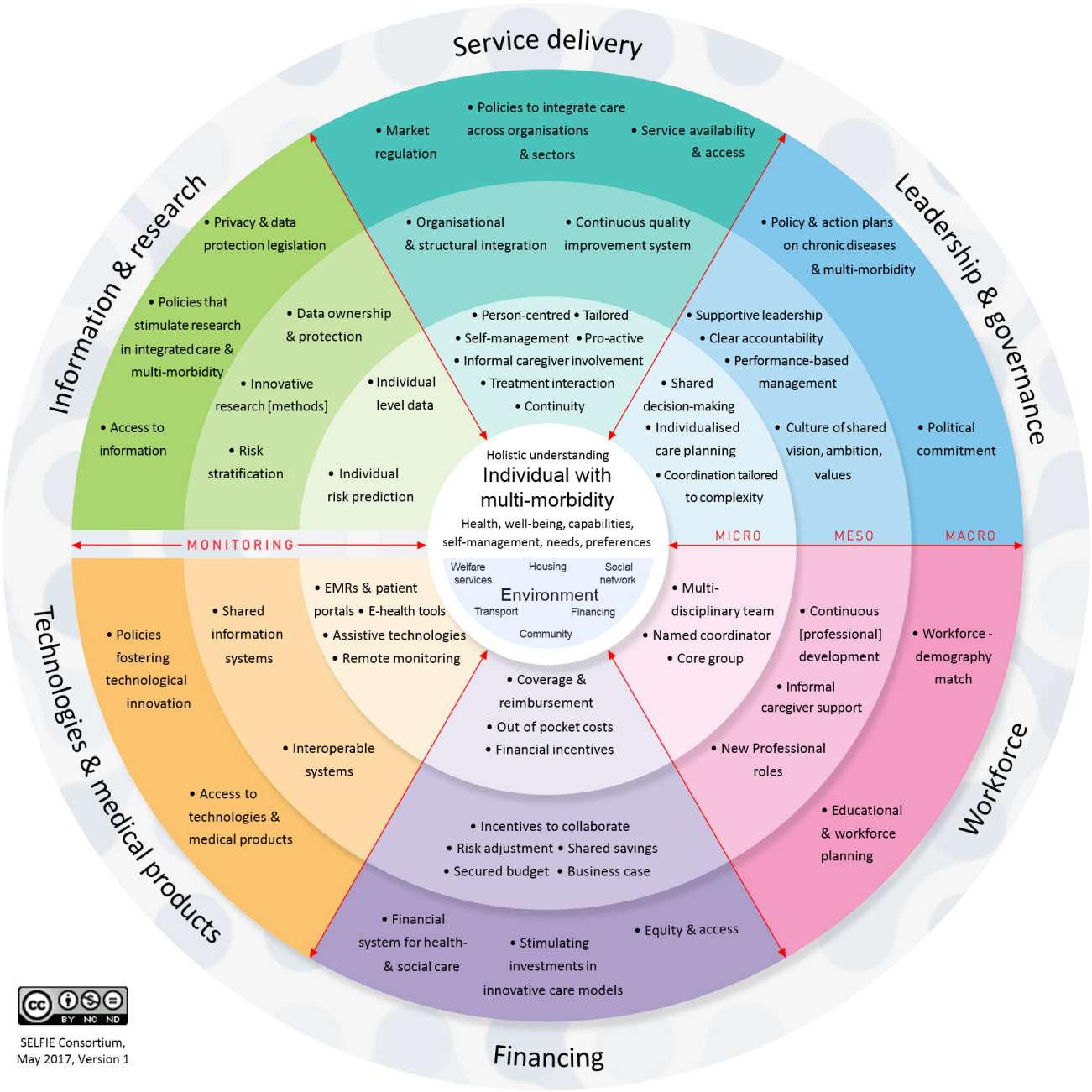
However, at the macro level policies that stimulate the integration of care across organisations and sectors are needed, meaning that market regulation that permits such collaboration needs to be in place. Policies that ensure service availability and access are also important to protect vulnerable groups – such as people with multi-morbidity, e.g., acceptable waiting times and reasonable travel times.

Leadership and governance

For persons with multi-morbidity different problems often occur simultaneously; thus prioritisation, individual care planning and tailoring are necessary. These should all occur throughout a process of shared decision-making between formal providers, informal caregivers and the individual with multi-morbidity.

At the organisational, meso level, integration can be facilitated by supportive leadership, organisational transparency and clear accountability. Collaborations that have a culture of shared vision, ambition, and values are more likely

Figure 1: SELFIE Framework for Integrated Care for Multi-Morbidity



Source: SELFIE Consortium, for more information see [5]

to succeed in the long run. Integrated care programmes could be supported by performance-based management on all levels, dis-incentivising opportunistic behaviour. Political commitment at the macro level can also facilitate the success of integrated care programmes.

Workforce

Integrated care for people with multi-morbidity requires teamwork that is multidisciplinary and, when needed, crosses organisational- and sectoral boundaries. Often, however, it is beneficial to distinguish a core team and a named coordinator that is the central contact point for the individual with multi-morbidity.

Professionals with a specialist background can benefit from continuous education and further development to help enhance their skills in managing people with multi-morbidity, e.g., teamwork, providing truly person-centred care, conducting holistic assessments, creating individualised care plans, and navigating the health- and social care systems. Professionals also need to focus attention on the informal caregiver and should organise the necessary support

for him/her. At the more organisational level it is also important to systematically consider new professional roles that are arising in the context of integrated care for multi-morbidity, such as physician assistants, specialised nurse practitioners, or social district support teams that take on case management.

The above requires educational and workforce planning, whereby new skills are taught early on in the curriculum. With an ageing society and an ageing care workforce, there is also a need to create a workforce-demography match, supporting sustainable employment of care providers and informal caregivers, who also need to remain in employment alongside their caregiving roles for longer.

Financing

Coverage and reimbursement of integrated care programmes or interventions need to be generous enough to ensure equity in financial access. Attention to out-of-pocket costs is also needed when it comes to financial access; these can take the form of co-payments, co-insurance, deductibles, and in some contexts also informal payments. On the other end, experiments with financial incentives to motivate persons with multi-morbidity to partake in integrated care programmes are also arising–for example, providing vouchers or free gym memberships. Reimbursement should allow professionals to spend enough time with individuals with multi-morbidity, whereby multiple issues at hand need to be addressed in a holistic manner.

Fragmentation not only occurs in service delivery, but also through the silo structure of financing of care for people with multi-morbidity.[6] Dominant existing payment schemes lack incentives to stimulate multidisciplinary collaboration and actually dis-incentivise addressing patients' needs. New payment systems are being introduced to tackle these issues, such as pay-for-coordination and bundled payments. The most comprehensive form to date is population-based payment, usually involving the definition of a virtual budget that is based on the case mix of the catchment population. When actual costs are lower than expected, these types of payments also allow for shared savings between organisations. For multi-morbidity it is essential that there is a risk adjustment in place to counter adverse selection and cream-skimming. For innovative integrated care programmes organising a basic secured budget may be an important facilitator to ensuring the sustainable commitment of all involved.

Such payment schemes, specifically for multi-morbidity and/or integrated care, need to be embedded in a supportive national or regional system that recognises their necessity and supports the further development of innovative schemes. Also at the macro level, attention is needed to safeguard access and equity for vulnerable groups in the payment system, such as those with multi-morbidity.

Technologies and medical products

Information and communication technology (ICT) can act as a key facilitator in integrated and coordinated care, although this is not necessarily a prerequisite. ICT applications relevant at the micro level include electronic medical records (EMRs) and patient portals. EMRs allow for information exchange between professionals, patients, and informal caregivers that link information and thus improve communication. This is, however, very complex for people with multi-morbidity that deal with different organisations across sectors. E-health tools, telemedicine, and assistive technologies also play a role here as they can allow individuals with multi-morbidity to live independently for longer.

A shared information system that is accessible by multiple professionals can facilitate care processes. A prerequisite is interoperable, or linked, information systems. At the macro level policies that foster technological development and innovation in the field of ICT and e-health can aid integrated care for multi-morbidity. Furthermore, equitable access to technological and medical products is important.

Information and research

Individual level data, as often automatically collected via ICT, can effectively be used in the care process. This includes automated notifications in information exchange (e.g., notifying primary care upon hospital discharge). Collected data can be used for individual risk prediction. Individual and group level information can also be used to apply risk stratification. Innovative research methods are needed and being developed that allow such data to be successfully used to increase the evidence-base of complex integrated care programmes for people with multi-morbidity.

Issues surrounding data ownership and protection come to the forefront in ICT, in all care fields, but perhaps even more so in multi-morbidity, again due to the different organisations and sectors (e.g., health- and social care) involved: what information can be shared with what professionals? These issues should not hamper the care process.

> "smooth and monitored transitions between professionals and organisations

Also at the macro level privacy and data protection legislation is important to consider. Policies that stimulate research can also benefit the status quo. Lastly, patient- and informal caregiver-access to information is especially relevant for multi-morbidity, as disease-specific information can easily be found online, but information on navigating different fields within the health- and social care sector (e.g., what is covered in an insurance package) is much more difficult, as well as information on treatment interactions.

Information and research can also be used as inputs for *monitoring* integrated care for multi-morbidity with a three pronged: improving population health, patient experience, and reducing costs.[7] The evidence-base for integrated care

programmes for multi-morbidity needs to be expanded in order to ensure wider implementation and sustainability of programmes.[8]

Curious to see how the framework has already been used? In the SELFIE project, 17 promising integrated care programmes for multi-morbidity have been extensively described in 'thick description' reports. These reports are based on document analyses and interviews with key stakeholders, and are structured according to the framework. The reports can be found on the SELFIE website (publications). www.selfie2020.eu

Conclusion

This framework structures relevant concepts and elements of integrated care for multi-morbidity. By grouping these into six components and three levels, the comprehensive framework can be applied in different contexts. Integrated care is not a noun but rather an active process that spans across different sectors and grows through time – the framework will also grow and change. It can be used as a starting point to develop and systematically describe programmes for multi-morbidity (micro-meso), and their target groups (the core) within their respective contexts (meso-macro). These descriptions can aid comparison and understanding that in turn can translate into other implementation processes. The framework can subsequently be used to evaluate programmes.

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The former Yugoslav Republic of Macedonia: health system review

By: N Milevska Kostova, S Chichevalieva S, NA Ponce, E van Ginneken & J Winkelmann

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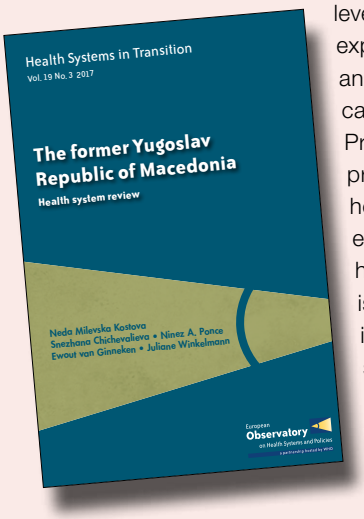
Since its independence in 1991 population health in the former Yugoslav Republic of Macedonia has improved significantly, with life expectancy and mortality rates for both adults and children reaching similar levels to those seen in ex-socialist EU Member States. However, death rates caused by unhealthy behaviour remain high.

The country has also made important progress in transitioning from a centrally-steered to a more market-based health system. Having inherited a large health care infrastructure, good public health services and well-distributed health service coverage, the country after independence reverted to a social health insurance system. Despite the broad benefit package, the levels of private health expenditure are still quite high and satisfaction with health care delivery is very mixed. Primary care providers were privatised and new private hospitals were allowed to enter the market. The public hospital sector in particular is characterised by inefficient organisation and service delivery. However, significant efficiency gains were achieved through the introduction of a pioneering health information system that has reduced waiting times and led to the better coordination of care.



More broadly, the impact of professionals moving to other countries and to the private sector is being felt. This is also why future reforms will need to focus on sustainable planning and management of human resources, as well as enhancing quality and efficiency of care.

TIME TO FOCUS ON BENEFITS BEYOND THE HEALTH SECTOR: THE EXAMPLE OF HEALTH LITERACY

By: David McDaid

Summary: Many actions to promote and protect health may be funded and delivered outside of the health sector. However, these actions may be seen as activities that may deflect valuable resources away from these sectors' core goals. Thus, while promoting Health in All Policies as a concept is appealing, in practice implementation can be difficult. The importance of looking beyond health outcomes becomes important when making a case for investment in health literacy actions targeted at children and young people. These outcomes and impacts are still too often neglected when arguments are being made for health in all policies.

Keywords: *Return on Investment, Cross-sectoral Investment, School-based Health Promotion, Health Literacy, Health in All Policies*

Introduction

A continuing challenge in health promotion is to facilitate the implementation of effective actions beyond the health sector. This can be particularly challenging if the non-health sector in question is expected to finance and administer the health promoting activity. External sectors may not see health promotion as a critical objective, but rather as something that may deflect valuable resources away from activities that are core to their own sector-specific goals. Thus, while promoting Health in All Policies as a concept is appealing, in practice implementation can be difficult. One way of overcoming this challenge and facilitating implementation may be to demonstrate that in addition to impacts on health there are substantial co-benefits to other sectors from investing in health related actions. This article illustrates this issue by looking at the potential benefits beyond the health sector of investing in actions to foster health literacy in young people. These themes have been discussed in more detail in a recent policy brief.[1]

The health benefits of good health literacy

Good health literacy can be thought of as having the knowledge, confidence and skills to seek out, as well as process, information to improve and protect health from a variety of sources. Too often people are not equipped with these skills: a survey of nearly 8,000 adults in eight EU countries found that 47% had inadequate or problematic levels of health literacy.[2]

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The beneficial impacts of health literacy interventions for health and lifestyles have been well discussed.[3] It appears particularly important to develop health literacy skills early in life to maximise potential benefits. Good childhood health literacy has, for instance, been associated with routinely having a healthier diet, and a better understanding and use of nutritional information on foods and drinks.[4] There are also positive impacts on mental health; building resilience in childhood through health literacy programmes can have a positive impact on psychological health and wellbeing across the life course, as well as reducing the severity of depression and anxiety problems experienced in adulthood.[5]

> helpful to point to evidence on the association between better physical health and educational attainment

Moving beyond health impacts

Nearly all children are educated in schools, meaning that school is a great setting in which to help enhance health literacy. In many countries, schools or ministries of education will have the responsibility for funding school-based health literacy programmes. It is important therefore to convey the benefits of such programmes to the education sector. The attention of policy makers can be drawn to growing evidence of the benefits to cognitive development and academic achievement associated with evidence-based social and emotional literacy/ learning programmes. For example, a major meta-analysis of school-based programmes delivered to promote pupils' social and emotional wellbeing found that these programmes were associated with a significant 11% improvement in academic performance.[6]

As well as specific evaluations of the direct impact of programmes that strengthen health literacy on educational and other non-health outcomes, it is important to look at the indirect relationship between better health behaviours, health status and educational outcomes. If health literacy interventions successfully influence health behaviours, then it is reasonable to infer that ultimately some further additional benefits to the education sector might be realised. To do this it is feasible to link two different sources of information:

(i) evidence on the effectiveness of health literacy programmes in respect of health behaviours and health outcomes; and

(ii) evidence on how changed health behaviours or health status impact on educational outcomes

For example, if health literacy actions do influence the physical health behaviours of children, then it can be helpful to point to evidence on the association between better physical health and educational attainment. There is a significant body of evidence indicating that children who are more physically fit and engage in aerobic exercise in pre-adolescence, have improved brain function and are likely to have superior cognitive performance and academic achievements compared with children who have low levels of exercise.[7] The obverse can also be emphasised: poor physical and psychological health have been associated with poor levels of educational achievement.[8]

Finally, although not of immediate concern to policy makers, it may still be helpful to note potential generational benefits of improved health literacy. In the very long term, better levels of education, due in part to higher levels of health literacy, will mean better outcomes for future generations of parents. Increased health literacy in the parents of tomorrow may also have a positive impact on the health literacy levels of future generations of children.

Assessing the economic impacts of co-benefits from health literacy programmes

It is also important to assess the economic case, including the return on investment, for the funding sector from health literacy programmes. Undoubtedly it is a limitation that there are few specific examples of the cost effectiveness of health literacy interventions for children.[9] However, this lack of published evidence on cost effectiveness or economic impact does not mean that nothing can be said about the economic impacts of health literacy programmes.

A first step is to ascertain the resources required to deliver programmes and attach costs to these programmes (**see Box 1**). Even if programmes have been shown to be effective in specific settings, policy makers will want to know what would be the economic cost of delivering the same intervention (perhaps adapted to take account of differing local circumstances) in their local context.

In the case of interventions delivered within the education sector, these costs may appear modest if interventions are implemented by teachers as part of the school curriculum in normal working hours, but there may be training costs to consider, as well any economic consequences of activities that are displaced from the school curriculum. If additional members of school staff or external service providers are needed to deliver health literacy programmes, then the costs will be much more substantial. There may also be costs associated with materials or technologies that are used to help engage with children, as well as any licensing fees that may have to be paid to use manualised literacy programmes. It is also important to identify any gaps in the current provision of services in order to then be able to estimate the resource requirements and costs of scaling up programme provision, and to determine which group or groups from which sector(s) would be responsible for paying for these programmes.

Box 1 also highlights the importance of identifying outcomes and resource impacts that are of direct interest to programme funders. A monetary value can be placed

Box 1: Information needed to determine the costs and economic impacts of delivering school-based health literacy programmes

- Undertake assessment to identify the extent to which aspects of health literacy programmes may already be delivered within the existing teaching curriculum.
- Estimate resource use, time and costs of implementation, including training. This should include determining whether programmes can be delivered by existing school staff (as part of current school day) or alternatively will need additional staff/external input.
- Determine who is responsible for funding literacy programmes: e.g. education ministry, individual school budget holders, ministry of health, local government, etc.
- In addition to health outcomes, identify sources of information on other outcomes and resource impacts that are of direct interest to programme funders.
- Identify resource unit costs to attach to changes in resource impacts relevant to programme funders.
- Determine short, mid and long term return on investment to programme funders.

on costs avoided by non-health sectors. From a school perspective these might include a reduction in costs of classroom disruption arising from the poor behaviour of some children. Better behaviour should also reduce the likelihood that teachers become stressed and take time off work, reducing costs associated with the employment of temporary or permanent substitute staff. There will also be savings to the education system if fewer children have to be educated in costly special educational settings as a result of a reduction in exclusions from mainstream schools.

The return on investment to different sectors, including programme funders, can then be calculated, recognising that the return on investment is likely to differ over time. It will take time to generate data on the actual return on investment of any programme; in the meantime, economic modelling techniques can be used to synthesise existing evidence on long-term effects and benefits and to project a return on investment. This approach has been used to influence health promotion interventions in many different country contexts.[10]

> A monetary value can be placed on costs avoided by non-health sectors

Previous evaluations of return on investment can also be cited. This can be illustrated by referring to the ten-year follow up of the effects of a universal, comprehensive, community-based social and emotional health promoting project for primary school children and their families in the Canadian Better Beginning Better Futures evaluation.[11] Not only did this evaluation look at health outcomes but it also documented improvements in educational performance, as well as a reduction in the need to repeat school years and use expensive special educational needs services. It also documented a decline in contacts with social welfare services by families. The overall economic analysis demonstrated that the programme had net benefits of €2,599 per family or around €2.50 for every €1 spent. Health care costs increased but these were more than offset by costs avoided due to the reduced use both of education and social welfare services.

Making it happen

This short article has argued that it is essential to look beyond health outcomes and health sector impacts when making the case for health promoting activities that are sometimes funded and certainly delivered outside of the health sector. This has been illustrated using the example of school-based health literacy programmes. The case for investment is strengthened when also looking at education-sector specific outcomes and impacts. The case is also strengthened for the use of mechanisms to overcome any financial disincentives to cross-sectoral collaboration. These outcomes and impacts are still too often neglected when arguments are being made for Health in All Policies.

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NEW DRAFT EU DIRECTIVE SUBMITS THE REGULATION OF HEALTH PROFESSIONS TO A PROPORTIONALITY TEST

By: Rita Baeten

OPINION PIECE

Summary: With a new draft Directive, the European Commission proposes to apply a general proportionality test on the regulation of professions, including health professions. Member States must prove that the measures they adopt are necessary to achieve a public interest objective, and that the result cannot be achieved by measures which are less restrictive to free movement. The lack of clarity as to what measure can stand this proposed test could lead to substantial legal uncertainty on regulations that can be crucial to preserving high-quality health services and universal access to care. Therefore, an adapted approach for health professions would be advisable.

Keywords: *Health Professions, Regulation, Proportionality, EU Directive*

Regulated health professions and EU integration

According to the European Commission, over 6,000 different professions are regulated across the European Union (EU), 42% of which are to be situated within the health and social services sector.[1] Regulation can make access to a profession conditional upon the possession of a specific professional qualification. It can submit the pursuit of that profession to certain requirements or standards and can reserve the use of a specific professional title to those who fulfil all these conditions. The objective is to reduce the information asymmetry between service providers and consumers and to protect the public from unqualified practitioners.

This is certainly also true for health professions, where Member States have traditionally tried to protect both patients and licensed health care providers. However, such nationally-set conditions can de-facto create barriers for professionals coming from another Member State. Indeed, the variation in regulations across the EU potentially obstructs the fundamental freedom of health providers to establish in another Member State or temporarily provide services there. This is why the EU established a European regulatory framework that ensures the mutual recognition of professional qualifications based on either a minimum harmonisation of training requirements or the coordination of access conditions and licensing rules. Within the boundaries

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Box 1: The Proportionality Principle

The proposal for a proportionality test requires Member States, when reviewing existing rules on regulated (health) professions or introducing new ones:

- to assess whether the provisions are necessary to attain a public interest objective,
- are suitable for securing the attainment of the objective pursued, and
- do not go beyond what is necessary to attain that objective.

set by the so-called Professional Qualifications Directive (PQD), Member States can continue to regulate health professions for as long as the conditions they impose are non-discriminatory and do not unduly infringe on the principles of free movement. In this respect, the Court of Justice of the European Union (CJEU) plays a central role as it interprets EU law and makes sure it is applied in the same way in all EU Member States. In its case law, the CJEU has made it clear that not only rules that discriminate against foreign trained health professionals can be liable to restricting free movement but also measures that equally apply to domestic professionals and providers from abroad. Consequently, almost any regulation can be challenged as a potential obstacle to the free movement of services.[2]

A proportionality test for the regulation of professions

In January 2017, as part of its Single Market Strategy, the European Commission came up with several initiatives to simplify procedures for cross-border service providers and to increase EU scrutiny on regulation in the services sectors. According to the Commission, unnecessarily burdensome and outdated rules can make it unreasonably difficult for qualified candidates to access jobs in other Member States. The proposed measures should make it easier for professionals to provide services in the EU, would benefit consumers, jobseekers and businesses, and would generate economic growth across Europe.[3] The package also includes a proposal for an EU Directive which introduces a general obligation for Member States to conduct an ex-ante proportionality assessment of any new or any amendments to existing provisions that are likely to restrict access to or the pursuit of regulated professions (hereafter 'the proposal for a proportionality test', **see Box 1**).[4]

The type of regulations referred to in the proposal for a proportionality test include: continuous professional development; language knowledge; reserving specific activities for professionals with a particular professional title; rules relating to the organisation of the profession, professional ethics and supervision; compulsory chamber membership, registration or authorisation schemes; requirements limiting the number of authorisations to practice, or fixing a minimum or a maximum number of employees, managers or representatives holding particular professional qualifications; and finally territorial restrictions, in particular where the profession is regulated in a different manner in different parts of a Member State. These kinds of measures are indeed applied in many health systems.

The importance of regulation in health care

Some specific features of the health sector require strong regulatory frameworks. First, in Europe health and access to health care are generally acknowledged as fundamental human rights. To guarantee these, public intervention and financing are considered necessary. Second, from an economic perspective the health care sector is characterised by significant externalities and market failures, which make it impossible to achieve an efficient market for health care. Indeed, patients generally lack the necessary background knowledge to make an informed decision about the care they need and the quality and effectiveness of the service(s) they receive. Since health care providers may have interests other than their patients, this information asymmetry makes the relationship very precarious. Health care providers have the unique power to induce demand and to set prices. Furthermore, since health care in the EU is mainly publicly financed, both patients and health providers might seek to respectively receive and supply more health care (moral hazard), due to the fact that the cost is mainly borne by a (public) third party. For these reasons, health care is a field with extensive regulation, aimed at addressing the important market failures in this sector, ensuring quality and safety of services delivered to patients, and achieving the most cost-effective use of limited public resources.

These are all valid reasons to justify public regulation. However, regulation of health professions can also be subject to regulatory capture. Regulatory capture is the phenomenon whereby regulation or regulatory bodies set up to safeguard the public interest may instead be 'captured' by the interest groups that dominate the sector it is charged with regulating, to protect specific corporate or private interests. In other words, health care providers may use regulation to avoid competition and sustain their incomes, which could result in scarcity of certain necessary services and inefficiencies.

Mutual screening exercise

With the last revision of the PQD in 2013, a new provision was introduced (Article 59), obliging Member States to list the professions they regulate and to explain why regulation is necessary. As a result during 2015–16, Member States carried out a mutual screening exercise, entering all regulated professions into an EU Database, with all the regulatory measures implemented for each profession notified. They had to examine whether their regulatory requirements were compatible with the principles of non-discrimination, necessity and proportionality, and had to justify any decisions taken as a result of this analysis to maintain or amend professional regulations. Other Member States and stakeholders were invited to submit their observations on these assessments. Furthermore, 12 professions were chosen as examples of different regulatory approaches, including four health professions: physiotherapist, psychologist, dental hygienist and optician. The Commission has published a sector report on each of these professions,[5] drawing on information communicated

by the Member States and discussions which took place during a meeting in 2015 on mutual evaluation for each sector. These sector reports call on Member States to assess in more depth the necessity and proportionality of specific requirements, most of which have subsequently been listed in the proposal for a proportionality test.

The proposal stems from the Commission's findings following this mutual screening exercise. The Commission considers this draft Directive necessary to enforce compliance with the proportionality principle as it argues that Member States in the mutual evaluation exercise repeatedly did not sufficiently demonstrate the proportionality of the measures imposed on professions.[6]

Back to the future: the Services Directive

This proportionality test closely recalls the heated discussions more than ten years ago that predated the adoption of the Services Directive in 2006 (**see Box 2**).[7] Under this Directive, Member States were also obliged to engage in a systematic screening exercise of their regulation of services (Article 15). The application to health services of the initial proposal in 2004 – in particular the screening under Article 15 – provoked serious controversy. The main criticism was that this proposal did not take into account the specificity of the health care sector, where extensive regulation is needed to correct market imperfections and to guarantee universal access to care. It was feared that the implementation of this draft Directive would lead to considerable legal uncertainty for public authorities, providers and patients. This finally led to health services being excluded from the scope of the Services Directive.

In its impact assessment of the current (2017) draft Directive for a proportionality test, the Commission clarifies that this proposal is complementary to the Services Directive and in particular that, in terms of scope, the Services Directive "does not cover the medical professions".[6] This seems to suggest that this is a new attempt to submit health sector regulation – or at least the part that deals with health professions – to the same scrutiny, from which it was excluded ten years ago.

Excluding health professions?

Whereas previously there were fierce reactions in both the Council and the European Parliament, today there appears to be much less political controversy around the current proposal. The Competiveness Council gave the Commission a mandate to provide an analytical framework for a comprehensive proportionality assessment of professional regulations, and reached a "general approach" on the proposal for a proportionality test[8] surprisingly fast and without much debate, which will serve as a basis to negotiate with the Parliament. In the European Parliament, the ENVI (Environment, Public Health and Food Safety) Committee which is the prime forum for investigating any EU initiative that affects public health, initially even decided not to put it on its agenda.

However, positions seem to be slowly moving. The ENVI Committee revoked its initial decision and is now preparing an opinion on the proposal for a proportionality test. Together with the JURI (Legal Affairs) Committee they are proposing to exclude the health

Box 2: Recalling the controversy over the Services Directive in 2006

This opinion paper shows that the concerns that led to the exclusion of health services from the Services Directive in 2006 apply in the same way to the proposed Directive for a proportionality test on regulation of professions. It argues that a specific approach for national regulation on health care professionals would be advisable.

Baeten R. Was the exclusion of health care from the Services Directive a pyrrhic victory? A proportionality test on regulation of health professions. OSE Paper Series, Opinion Paper 18, Brussels, OSE, 2017.

Available at: http://www.ose.be/files/publication/OSEPaperSeries/Baeten_2017_OpinionPaper18.pdf

professions from the scope of the proposal. Meanwhile, several national parliaments have adopted reasoned opinions stating that the draft does not comply with the principle of subsidiarity. In a resolution, the German Bundesrat requests an exemption for health professions or alternatively to take patient protection into better consideration.[9]

So far, the most vigorous stakeholder reactions to the proposal for a proportionality test have come from the EU-level organisations of some key health professionals. In a joint position statement the Standing Committee of European Doctors (CPME), the Pharmaceutical Group of the European Union (PGEU), and the Council of European Dentists (CED), are calling for the exclusion of health professionals' regulation from any EU-wide proportionality test. They express concerns about the lack of specificity in addressing the overall issue of health profession regulation, and are convinced that health professions should be considered distinctly from other professions. They argue that policy decisions relating to the regulation of the health professions must serve the objective of attaining the best possible quality of care for every patient and that under no circumstances should quality of care, access to care or patient safety be put at risk by policies driven by other agendas, in particular economic considerations.[10]

Towards an adapted approach for health professions?

A general proportionality screening could, in principle, help to clarify what objectives are really pursued in the regulation of health professions, and to distinguish between genuine general interest objectives and corporatist interests or national protectionist reactions. However, in the proposal for a proportionality test, as in European law in general, the regulation of health professionals, rather than being seen as a way of protecting patients, or inherent to the proper functioning of national health care systems, is viewed as an obstacle to the operation of the EU market.[11]

The lack of clarity as to the extent to which a specific approach for health professionals could be justified under the proportionality test, could lead to substantial legal uncertainty on regulation that can be crucial to preserving high-quality health services and universal access to care. Therefore, an adapted approach in the application of the free movement rules to national regulation of health professions would be advisable. Such a legal clarification should take into account the role of health professionals in protecting human life and health and their embeddedness in national publicly funded health systems.

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NEW MEASURES TO INCREASE THE HEALTH BUDGET IN ROMANIA

By: Silvia Gabriela Scîntee, Cristian Vlădescu and Cristina Hernández-Quevedo

Summary: Romania's health system is characterised by low funding and the inefficient use of public resources. There is a weak link between planning decisions and population health needs, due to a lack of appropriate information systems. The new government has increased the budget for health to: retain the health workforce by stopping the immigration of health workers, dedicate more funds to national health programmes, and ensure better access to medicines. It is hoped that the new measures considered by the recently-elected Romanian government will lead to better outcomes and that increased funding will lead to improved performance of the health system.

Keywords: *Health Budget, Workforce, Access, National Health Programmes, Romania*

Introduction

The new Romanian government, which came to power in December 2016, has increased the budget for health in order to achieve three main objectives on the health policy agenda:[1] retaining the health workforce by stopping immigration; dedicating more funding to national health programmes; and ensuring better access to medicines. These efforts are particularly relevant for a country characterised by an underfunded health system and it is the first time an increase in health care funding is linked to the stated objectives of the government.

In particular, the budget allocated for health in 2017 increased by 23.5%, compared to the budget in 2016 (from 30.28 to 37.4 billion lei / €6.7 to €8.3 billion), representing a total health expenditure of 4.7% of GDP (compared to 4% in 2016). The increased budget is dedicated mainly to improving access to medicines, initiating the building of three regional hospitals and procuring medical technology for hospitals and vaccines.[2] According to the 2017 budget, the Statutory Health Insurance budget administered by the National Health Insurance House (NHIH) takes up 77% of public funds dedicated to health. This is 10.4% higher than the previous year, with the main increase envisaged for home care (14.49%) and ambulatory care (9.89%).[3] These focus areas are in keeping with the National Health Strategy 2014–2020 of increasing the volume of services provided within ambulatory and community care settings and of rationalising the use of hospital services.[4]

Romania ranks last among EU Member States in terms of total health expenditure (THE) per capita (€PPP 816

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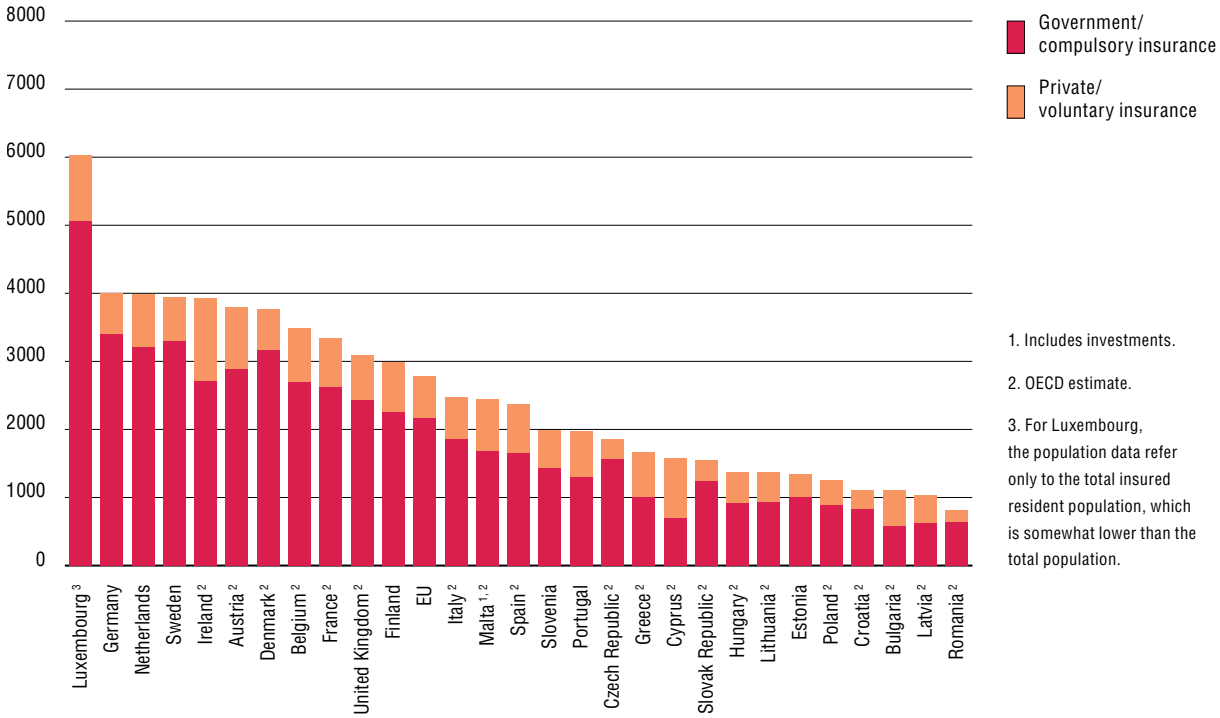
Figure 1: Health expenditure per capita in the EU (2014)



1. Includes investments.

2. OECD estimate.

3. For Luxembourg, the population data refer only to the total insured resident population, which is somewhat lower than the total population.

Source: OECD Health Statistics 2016; Eurostat Database; WHO, Global Health Expenditure Database.

per capita in 2015) and as a share of GDP (**see Figure 1**). THE as a share of GDP has been decreasing steadily since 2010, influenced by the spending cuts implemented to meet the country's fiscal deficit target and the unstable political situation. Public expenditure on health as a share of total public expenditure (11.9%) is well below the EU average (16.3%), although it has been increasing since 2011. The public sector accounts for the largest part of THE (78.9%), in line with the EU average (78.8%). Public sources account for 79% of total health financing, converging with the EU average.[5]

The Romanian health system in context

The Romanian health system is a social health insurance (SHI) system that has remained highly centralised despite recent efforts to decentralise some regulatory functions. The national level is responsible for setting general objectives, while the district level is responsible for ensuring service provision. The Ministry of Health (MoH) is the central administrative authority in the health sector responsible for the stewardship of the system and for its regulatory framework. District public health authorities (DPHAs) represent the MoH at the local level. Also at central level, the NHIH administrates and regulates the SHI system and it is represented at district level by district health insurance houses (DHIHs).[6]

> Increasing income alone will not stop immigration of health workers

Although SHI is compulsory, it covers only 86% of the population. Insured individuals are entitled to a comprehensive benefits package while the uninsured are entitled to a minimum benefits package, which covers life-threatening emergencies, infectious diseases, and care during pregnancy. Out of pocket (OOP) payments take the form of direct payments and informal payments. The share of OOP payments is the second largest source of revenue for health care spending (20%), while the contribution of voluntary health insurance (VHI) is marginal (0.2%).[5] The share of informal payments is thought to be substantial but unknown, although recent legislative changes, which heavily incriminates both making and taking informal payments, could have an impact.

New measures to increase the collection of funds

The 2017 budget increase for health relies on some recent measures. Since February 2017, the national minimum monthly wage has increased from 1,250 to 1,450 lei (from €278 to €322), and the average gross monthly wage from 2,815 to 3,131 lei (€625 to €696).[7] This follows the trend since the second half of 2015, where successive increases of salaries in some public sectors, such as health, education, social assistance, public administration, culture (ranging from 10% to 50% depending on the area) have been taking place. This latest measure is

expected to increase SHI contributions, as they are paid as a percentage from gross income (5.5% from gross salary and 5.2% from the employer, or 5.5% for the self-employed).

Previously, the way SHI contributions were calculated had a limit on the total salary base used, set at five times the average gross monthly wage. This favoured high earners who earned more than this. This measure was recently modified to eliminate the upper limit for the health contribution calculation base. According to the prime-minister, around 36,000 people with a monthly income higher than five average gross wages would now pay a surplus of 500 million lei per year (€111 million) to SHI.[8]

> Access to medicines is limited for patients on low incomes

On the other hand, some measures have been taken which are expected to have a negative impact on the SHI budget. These have an alternative aim of raising population living standards, such as exempting pensioners with a pension below €444.40 per month from making contributions and (from 2017) no longer counting some supplementary incomes, such as investments or bank deposits, as part of total income. Overall, the 2017 health insurance budget from contributions is estimated to increase by 10.6% (€5,233.7 million vs. €4,731.5 million in 2016). Besides this increase in the SHI budget, more funds are expected to flow into the system from introducing tax deductible health subscriptions for employees towards VHI, with a value of up to €400 per year.[7] While it is not clear whether the share of VHI will increase, the value representing the VHI expenditures is expected to rise with this measure. According to national health accounts, the share of VHI as a proportion of THE already increased from 0.2% in 2012 to 0.6% in 2014.[9]

Implications for new legislation

Retention of health workforce

Over the last decade, Romania has faced big waves of workforce emmigration. Although there is a lack of precise data, the MoH issued over 43,500 certificates of conformity for health professionals in 2016 that offer the right to work in another EU country.[10]

To counteract this trend, since 2015, there have been successive increases in health workforce salaries. In addition, the new government has set new allowances for different working conditions:[11] i.e. up to 85% of basic salary for those that apply outbreak control measures, those exposed to microorganisms and those that work in burns units; up to 70% for staff in emergency departments, intensive care units and psychiatric wards; up to 25% for staff in infectious diseases, new-born and maternity wards, laboratories, stroke units, neurology and neurosurgery wards; and other allowances between 5–15% for different personnel categories exposed to different ergonomic risk factors. These measures are currently under debate between specialists, particularly those who stand to lose out from the new allowances, for example, forensic medicine already receive allowances for working conditions of 100% of basic salary and under the new regulation their income will decrease. Moreover, a new law on salaries will come to force by January 2018 that aims to increase the average income for doctors to the equivalent of 70% of the EU averages.

Increasing income alone will not stop emmigration. Besides low salaries, the most common reasons for leaving the country include low levels of satisfaction with social status and lack of recognition, limited career development opportunities, and discrepancies between the level of competencies required and working conditions (equipment, access to consumables, drugs and modern diagnostic tests).[6] During 2016, a multiannual plan for human resources strategic development was developed, but was not officially adopted.

More funds for the national health programmes

Current national health programmes are not contributing enough to increasing the health status and satisfaction of patients. The preventive component is often weak and some important health problems, such as cardio-vascular diseases, are not included. Moreover, patients have difficulties accessing treatment offered under curative health programmes due to the fact that drugs can only be disbursed after a complicated authorisation process.[6]

The Government Programme for 2017–2020 includes the introduction of a national programme for early detection of cardio-vascular diseases and establishing a dedicated budget for the treatment of rare diseases. A first step in improving existing health programmes is to include patients with advanced fibrosis under the new treatment (interferon free) for Hepatitis C.

Another measure already taken is the simplification of drugs disbursement under the national health programmes. Previously, the process to obtain reimbursement was cumbersome; however, through a recent government decision, medical specialists are able to prescribe specific medicines under certain criteria. Patients now have rapid access to 106 drugs covered by SHI that previously needed authorisation. These latter measures have raised cost concerns as the authorisation process was the main mechanism for cost control of medicines. Since the health programmes have a dedicated budget but physicians have no prescribing limits, the system may face the challenge of accumulated debts. In response, the NHIH has prepared an online system for validating prescriptions based on a set of therapeutic criteria. Through the new system, the specialist fills out an electronic form sent instantly to the DHIH and after the confirmation is received, he/she may issue the e-prescription.

Ensuring better access to medicines

Access to medicines is limited for patients on low incomes by co-payments. Moreover, when a generic medicine (covered by health insurance) is not available, the patient must pay the full

price of the available product. Also new treatments may not yet be added to the reimbursement list.

> Romania spends less on health care than most EU countries

The new government has attempted to improve access to medicines on one hand by increasing the income of vulnerable groups, and on the other hand by decreasing the cost of medicines and increasing their availability. Thus, besides increasing the national minimum monthly wage and minimum monthly pension, it was decided that pensions under 2,000 lei (€444) are exempted from income tax (16%) and the health insurance premium (5.5%), leaving pensioners with more resources available for basic needs, including drugs.

Further, thirteen new innovative medicines are now covered, with or without co-payment, mainly for cancer, for conditions and diseases relating to blood and blood-forming, lung diseases, rare diseases, rheumatic diseases, and diabetes. New innovative drugs are included after a Health Technology Assessment evaluation of new molecules. Measures to reduce the price of medicines have also been proposed through changes in the pricing methodology, but this has raised opposition from the pharmaceutical industry. There may also be the risk of parallel exports if prices were to be reduced, which may further decrease access to those medicines.

Conclusions

Romania historically has committed a relatively low share of its GDP to health care. Part of the difference arises from Romania's relatively low public expenditures on health and part from low private expenditures. Most comparisons suggest that Romania spends less on health care than most EU countries and in parallel, health outcomes are lagging behind EU standards. Thus, Romania is facing several challenges, including user dissatisfaction, lack of access to quality care by the poor and other vulnerable groups, and decreasing numbers of medical staff. There is broad agreement within the Romanian community that investments in human development, and particularly in health and education, represent important factors contributing to the acceleration of Romania's convergence and integration with the EU.

The program of the new government includes measures to tackle some of the problems in the health sector, which aim to increase the quality and efficiency of health services delivery and to generate better health outcomes, including an important growth in the incomes of medical staff as a method of retention, together with the overall increase of the health care budget. These changes are expected to be developed in a financially sustainable manner, without neglecting the required fiscal consolidation. Whether these measures are sufficient to enhance the competitiveness of the Romanian economy and to reduce inequalities in health and access to health care services for the Romanian population, remains to be seen.

Romania: health system review

By: C Vlădescu, SG Scîntee, V Olsavszky, C Hernández-Quevedo & A Sagan

Copenhagen: World Health Organization 2016 (on behalf of the Observatory)

Number of pages: 170 pages; **ISSN:** 1817-6127

Freely available to download at: http://www.euro.who.int/__data/assets/pdf_file/0017/317240/Hit-Romania.pdf?ua=1

The Romanian population has seen increasing life expectancy and declining mortality rates, however both remain among the worst in the European Union. Some other troubling trends are also apparent; for example, although social health insurance is compulsory, only 86% of the population is actually covered. Those that do have such insurance should have access to a comprehensive benefits package, however, the population seems dissatisfied with both service delivery and quality.

Reform to tackle these and other issues affecting the Romanian health system has frequently proved ineffective, due in part to instability in health governance. Whilst efforts have been made to strengthen the role of primary care, health care provision remains characterised by under-provision of primary and community care and inappropriate use of inpatient and specialised outpatient care. Reforms have been hampered by the relatively low number of physicians and nurses, compared to EU averages, something attributed to the high rates of workers emigrating abroad over the past decade. However, measures introduced to counter these shortages do not seem to have made a difference.

Contents: Preface, Acknowledgements, Abstract, Executive summary, Introduction, Organisation and governance, Financing, Physical and human resources, Provision of services, Principal health reforms, Assessment of the health system, Conclusions, Appendices.

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NEW PUBLICATIONS

Health system efficiency: how to make measurement matter for policy and management

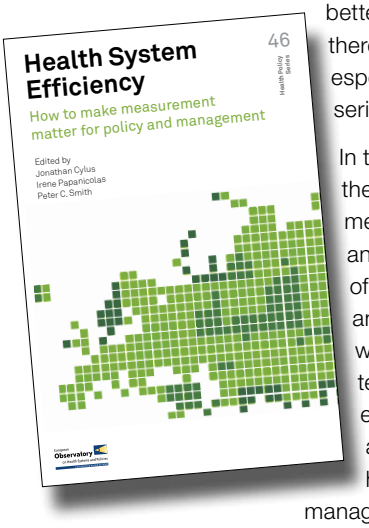
Edited by: J Cylus, I Papanicolas and PC Smith

Copenhagen: World Health Organization, 2016

Number of pages: xxii + 242 pages; **ISBN:** 978 92 890 50 418

Freely available for download: http://www.euro.who.int/__data/assets/pdf_file/0004/324283/Health-System-Efficiency-How-make-measurement-matter-policy-management.pdf?ua=1

Efficiency is one of the central preoccupations of health policy-makers and managers. Inefficient care can lead to unnecessarily poor outcomes for patients, either in terms of their health, or in their experience of the health system. Further, inefficiency anywhere in the system is likely to deny health improvement to patients who might have been treated if resources had been used better. Improving efficiency is therefore a compelling policy goal, especially in systems facing serious resource constraints.



In this book the authors explore the state of the art on efficiency measurement in health systems and international experts offer insights into the pitfalls and potential associated with various measurement techniques. The authors use examples from Europe and around the world to explore how policy-makers and managers have used efficiency measurement to support their work in the past, and suggest ways they can make better use of efficiency measurement in the future.

Contents: A framework for thinking about health system efficiency; Measuring and comparing health system outputs; Using registry data to compare health care efficiency; Management accounting and efficiency in health services; Measurement and policy; Cost–effectiveness analysis; Cross-national efficiency comparisons; Efficiency measurement for policy formation and evaluation; Efficiency measurement for management; Conclusions.

Targeting innovation in antibiotic drug discovery and development: the need for a One Health – One Europe – One World Framework

Edited by: MJ Renwick, V Simpkin and E Mossialos

Copenhagen: World Health Organization, 2016

Number of pages: viii + 126 pages; **ISBN:** 978 92 890 5040 1

Freely available for download: http://www.euro.who.int/__data/assets/pdf_file/0003/315309/Targeting-innovation-antibiotic-drug-d-and-d-2016.pdf?ua=1

Antimicrobial resistance is a global crisis that threatens public health and modern medicine. The discovery and development of novel antibiotic products are critical components in combating it. Many international, European Union and national initiatives address the scientific, regulatory and economic barriers to antibiotic innovation.

This study identifies, reviews and critically assesses these initiatives, and provides policy recommendations for improving the global and European agendas for research and development of antibiotics.

Contents: Foreword; Acknowledgments; Executive Summary; List of abbreviations; List of figures and tables; Objectives, Background, Research Methodology, Results, Discussion, Conclusions & Recommendations; References, Appendices.

NEWS

International

EU Semester process: country specific recommendations for health and care systems

The European Commission (EC) has published the 2017 Country Specific Recommendations (CSRs), the proposals for Member States which are part of the EU Semester economic governance process. Health is mentioned in recommendations for 17 countries. Most of these recommendations address the issue of the sustainability of healthcare systems, along with recommendations on reform.

Some of the issues addressed include strengthening community care and primary care (instead of hospital care), disease prevention and affordability of care. There are also references to informal payments and out-of-pocket expenditure. From an equity perspective, the reduction of (income) inequalities, poverty, and social exclusion, – particularly among disabled and older people, is highlighted together with the importance of improved social safety nets.

The recommendations are available at: http://tinyurl.com/ybrdzzgo

Nordic and Baltic countries gather to discuss intersectoral action to prevent child maltreatment

On June 1 and 2 a workshop was held in Riga, Latvia, on strengthening intersectoral working to prevent child maltreatment in the Nordic and Baltic countries. The workshop, a joint venture of the WHO Regional Office for Europe, the Nordic Council of Ministers and the Government of Latvia, focused on intersectoral collaboration involving the health, welfare, education and justice sectors. A total of 100 participants from these sectors, representing 14 countries, took part in the workshop. Participants were presented with good practices and evidence-based experience about what works for maltreatment prevention and how this can be implemented at a country level.

Child maltreatment is a leading cause of inequality and social injustice, with poorer and disadvantaged populations at higher risk. It is estimated that tens of millions of children and young people in the WHO European Region have been affected by sexual, physical or emotional abuse and maltreatment. The consequences are grave, with far-reaching effects on children's physical, mental and social well-being, yet it is estimated that only 10% of such maltreatment comes to the attention of protection agencies.

The United Nations Sustainable Development Goals recognise the importance of intersectoral actions to address this issue, setting the specific target (16.2) for eradicating violence against children by 2030. Many actions are only possible through intersectoral collaboration. These include creating safe environments, encouraging better parenting, changing norms, making preschool education available, implementing and enforcing laws on child maltreatment, reducing gender inequality and providing social support.

The European Child Maltreatment Prevention Action Plan is available at: http://tinyurl.com/y6vu8cw8

Action required to address widening child health and development inequalities

A new report from the United Nations Children's Fund (UNICEF), covering high income countries has found that one in five children lives in relative income poverty and on average one in eight faces food insecurity. The report – Building the Future: Children and the Sustainable Development Goals (SDGs) in Rich Countries – is the 14th edition of the Report Card series produced by the UNICEF Office of Research – Innocenti. It focuses on the ten SDGs considered most relevant to child wellbeing and uses comparable data sources on 25 indicators specifically selected to assess the status of children in high-income contexts. A composite league table summarises 41 European Union and Organisation for Economic Co-operation and Development (OECD) countries' performance across the full range of indicators. Sarah Cook, Director of UNICEF Innocenti called the report "a wake-up-call that even in high-income countries progress does not benefit all children."

As well as results on income poverty and food insecurity the report notes that neo-natal mortality has dramatically fallen in most countries; and rates of adolescent suicide, teenage births and drunkenness are declining. For some indicators – income inequality, adolescent self-reported mental health and obesity – the trends suggest cause for concern in a majority of rich countries. In two out of three countries studied, the poorest households with children are now further behind the average than they were in 2008. The rate of obesity among 11–15 years old and the rate of adolescents reporting two or more mental health problems a week is also increasing in the majority of countries.

Overall the Nordic countries, Germany, Switzerland, Slovenia and the Netherlands rank among the ten best performing countries, along with the Republic of Korea. Bulgaria, Romania, Turkey, Lithuania, Israel and Hungary are in the bottom ten countries, alongside New Zealand, the United States, Mexico and Chile. The UK and Ireland rank poorly in terms of child hunger; 34th and 31st respectively, in contrast to their overall rankings. 8% of 11–15 years old are obese or overweight in Denmark compared with 27% in Malta. The highest suicide rates in adolescents (more than 10 per 100,000 population) in Europe are found in Ireland, Finland and Lithuania. Only 14% of adolescents in Germany and Austria report two or more mental health issues per week, compared with 33% and 37% in Bulgaria and Italy respectively. In general although many countries have seen broad progress in a number of indicators, there are still wide gaps between them in other areas. National income levels fail to explain all of these differences: for example, Slovenia is far ahead of much wealthier countries on many indicators, while the United States ranks 37th out of 41 countries in the summary league table.

Based on the results presented in Report Card 14, UNICEF calls for high-income countries to take action in five key areas:

- Put children at the heart of equitable and sustainable progress; improving the well-being of all children today is essential for achieving both equity and sustainability.
- Leave no child behind; national averages often conceal extreme inequalities and the severe disadvantage of groups at the bottom of the scale.
- Improve the collection of comparable data; in particular on violence against children, early childhood development, migration and gender.
- Use the rankings to help tailor policy responses to national contexts; no country does well on all indicators of wellbeing for children and all countries face challenges in achieving at least some child-focused SDG targets.
- Honour the commitment to global sustainable development.

The report is available in English, French, Italian and Spanish at: https://www.unicef-irc.org/publications/890/

New report highlights poor conditions in Europe's nursing homes

In 2015, the European Network of National Human Rights Institutions (ENNHRI) started a project funded by the European Commission to increase awareness of the human rights of older persons living in or seeking access to long-term care in Europe, as well as to develop the capacity of NHRIs to monitor and support human rights based policies in this area. As part of the project, six members of ENNHRI (NHRIs in Belgium, Croatia, Germany, Hungary, Lithuania and Romania) carried out intensive monitoring within their jurisdictions, based on ENNHRI reports on human rights standards for older peoples' long term care and monitoring methodologies of NHRIs. They each drafted national reports, setting out their findings and recommendations. A new report has now been published identifying key trends relating to the human rights of the residents of long term care services. Sadly it documents some severe human rights abuses.

It points out that in many cases older people were admitted to care homes without their consent. In addition, some were transported down corridors in a state of undress, while bathing several residents at the same time was also a common practice. Some older people were also faced with verbal or physical aggression, lack of medical support such as dental care, insufficient daily meals and "prohibitive or hidden costs" for their care.

The report notes that as long-term care has become more pervasive, ensuring its quality has become an ever-pressing issue for local, regional and national policy-makers. It argues that it is essential to monitor residential and home care services on an ongoing basis to protect human rights. However the report states that few EU Member States have continuous quality monitoring systems, with independent regulators, in which human rights are taken into account.

More information on the project and the report are available at: http://ennhri.org/Human-Rights-of-Older-Persons-in-Long-Term-Care

Study: consistent association between depression in youth and risk of violence in Europe

Using data from three longitudinal studies in England, Finland and the Netherlands, researchers have found a consistent association between adolescent depressive symptoms and an increased risk of committing violent acts. The study, led by Rongqin Yu at the University of Oxford and published in the *Journal of the American Academy of Child and Adolescent Psychiatry,* found that there were positive associations between depression and subsequent violent behaviours, even after taking account of family status and any past history of violence. The increased risk of future violence ranged between 1.7 and 2.1 times that seen in young people who did not experience depression. The authors concluded that the study supports the case for better efforts at a population level for early identification and treatment of depression.

The open access paper is available at: http://dx.doi.org/10.1016/j.jaac.2017.05.016

Health and safety risks at the workplace: a joint analysis of three major surveys

A new report for the European Agency for Safety and Health at Work (EU-OSHA) presents the key findings of a joint analysis of EU-OSHA's second European Survey of Enterprises on New and Emerging Risks (ESENER-2), Eurostat's Labour Force Survey (LFS) 2013 ad hoc module on accidents at work and other work-related health problems, and Eurofound's Sixth European Working Conditions Survey (EWCS). The aim was to have a comprehensive overview of the state of occupational safety and health (OSH) in Europe by bringing together, on the one hand, the perspectives of establishments on risk management and risk awareness, and on the other, those of workers on exposure to risks and OSH outcomes.

The analysis found that exposures to risks, as perceived by employees, and particularly to specific environmental, musculoskeletal and psychosocial risks, appear to be important drivers of the management of OSH. Additionally, where employees have reported mental health problems, more attention had been paid to management of psychosocial risk in workplaces. The authors recommended that more focus be paid to strengthening employers' commitment and resources for the management of all OSH, including musculoskeletal disorders. More could also be done to strengthen employee participation in the management of OSH as improving formal employee representation is strongly associated with better OSH risk management. National and sectoral stakeholders could also support the development of risk assessment tools.

The report is available at: http://tinyurl.com/yardcf7b

European Commission opens first investigation into concerns of excessive pricing practices in the pharmaceutical industry

In the EU, national authorities are free to adopt pricing rules for medicines and to decide on treatments they wish to reimburse under their social security systems. Each country has different pharmaceutical pricing and reimbursement

policies, adapted to its own economic and health needs. The pricing of original medicines that are protected by patents is highly regulated. For off-patent medicines, Member States may directly influence prices of generic entrants, but also encourage competition to achieve lower prices. As a result, prices generally fall significantly when a medicine goes off-patent.

However on May 15 the European Commission announced that it had opened a formal investigation into concerns that Aspen Pharma, a global pharmaceutical company headquartered in South Africa, has engaged in excessive pricing of some cancer medicines. It is investigating whether Aspen has abused a dominant market position in breach of EU antitrust rules. The investigation concerns Aspen's pricing practices for niche medicines containing the active pharmaceutical ingredients chlorambucil, melphalan, mercaptopurine, tioguanine and busulfan. The medicines in question are used for treating cancer, such as haematologic tumours. They are sold with different formulations and under multiple brand names. Aspen acquired these medicines after their patent protection had expired.

The Commission will investigate information indicating that Aspen has imposed very significant and unjustified price increases of up to several hundred percent, so-called 'price gouging'. The Commission has information that, for example, to impose such price increases, Aspen has threatened to withdraw the medicines in question in some Member States and has actually done so in certain cases.

Aspen's behaviour may be in breach of the EU's antitrust rules (Article 102 of the Treaty on the Functioning of the European Union (TFEU) and Article 54 of the European Economic Area (EEA) Agreement), which forbid the imposition of unfair prices or unfair trading conditions on customers. The investigation covers all of the EEA except Italy, where the Italian competition authority already adopted an infringement decision against Aspen on 29 September 2016. The Commission notes that the opening of formal proceedings does not prejudge the outcome of the investigation.

There is no legal deadline to complete inquiries into anti-competitive conduct. The duration of an antitrust investigation depends on a number of factors, including the complexity of the case, the extent to which the undertaking concerned cooperates with the Commission and the exercise of the rights of defence. More information on the investigation will be available on the Commission's competition website, in the public case register under the case number 40394.

Eight EU countries commit to working together to secure affordable access to new medicines

In Malta on May 9 at the Third Roundtable meeting of EU Health Ministers and CEOs and Heads of Europe-based pharmaceutical companies, ministers of eight Member States – Cyprus, Greece, Ireland, Italy, Malta, Portugal, Romania and Spain – signed the Valletta Declaration. The signatories have agreed to work together to explore possible ways to guarantee access to new medicines for patients. A Technical Committee will be established, with the first meeting taking place in June in Cyprus. This group will explore possible areas for cooperation including information sharing, horizon scanning and possible price negotiations and joint procurement.

After the signing one of the signatories, Irish Minister of Health Simon Harris said, "since coming into office [in May 2016], I have seen the challenges our health service and, more importantly, patients have experienced in terms of access to new medicines at an affordable price. International collaboration is key to addressing this issue. The Valletta declaration marks a concrete step forward in this regard. Ireland will continue to build on this and our relationship with other member states in our efforts to secure affordable access for Irish patients to innovative medicines."

Impact of Brexit: Medical Devices and CE Marking

Medical devices are highly regulated and currently the UK legal framework that governs these devices originates from long-established EU Directives that have taken EU Member States decades to achieve. At present, medical devices can be marketed across Europe only once they have been issued with a Conformité Européene (CE) mark via the Medicines and Healthcare Products Regulatory Authority (MHRA) and its recognised Notified Bodies (of which there are five in the UK). In order for these bodies to function under the existing legislation, they must reside within the EU.

Thus the Institution of Mechanical Engineers (IME) has published a policy paper with recommendations on actions to be taken to reduce regulatory uncertainty as a result of Brexit. The IME stresses that ahead of the UK leaving the EU, it is imperative that the UK Government acts quickly to create a stable regulatory platform from which device manufacturers can implement any changes necessary to maintain their access to market. They recommend that the government negotiates a Med Tech compliancy arrangement with the EU to ensure continuity in the CE marking process for UK manufacturers. This arrangement they suggest should be supported by parallel policies to encourage long-term investment in the sector with the goal of attracting Med Tech small and medium sized enterprises to the UK through clear support for innovation and product development.

They further believe that UK industry and the National Health Service (NHS) must work together to ensure that they retain influence over future European regulation. This influence could flow from the purchasing power of the NHS but should also be based on more formal post-Brexit arrangements negotiated by the UK Government on its behalf. Finally they call for UK Research and Innovation to address the EU funding shortfall.

The policy paper is available at: http://tinyurl.com/ybcn9szq

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