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- Effectiveness and ethics of health incentives
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EUROHEALTH

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EUROHEALTH OBSERVER

2 EDITORS' COMMENT

Eurohealth Observer

3 TO NUDGE, OR NOT TO NUDGE, THAT IS THE QUESTION – David McDaid and Sherry Merkur

6 THE PERSISTENCE OF **HEALTH INEQUALITIES** IN MODERN WELFARE STATES: THE ROLE OF **HEALTH BEHAVIOURS** – Johan P. Mackenbach

10 PLANNING, IMPLEMENTING AND EVALUATING THE **EFFECTIVENESS AND ETHICS OF HEALTH INCENTIVES:** KEY CONSIDERATIONS – Harald Schmidt

14 **NUDGING AND SOLIDARITY: DO THEY GO TOGETHER?** – Barbara Prainsack and Alena Buyx

18 INFLUENCING **LIFESTYLE AND INSURANCE** **PREMIUM DIFFERENTIATION: THE ETHICAL DEBATE IN** **THE NETHERLANDS** – Marieke ten Have and Dick Willems

Eurohealth International

21 EFFECTIVE **POLITICAL STRATEGIES** IN **PUBLIC HEALTH** – Scott L. Greer and Denise F. Lillvis

Eurohealth Systems and Policies

25 MANAGING THE INTRODUCTION OF **NEW AND HIGH-COST** **DRUGS** IN CHALLENGING TIMES: THE EXPERIENCE OF **HUNGARY** AND **POLAND** – Danica Kwong, Alessandra Ferrario, Jakub Adamski, András Inotai and Zoltán Kaló

29 NEW **JOINT HOSPITAL PROCUREMENT** PROGRAMME IN **CROATIA** – Luka Vončina and Anna Sagan

Eurohealth Monitor

33 NEW PUBLICATIONS

34 NEWS

List of Contributors

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The last decade has seen an increasing interest in some countries of the potential of using behavioural science to inform our understanding and influence policy design. The **Eurohealth Observer** section kicks off with a look at the fashionable area of applying the principles of behavioural science to nudge populations towards better health and wellbeing. It discusses the growth in popularity of these health nudges and questions the evidence base on their effectiveness and cost effectiveness. It goes on to suggest where these principles may have a role to play in enhancing elements of health promotion and public health policy.

In an effort to set out the broad context on why health behaviours matter, Mackenbach discusses their role within the persistence and widening of health inequalities in modern welfare states. With observed disparities in smoking and alcohol consumption, the uptake of exercise and healthy diet linked to socio-economic status, it becomes apparent that tackling these risk factors with effective interventions could have an impact on the inequalities in population health status. Whether or not incentives to change health behaviours are desirable or ethical depends on a complex mix of factors. The article by Schmidt attempts to disentangle the salient issues by identifying four goals and ten key dimensions of incentive programmes. The tool kit provided is a first step to systematically analysing different types of incentives, and could supply the basis for comparing incentive programmes of similar design.

Prainsack and Buyx contribute to this debate by bringing in a unique perspective – that of solidarity. They argue that by focusing on what people have in common rather than what sets them apart, solidarity is particularly relevant and compatible with ‘nudging’ practices because it can foster sensitivity to social inequalities and safeguard against inappropriate stigmatisation of target groups. Providing us with a national perspective, ten Have and Willems discuss the current debate in the Netherlands on using incentives to influence lifestyle and promote better health, and whether or not health insurance premiums should be differentiated to take into account people’s unhealthy lifestyle choices.

In the **Eurohealth International** section, Greer and Lillvis look at the difficulties of establishing intersectoral governance for Health in All Policies. They go on to suggest potential

solutions for how policy-makers can create good functioning and enduring intersectoral governance to promote public health strategies.

Both of the articles in the **Eurohealth Systems and Policies** section reflect reforms to address budgetary pressures posed by the recent difficult economic climate. Kwong and colleagues discuss additional challenges faced by the health care payers in Poland and Hungary and how they have been confronted through pharmaceutical cost containment strategies. They also present the potential for risk-sharing schemes for medicines in the face of financial and performance uncertainty. Vončina and Sagan report on the newly implemented joint hospital procurement programme in Croatia. They describe the details of this decentralised approach and reflect on success in terms of the quality and the cost of procured goods.

Eurohealth Monitor features a new book on health professional mobility, which presents practical tools and policy responses in a changing Europe. Also featured is a new book on regulating long-term care quality that provides country-specific case studies to highlight policy options. As usual, the News section brings you a selection of national and international developments in the health sector.

We hope you enjoy the Summer issue.

Sherry Merkur, Editor

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TO NUDGE, OR NOT TO NUDGE, THAT IS THE QUESTION

By: David McDaid and Sherry Merkur

Summary: The use of techniques from behavioural science to nudge populations in subtle ways to choose behaviours and activities positive to their health and wellbeing is certainly fashionable. One question, yet to be resolved, is whether these nudges will become integral components of public health policy or just passing fads. There should be scope for nudging to play an important role augmenting other elements of health promotion and public health policy. This is likely to depend on whether or not the evidence base on the effectiveness and cost effectiveness of different types of health nudges, targeted at different population groups and in different settings, develops sufficiently.

Keywords: *Behavioural Science, Behavioural Economics, Health Promotion, Public Health, Nudge*

There are fads and fashions in all walks of public policy. Some of these fads will over time be recast as successful examples of radical and innovative thinking that have been demonstrated to be effective. They will go on to be mainstays of public policy for many years by successive governments. At the same time many erstwhile much heralded governmental interventions will eventually, albeit quietly, be consigned to that graveyard of failed or no longer ideologically sound policy initiatives.

Health policy-makers are no strangers to looking beyond orthodox approaches to the promotion and protection of public health. As this article will describe, the use of techniques from behavioural science to nudge populations in subtle ways to choose behaviours and activities positive to their health and wellbeing is certainly fashionable. One question, yet

to be resolved, is whether these nudges will become integral components of public health policy or just passing fads.

Governments have long had powerful tools at their disposal to influence population health, both directed ‘upstream’ at some of the underlying causes of poor health as well as at downstream challenges when poor health behaviours are already manifest. Actions might include income distribution policies or access to education. They will include legislation supported by enforcement actions, for instance to ban harmful substances or regulate what goes into our food. Fiscal policies have traditionally been used to increase the price of cigarettes and alcohol and less often to subsidise the price of health promoting products and activities. Governments will run health information and awareness campaigns; they may also

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take action to improve access to sports clubs and swimming pools, or invest in cycle lanes.

The problem is that any combination of these strategies will not work for everyone. Individuals can act in a way that economists would call irrational when it comes to health behaviours. For instance, many in society will be resistant to any changes in entrenched behaviours; they may be more influenced by peer pressure and addiction. Many people can have difficulties in weighing up the gains in participating in an unhealthy activity today, such as smoking, with the increased risks to health in years to come. A poor appreciation of risk is one reason why some individuals are highly optimistic about their chances of avoiding any future harm to their health. Individuals do not always respond and may be resistant to change their behaviours even in the face of significant financial cost.

“ little evidence to suggest that nudges are an alternative

There may also be social or environmental factors that make it hard to adopt healthier behaviours. Countering obesity may only require modest changes to physical activity and dietary habits, but these changes are still difficult for many people to adhere to, particularly for those living in an obesogenic environment with less active jobs and easy access to high energy density foods and sugary drinks. Yet legislation to restrict access to unhealthy foods may be seen by elements of the public as an unnecessary encroachment into matters of personal choice. These challenges have been used to argue for a greater focus on behavioural science applications that can influence the choices that we make. Can our choices be influenced in subtle ways that ultimately help society achieve more of its health policy goals?

The rise of behavioural science

Applying principles drawn from behavioural science to inform our understanding and influence health policy design is certainly in vogue. The award of the Nobel Prize for Economics to Daniel Kahneman in 2002 significantly raised the profile of behavioural science, while Richard Thaler and Cass Sunstein's book, *Nudge*, expounding on ways in which to make use of these insights came to prominence in some policy circles.¹ Subsequently in the UK, the Coalition government established a Behavioural Insights Team in the Cabinet Office to look at these issues in 2010.

The approach appears attractive to policy-makers. It does not involve compulsion yet in theory can powerfully persuade more individuals freely to engage in behaviours and activities that should be positive to their health and wellbeing. In fact much of this is not new, advertisers and retailers have relied on behavioural science for decades to influence our purchasing patterns and the prices that we pay for goods and services. Our general inertia has long been used by the banking industry to hook us into accounts with short term attractive interest rates, safe in the knowledge that very few of us will take the time and trouble to switch to a different account when the interest rate decreases.

Applications of nudges to health policy

So how has nudge been applied to health? Actions which make use of behavioural science can be targeted at the general population or at specific population groups. One example focused on the general population concerns organ donation – a number of countries including France, Portugal and Spain have systems where individuals have to actively choose to opt-out of the organ donation system. At least 80% of the adult population are listed as potential donors, in contrast to most of the UK where an opt-in system is in place and there is a donor rate of roughly 20%. Understanding this, in Wales from 2015 a 'soft' opt-in system of presumed consent to organ donation will apply; individuals will be able to opt out while alive but close friends and relatives will also be able to object in the event of a death.

Behavioural science can also be used to influence public health campaign messages. Prompts can encourage behaviour change, by changing the way in which the population define 'good' behaviour. One example of this has been the use of the simple slogan 'five a day' to encourage fruit and vegetable consumption in the UK. This has had some success in increasing consumption of fruit and vegetable by 0.3 portions per day between 2002 and 2006. Low income groups appeared to benefit at least as much as higher income groups.²

Another example of how public health campaigns can be altered by behavioural science is the LazyTown scheme. Operating since 1996, initially in Iceland but now broadcast in almost 100 countries, this television programme and mobile media application focuses on the antics of a healthy superhero character, Sportacus, who motivates children to eat healthily and be more active. Young children sign an 'energy contract' with their parents and receive rewards for eating healthily (fruit is labelled 'sports candy'), going to bed early and being active. In Iceland, the programme has been associated with a sustained reduction in the rates of childhood obesity, while between 27% and 42% of pre-school children in a trial in Iceland perceived LazyTown branded food to taste better than identical non-branded food. These findings indicate children's preferences for child-oriented wrapping rather than regular wrapping.³ While this fact has long been used as a tool by the food industry to market unhealthy foods, Lazytown suggests the same approach could be used as one element of a strategy to promote healthy eating among young children.

There are also approaches that are much more targeted at individuals rather than the general population. Financial and other incentives have also been used in an attempt to reinforce behaviour change, such as payments made for smoking cessation and weight loss. As Harald Schmidt points out in this issue, these incentive structures can be complex and it is impossible to draw one general conclusion on their effectiveness, this will depend on the nature of each individual scheme.⁴ In saying this, getting public acceptance of schemes that reward

bad behaviour may be difficult,¹ while schemes will need to be carefully designed to ensure that there are reliable, accurate and acceptable measures of behaviour change, and opportunities for gaming are minimised.²

In a variant on the financial incentive schemes, individuals can also make a formal commitment to change their behaviour through commitment contracts. In many of these schemes real money can be earned or lost depending on progress in achieving a stated health promotion goal. Evidence on the effectiveness of these contracts remains limited, although they are fashionable. Any health benefits achieved, such as weight reduction, tend to be lost when programmes end. This then begs the question as to how long contracts should be and whether they represents a good way of achieving any health promotion outcome. Does the longer timeframe help to habituate the changed behaviour or is it simply delaying the return to poor health behaviours? If the time needed to generate health benefits is short, then both financial incentive schemes and commitment contracts may be a powerful aid: for instance a review of six financial incentive schemes targeted at pregnant women indicates that smoking abstinence rates increase, with benefits for foetal growth, mean birth weight, number of low-birth-weight deliveries, and breastfeeding duration.³

Should governments use nudge or rely on budge?

There is certainly scope for governments to make use of insights from behavioural science in developing health policy. Behavioural science is undoubtedly fashionable but the techniques have long been used outside of the health sector, thus it makes sense to apply them in the health arena. What is crucial is the way in which these approaches are used.

At the heart of any health promoting policy must be actions to tackle social and economic factors that increase risks to health. Long standing public health actions, with fiscal policy, legislation and regulation at their core, have been shown to be highly cost effective in many areas of health promotion and disease prevention.⁴ There is little evidence to suggest that

nudges are an alternative to mechanisms used to ‘budge’ the population towards better health. Instead policy-makers must look at how they can apply nudges, to paraphrase an advertising slogan, ‘to influence behaviour choices that no other mechanisms can influence’. There is scope for nudging to play an important role augmenting other elements of health promotion and public health policy. A good example of this could be the introduction of stark warning images on packs of cigarettes in an attempt to reach some of the hard core of smokers immune to other mechanisms.

“influencing choices at the margin”

While the theories on behaviour change are well established, the actual application of theories and findings to public health policy is still developing. Much more needs to be done to build up this evidence base. It is important to build in evaluation to any implementation process, particularly given that actions may have more impact on some population groups than others, potentially widening health inequalities. There may also be other unintended positive or negative consequences of actions that need to be understood – for instance do those who give up smoking start eating more, and if so how can this be countered? Evaluating how these actions work in practice may also help in tailoring approaches to meet the needs of different groups, e.g. those from different cultural or social backgrounds.

Generally, in deciding on how to use scarce resources for health policy we are interested in assessing the cost effectiveness of different policy options. This remains somewhat of a black hole when it comes to evaluation of the use of ‘nudging’ tools; we know precious little about their value for money. Of course some tools may be almost costless or not borne by the health sector – take for example a decision to reduce the size

of plates used in a buffet restaurant, or a decision of a workplace canteen to provide pictures of balanced meals. Supermarkets may be willing to fund phased introductions of modified versions of supermarket trolleys to encourage the purchase of fruit or vegetables. However, many other nudging tools may have substantive development and implementation costs and we urgently need to build the evidence base on their cost effectiveness.

The way forward is to proceed with caution. Nudges can help society move towards health promotion goals by influencing choices at the margin, but they are no replacement for traditional stringent ‘budge’ measures such as taxation, legislation and regulation. Nudging has been a fashionable development. In early 2014, the high profile Behavioural Insights Team in the UK Cabinet Office was transformed into a private social purpose company whose mission is to help organisations in the UK and overseas to apply behavioural insights in support of social purpose goals. Their emphasis is very much on rigorous evaluation. If they and others can strengthen the evidence base, then nudging for health will avoid being a fad and instead become an established additional tool for health policy.

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THE PERSISTENCE OF HEALTH INEQUALITIES IN MODERN WELFARE STATES: THE ROLE OF HEALTH BEHAVIOURS

By: **Johan P. Mackenbach**

Summary: Despite the rise of the modern welfare state, health inequalities by socioeconomic position are substantial in all European countries with available data. One reason is that people with a higher socioeconomic position often are the first to abandon behaviours that are found to damage health, such as smoking and high-fat diets, or to adopt behaviours that are found to promote health, such as leisure-time physical activity. As a result, and as shown by recent European studies, inequalities in smoking, excessive alcohol consumption, diet, obesity and other factors are common, contributing importantly to inequalities in morbidity and mortality. Tackling inequalities in health-related behaviours therefore is key to success in reducing health inequalities. Although some examples of effective interventions are available, more research and development is necessary to develop adequate countermeasures.

Keywords: *Health Inequalities, Health Outcomes, Health Behaviours, Tobacco, Alcohol*

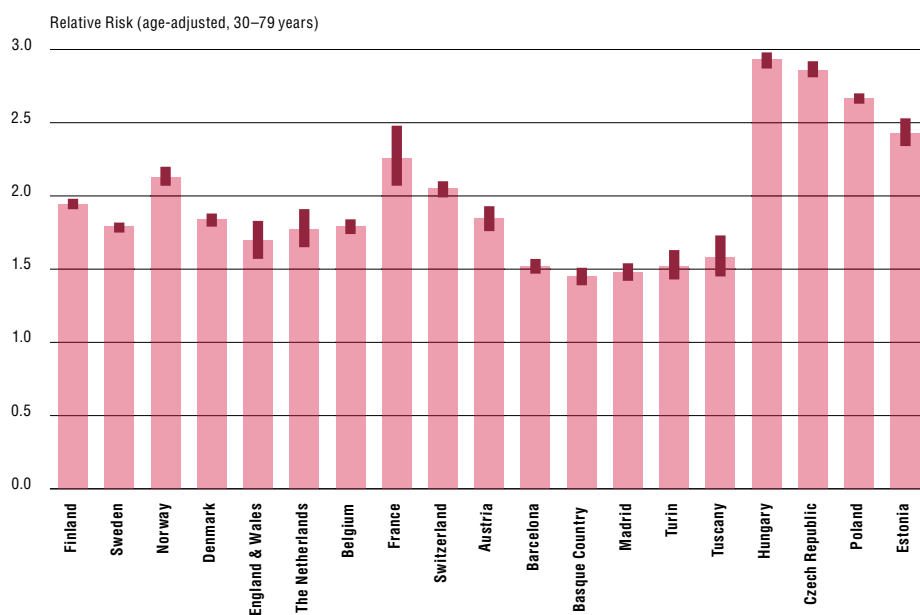
Health inequalities are surprisingly large

It is now widely known that people who have lower socioeconomic positions (indicated by their level of education, occupation or income) have, on average, shorter and less healthy lives than those who are better off. Indeed, life expectancy at birth often varies by five to ten years, with less educated and poorer people also spending ten to twenty more years of life

suffering from illness or disability.⁸ As **Figure 1** indicates, the magnitude of these inequalities varies considerably between European populations, with smaller inequalities in populations in Spain and Italy, and larger inequalities in central and eastern Europe. Nevertheless, inequalities in mortality are substantial everywhere, even in countries with highly developed welfare states like the Nordic countries.

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Figure 1: Relative inequalities in premature mortality, men 30–79 years, 19 selected European countries and regions, 2000s



Source: Unpublished data from EURO-GBD-SE project (<http://www.euro-gbd-se.eu/>).

Notes: A Relative Risk of, e.g., 2 indicates that the risk of premature mortality is twice as high among the low compared to the high educated. Vertical lines indicate 95% confidence intervals.

In the nineteenth century, this would not have been surprising, given low average income, widespread poverty and lack of social security. But it is surprising that such large inequalities are commonly found in high-income countries today, including those ranking high on indices of human development. Since the end of World War II, many countries have tried to reduce socioeconomic inequality, or offset its consequences, through progressive taxation, social security programmes, and a wide range of collectively financed provisions, such as public housing, education, health care and cultural facilities.

While there is no doubt that these policies have reduced inequalities in some social and economic outcomes, including income, housing quality and health care access, they have apparently been insufficient to eliminate health inequalities. Long-term time-series data indicate that the socioeconomic mortality gap narrowed in the first half of the twentieth century, but has grown again since the 1950s.² Even more puzzling is the fact that, as can be seen in **Figure 1**, countries with more generous welfare

policies, such as the Nordic countries, do not have smaller health disparities than other western European countries.

The explanation of a paradox

Many researchers have struggled to explain this paradox, and what emerges from the scientific literature is that the persistence of health inequalities in modern welfare states results from a combination of three factors.³ First, and perhaps most importantly, despite increases in average prosperity and some redistribution of income from higher income earners to those with lower incomes, inequalities in access to material resources have not been eliminated. The welfare state does redistribute lifetime income through taxation, cash transfers and non-cash benefits, but what remains of inequalities in material living conditions is still substantial, even where there are relatively small income inequalities as in the Nordic countries.

Second, social mobility, with children ending up in higher social positions than their parents, has been widespread in all high income countries. Due to this process of upward social mobility, the lower socioeconomic groups have not only

shrunk in size, but have also probably become more homogeneous in terms of disadvantage. The reason for this is that the more social mobility there is, the more opportunities there are for selection into higher social positions on the basis of personal characteristics like mental health, cognitive ability and personality. We know that these personal characteristics are important for health, e.g. because they determine health-related behaviour, and the increased importance of these selection processes will therefore tend to increase inequalities in health.⁴ This may be the case particularly in countries with well-developed welfare policies such as the Nordic countries, which usually also have egalitarian education policies.

Third, people with a higher socioeconomic position often are early adopters of new behaviours, only later to be followed by those with a lower social position.⁵ This also applies to health-related behaviours, and thus people with a higher socioeconomic position often are the first to abandon behaviours that are found to damage health, such as smoking and high-fat diets. Over the past decades, these behaviours have been pushed back in many western European countries, partly as a result of health promotion efforts, but during this dynamic phase large and widening inequalities in health behaviours have emerged, which in their turn have led to large and widening inequalities in mortality.

Inequalities in health-related behaviours

Significant disparities in smoking, physical exercise, diet, alcohol consumption, and several other health-related behaviours now afflict many of Western Europe's welfare states. Their welfare arrangements, which were created to combat poverty, obviously have been less effective against the causes of "diseases of affluence" like heart disease and lung cancer, which are often linked to modern consumption behaviour.

Among men, smoking nowadays is more prevalent among the lower educated in all European countries, with inequalities being particularly large in some of the Nordic countries. Among women, similar international patterns are seen, but in

southern Europe inequalities in smoking sometimes still have a “reverse” pattern, with smoking being more prevalent among the higher educated. Studies have shown that inequalities in smoking explain up to a third of inequalities in all-cause mortality, particularly among men.⁶

“Equal access to health care is certainly not enough”

While smoking is clearly bad for health, alcohol is a more complex risk factor: both abstinence and excessive alcohol consumption are bad for health (as compared to moderate drinking). Abstinence usually is more common in the lower socioeconomic groups but the pattern for excessive alcohol consumption is more variable. The clearest evidence comes from countries, such as some of the Nordic countries and central and eastern European countries, where ‘binge drinking’ is a major source of health problems. Binge drinking usually is more common in lower socioeconomic groups, and then makes an important contribution to the explanation of health inequalities, e.g. through a higher rate of cardiovascular disease and injury mortality.⁷

Dietary behaviours also vary systematically by socioeconomic position. Men and women in lower socioeconomic groups tend to eat fresh vegetables less frequently, particularly in the north of Europe. Differences in fresh vegetable consumption are smallest in the south of Europe, probably because of the larger availability and affordability of fruit and vegetables in Mediterranean countries. A similar north-south gradient has been found for inequalities in the consumption of fruit.⁸

Lack of leisure-time physical activity tends to be more common in the lower socioeconomic groups as well, as are overweight and obesity. Interestingly, this is one of the very few aspects of health where patterns of social variation are clearer for women than for men. Among

women, overweight and obesity are much more prevalent in lower socioeconomic groups in all countries with available data, and inequalities in overweight and obesity are largest in southern Europe where they make a larger contribution to the explanation of inequalities in mortality among women than smoking.⁹

The systematic nature of differences in health-related behaviour clearly demonstrates that these are not a matter of free choice, but must be determined by conditions which are at least partly beyond the control of the individual. The explanation of inequalities in smoking has been studied in some detail and the results of these studies point to a variety of specific factors that work together to produce a higher prevalence of smoking in lower socioeconomic groups. Because social norms in lower socioeconomic groups are more pro-smoking, adolescents from these groups are more likely to start smoking than their better-off counterparts, and they start at a younger age, leading to more nicotine dependence. Smokers from lower socioeconomic groups also stop less often, and with less success. Prevention of health problems at higher ages has less priority for people from lower socioeconomic groups, because they have more urgent problems to deal with – problems that are linked to their less favourable living conditions and higher exposure to psychosocial stress. Finally, tobacco control policies, particularly those relying on health education, have been less effective for smokers with a lower level of education or income.¹⁰

Partly different but equally complex explanations apply to inequalities in other health-related behaviours, and all of this highlights the need for creative solutions.

What to do about health inequalities?

This article has shown that modern European welfare states have been unable to stop the re-emergence of health inequalities, partly because of a failure to implement more radical redistribution measures, and partly because of concurrent developments which have changed the composition of socioeconomic groups and have made the reduction of health inequalities dependent on changes

in consumption behaviour. It follows that a substantial reduction of health inequalities can only be achieved by more radical redistribution measures, and/or a direct attack on the personal, psychosocial and cultural determinants of modern health inequalities.

In the last few decades, social policy in most Western European countries has moved away from redistribution. This is a mistake, given that the consequences of this shift – rising income inequality, weaker social safety nets and reduced health care access – will aggravate health inequalities in the long run. In fact, more and better-targeted redistributive policies are likely to be crucial to improving health outcomes in lower socioeconomic groups. For example, income support should be complemented by preventive health programmes, while health literacy programmes could help to diminish the link between low cognitive ability and bad health. Equal access to health care – still the main focus of health inequality reduction in many countries – is certainly not enough. Reducing inequalities in health outcomes requires more intensive health care for patients in lower socioeconomic groups, tailored to their specific needs and challenges.

Tackling inequalities in health-related behaviours probably is the key to success in reducing health inequalities. Unfortunately, we know very little about how to do this. Systematic reviews of smoking interventions covering price increases, access restrictions and smoking bans only found evidence for an inequalities-reducing effect of price increases. Whereas raising excise taxes may be effective, its regressive impact on the poorest smokers who cannot stop should be counteracted by active promotion of the use of nicotine replacement therapy and other forms of smoking cessation support. Revenues from tobacco taxation could be used to fund cessation-support programmes that target disadvantaged smokers. A national programme which created smoking cessation services in disadvantaged areas in England has effectively reached disadvantaged smokers and has somewhat reduced the gap in smoking.¹¹

Generally speaking, supply-side interventions are likely to be more effective in reducing inequalities in health-related behaviours than demand-side interventions. For example, Finnish nutrition policies have followed the Nordic welfare ideology where universalism has been the general principle. School children, students and employees in Finland receive free or subsidised meals at school or in the workplace, and special dietary guidelines have been implemented to ensure the use of low-fat food products. This has contributed to a favourable trend of narrowing socioeconomic inequalities in the use of butter and high-fat milk in Finland.¹²

As these examples show, tackling inequalities in health-related behaviours is possible, but it will require sustained efforts underpinned by systematic evaluation.

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New Policy Summary on Addressing needs in the public health workplace in Europe

By: Vesna Bjegovic-Mikanovic, Katarzyna Czabanowska, Antoine Flahault, Robert Otok, Stephen Shortell, Wendy Wisbaum and Ulrich Laaser

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One of the primary challenges facing European health systems is the need for a multidisciplinary public health workforce supported by new skills and expertise. This policy summary aims to outline these needs and to consider measures and options towards meeting them.

Starting off with a snapshot of the current workforce and training provisions in different European health systems, the policy summary goes on to discuss positive efforts to promote public health training and education such as the Bologna Process and the WHO Regional Office for

Europe's *Health 2020* policy. However, large gaps are apparent in both the numbers of professionals trained and the kind of training that exists. The discussion then turns to the need to agree upon core and emerging competences for a well-equipped workforce, including the important role of

employers in determining these competences. In addition, public health education needs to include a wider range of health-related professionals, including managers, health promotion specialists, health economists, lawyers and pharmacists.

Identified and agreed-upon competences can, in turn, be translated into competency-based training and education,

necessary to equip current public health professionals with the skills required in today's competitive job market. New developments in public health training, include flexible academic programmes, lifelong learning (LLL) which is vital for employability, and accreditation. Seven case studies present examples of current developments and practices.



PLANNING, IMPLEMENTING AND EVALUATING THE **EFFECTIVENESS** **AND ETHICS OF HEALTH** **INCENTIVES: KEY CONSIDERATIONS**

By: Harald Schmidt

Summary: Incentives are controversial, but increasingly widespread. Their basic rationales are not always clear, nor is the complexity of design options fully appreciated. Four common goals are outlined, and ten key dimensions of incentive programmes are described. Possible goal conflicts should be addressed through transparent communication and through monitoring the extent to which goals are in fact accomplished. Particular emphasis should be given to identifying the distribution of benefit among users. Regulators should specify broad categories in which data should be reported to help identify and promote appropriate programmes, and prevent or phase out inappropriate ones.

Keywords: *Incentives, Ethics, Personal Responsibility, Behavioural Economics, Health Promotion*

Introduction

Rising levels of chronic diseases have intensified interest in using incentives to promote healthy behaviour. The basic concept and rationale for using health incentives is deceptively simple. Yet, on closer inspection, a number of different reasons for their use can be identified, which influence their real as well as perceived acceptability. Moreover, a plethora of design options give rise to distinct practical and ethical issues. This complexity can make the use and understanding of health incentives daunting to policy makers, payers of health care, the insured population and others. The outline below seeks to clarify

the whys and hows of using incentives. Concrete suggestions are made for how to identify effective and fair policy in this rapidly evolving field.

Four rationales

Health promotion

In a way, using incentives for health promotion is perplexing. Typically, people want to be healthy. So why should they need further encouragement? Anyone who recalls their failed new years' resolutions quickly appreciates why. We often have the best of intentions to exercise more, eat less, and consume alcohol in moderation. But we also often fail to act on our goals.

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Standard accounts in both classical economics and bioethics rely on a strong concept of autonomous rational agents: they fail to capture such flaws in human agency and limits to intrinsic motivation. But the relatively recent field of behavioural economics has set out to map and understand the science of decision errors in detail.

Key insights include that people typically prefer short term and certain benefits – such as a slice of delicious velvety chocolate cake that is placed right in front of them. Longer term, less certain benefits – such as the likelihood of a slimmer waistline in years to come – have less pull on action. In other research that examined the role of choice architecture, the powerful grip that defaults have on our behaviour has been firmly established. We are often content with the path of least resistance; for example, by not using stairs when a lift is easier to reach, or choosing a less healthy option from a buffet if the healthier one is harder to reach. A series of observational and experimental studies also showed that when it comes to motivating people, losses loom larger than gains, and have superior traction in policy.² Furthermore, incentives may help people who already have sufficient motivation, but face adverse social pressure. For example, a pregnant woman may wish not to smoke. But her social environment may be such that she constantly has to justify herself for not smoking, and her quitting may be experienced by others as criticism of the dominant behaviour. In such cases, incentives may offer “argumentative cover”, by providing others with a reason for changing one’s behaviour.²

Much of this research can have direct applications in health care policy and practice. A proper understanding of decision errors that thwart healthy behaviour can be used to turn around the very mechanisms that underlie them, enabling healthy behaviour. To use the examples above, in buffets, healthier options can be made easier to reach. Rewards such as cash premiums can be used to help people quit smoking. Insurance premiums might be higher for people failing to comply with evidence based preventive exams. Of course, not

everyone requires such assistance. But for many, making more attractive those choices that are in the interests of their future selves can offer help where intrinsic motivation is just not strong enough.

Curbing health care expenditure

In addition to the rationale of health promotion, there are often other, sometimes less patient-centred motivations that drive the use of incentives. First, there is the hope that incentives will curb health care spending, if not lead to net-savings. However, there are fundamental questions about whether better health, in fact, leads to lower cost. Regarding the relative lifetime cost of smokers versus obese and healthy people in the Netherlands, it has been suggested that the latter, and not the former two groups, are most costly – chiefly due to higher cost of care at the end of life.³ Cost-savings, therefore, cannot be taken for granted. A focus on cost can also influence the choice of incentive mechanism, and favour penalty-based approaches. Financial incentives function either as ‘carrots’ or as ‘sticks’. Carrots may consist of a cash lump sum payment, or an insurance premium reduction, conferring a net benefit. Sticks are surcharges or penalties, and enable shifting part (or all) of the cost that is alleged to be associated with unhealthy behaviour back to the user: they experience a net loss, but the health care payers gain.

Competitive industry advantage

Insurers often compete for ‘good risk’ clients: people who solidly contribute through insurance premiums, but have low levels of morbidity and associated health care use. Solidarity-based systems typically prohibit overt risk selection, such as higher premiums for sicker people. But incentive programmes of the carrot type can evade the radar of overt risk selection detection, and may be used to attract and retain good risk insurees. For example, it has been shown that adding free gym membership to Medicare Advantage plans in the US leads to a 6% relative increase in enrollees reporting “excellent” or “very good” health.⁴ Risk pools can also be influenced through penalties, such as surcharges for a higher body mass index (BMI), which may lead obese people

to seek health insurance elsewhere. A more drastic approach which self-insured employers might pursue, is not to employ high risk groups, such as smokers. This option may also be attractive as healthier people often have lower rates of absenteeism, and higher rates of productivity – potentially enabling another form of a competitive advantage.⁵

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motivation is just
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enough

Promoting moral values

Health incentive justifications usually focus centrally on the goal of health promotion. But health is, of course, as much a medical as a social concept. This is especially relevant for the types of behaviours that are typically incentivised. The somewhat pejorative moniker of ‘lifestyle diseases’ is commonly used, with the implication that being a smoker, alcoholic, or overweight person is as much a personal choice as one might choose between playing golf or tennis as a hobby. Clearly, however, opportunity of choice and associated degrees of freedom and voluntariness differ immensely. Social and other determinants of health can make it extremely challenging for people not to smoke, drink excessively, or be obese. In societies with a cultural history in which the deadly sins of gluttony, sloth and lust still cast long shadows, sympathy can be limited for giving benefits to people presumed to lack self-control. Support for penalties may be stronger. Notions of deservingness and responsibility come into play in practically all incentive programmes, and it can be far from straightforward to ascertain what is really driving a certain programme ‘under the hood’.

Goals and goal conflicts

Since incentives may be driven by several different goals simultaneously, the possibility of goal conflicts needs to be considered. For example, programmes may reduce cost – through cost shifting – or give a payer a competitive advantage – through changes in the risk pool – without improvements in health. It would seem that in such cases health incentives have missed their mark, and that, more generally, health improvement should always ‘trump’ other goals. But at least in practice, health improvement is not universally paramount. For example, a recent comprehensive German government review found that it was not uncommon for incentives to be offered for interventions that had no, or at best an indirect impact on health promotion: consequently, a clearer focus on quality assured programmes was demanded.¹⁴ By contrast, recent US government guidelines expressly specified that programmes were “not required to be accredited or based on particular evidence-based clinical standards”.¹⁵ The developments in both countries are, in part, a reflection of the powers that seek to further goals other than health promotion alone. In part, they also reflect the fact that at this relatively nascent stage of the broader use of incentives, it is not straightforward to identify what constitutes best practice, to which we turn next.

The complex anatomy of incentive programmes

Perhaps more than other public health interventions, incentive programmes have a large number of moving parts. This feature makes them extremely complex as individual interventions, and poses challenges for reviews across interventions, whether conducted by academic researchers or regulators. The following overview delineates ten of the most central parameters characterising incentive programmes that need to be considered in planning, implementing and evaluating programmes.

Type of incentivised behaviour

Incentives can be used for a wide range of behaviours. At one end of the spectrum are ‘simple’ or one-off behaviours such as using vaccinations, or completing a

health risk assessment. At the other end there are ‘complex’ behaviours relating to chronic conditions: these may require repeated behaviour change, and may take the form of exercise, weight loss, smoking cessation, substance abuse, or medication adherence programmes. Since the baseline difficulty of achieving the target behaviours differs, and since incentives can, at best, support people’s motivation, it would generally be wrong to expect that incentives for complex behaviours are as effective as ones for simple ones.

Incentivised unit

Incentives are typically viewed as an individual-level intervention. But they can also be provided to groups of people, for example, where teams of people strive to lose the most weight collectively, and a prize is shared among the winning team’s members. In alternative approaches each team member might receive an incentive amount for sticking to a weight loss trajectory, but if one member fails, their reward is shared by all others.

Target population

Comparisons between programmes with identical design can also be complicated by relevant differences between target populations. For example, in the case of workplace-based programmes, some professional groups may be self-selecting for highly competitive personality types. But in others, employees may find the regular pressure resulting from their work sufficient to cope with, and they may not respond positively to additional challenges. Possible variation underlines the need to assess winners and losers among programme users. Ideally, programmes are tailored or patient-centred as much as possible.

Nature of the conditionality-triggering target

Incentives can be offered for behaviours that practically anyone could accomplish, such as attending a lecture on healthy eating, or making an active choice for or against cancer screening by working through evidence based materials. In a more challenging way, incentives can be provided for meeting specified hard targets, such as BMI thresholds. The former are sometimes called participatory, and the later health-contingent incentives.

The distinction is of central relevance for the fairness of incentives, as not everyone starts from a level playing field. Health-contingent incentives may be disproportionately more challenging for some groups of people. One way of making them less demanding is by incentivising the achievement of relative improvements (instead of meeting rigid targets), which can be more accommodating of base-line variations.

Incentive currency

Most incentives have monetary value (such as cash), but some do not (such as honours or achievement badges). Among incentives with monetary value, there are financial incentives and non-financial ones. The former consist centrally of fixed cash amounts and insurance premium variations. The latter may take the form of in-kind benefits, such as sports goods, wellness holidays, concert vouchers, or other items. Different incentive currencies can have different impacts in terms of their effectiveness, and are also likely to be experienced differently by users.

Incentive level

The value of monetary incentives can be small and mainly symbolic, such as a t-shirt or a mug, or large, such as a surcharge amounting to around €2,000 that US employers providing insurance for their employees may charge smokers, or around €1,000 for failing to meet biometric targets, such as BMI, blood pressure, or cholesterol values. High incentive levels may have more traction, but can also raise fairness issues where there are limits to the extent to which the target is under an individual’s control.

Incentive mode and framing

As noted, fundamentally, incentives come in a carrot and stick format. Sticks, however, can also be framed as carrots: a health plan could increase premiums at the beginning of the year, and then offer a rebate as an incentive for insurees who achieve a health-conducive behaviour. The effect for those who fail to accomplish the behaviour is the same as in the standard stick scenario: a net increase in cost. Yet, the health plan might advertise it as a carrot. Such ‘false carrot’ framing may be welcome by some users, but antagonise others.

A further difference in mode seeks to personalise incentive targets through deposit or commitment contracts. Users put their own money on the line, at amounts that they specify. For example, an employee might set herself a goal of losing one pound a week over three months. At the beginning she hands over €600 to an administrator. If she achieves her goal, she gets back the €600 after three months. But for every week that she fails to meet the target, €50 is deducted and wired to a charity of her choice. In variations, employers might match employees' stakes at specified rates, or lost amounts might be pooled and distributed among all those who are on target. Deposit contracts may engage employees more than carrot, stick or false carrot formats, but may also appeal disproportionately to those who already have strong baseline confidence that they will accomplish their goals.

Incentive certainty

Most incentives, such as cash rewards, insurance premium increases or deposit contracts have guaranteed outcomes. Yet, many worry that such forms of (partially) extrinsic motivation may replace or 'crowd-out' intrinsic motivation, and will not lead to sustainable behaviour change. One way of addressing such concerns is to make the gain less certain, by using a lottery or sweepstake format. Prizes can be made more valuable, which can make participation more attractive. At the same time, participants will be clear that they only stand a certain chance at winning. The incentive is then likely to be viewed more as a windfall: welcome, if it materialises, but if not, nothing is lost either. Consequently, the merits of engaging in the incentivised behaviour may loom larger than the prospect of reaping an associated net benefit of some value, reducing the possibility of 'mercenary' motives.

Time horizon

The optimal timing for an incentive depends, in part, on the type of behaviour. For example, an obvious way of creating incentives for regular dental check-ups would be through a waived copayment every six months, and for flu shots, a cash incentive could be offered annually during the flu season. But the timing of incentives for more complex behaviours,

such as smoking cessation or weight loss is less straightforward. Here too, an incentive could be offered once a year, for example for those whose BMI exceeds the normal range. Such an approach would be relatively easy to administer, and suitable for accomplishing other goals, such as cost-shifting, or sending a message that being overweight is undesirable. But it is not likely to be a particularly effective intervention, given the behavioural economics mechanisms that are at work. People might simply 'binge-diet' around the time of the weigh-in – but put weight back on afterwards. A year is a long time to reap a benefit for a behaviour that entails daily choices. Much shorter intervals, such as monthly, weekly, or even daily options of benefiting if one is on track on a reasonable weight control trajectory are likely to be more effective. The timing of incentives is therefore not merely something that needs to work within the policy maker's framework for making premium adjustments. But, foremost from a behaviour change perspective, it is also something that requires close consideration of the features of the target behaviour.

Alternatives standards

For some users, it may be impossible or unreasonably challenging to achieve the target behaviour. For example, pregnant women will not generally meet normal BMI thresholds, and certain genetic mutations can place weight control entirely outside of the reach of individual action. And there may be other difficulties arising from medical or non-medical factors that render incentives unachievable. In such cases, fairness demands that an alternative standard be provided, to avoid that people are held responsible for factors that are beyond their control. Planning for alternative standards invites a close consideration of the possible difficulties that the target population faces, and analysing the actual use of alternative standards can be one way of ascertaining their acceptability and appropriateness.

Conclusion

Should we welcome incentives as an effective tool to empower people to take charge of their health? Should we reject incentives because they are inherently coercive? For better or worse,

neither question can be answered at this general level. Incentives are complex interventions, and generalised statements about their effectiveness, acceptability or fairness are highly problematic. Robust lessons regarding the effectiveness of types of incentives across several discreet programmes can only be drawn where programmes with suitably similar design are compared. But where there are differences in just one or a few parameters, inferences face significant limitations.

Incentives are
complex
interventions

Given the controversies that surround the evidence and ethics⁹ of incentive programmes, this situation poses both a challenge and opportunity for regulators. The challenge arises from the complexity of the intervention and the variability of data. But the opportunity is threefold: first, by specifying even just broad categories in which data on programmes should be reported – whether in categories along the lines outlined above, or others – helpful orientation can be provided to those designing programmes. Secondly, in line with the US Institute of Medicine's recent call for continuous learning from routinely collected data as a central part of a learning health care system,⁹ gathering, analysing and making available for analysis by academic researchers data on implemented incentive programmes can enable a unique and broad set of evidence, to better understand both their effectiveness and acceptability. Lastly, by promoting appropriate programmes, and by phasing out poor designs, people can be provided with interventions that can improve their health, and be protected from ones that might turn out to be mere snake oil.

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NUDGING AND SOLIDARITY: DO THEY GO TOGETHER?

By: **Barbara Prainsack** and **Alena Buyx**

Summary: Since the late 2000s, policy makers have made increasing use of health incentives ('nudges'). At the same time, criticism of nudging has been mounting as well. In this article we argue that a perspective drawing upon solidarity can help to create incentives that are sensitive to social inequalities and that avoid increasing stigma. This requires that policy makers give careful thought to the definition of target groups for 'nudging'. Moreover, health incentives should also always focus on what people have in common, and not what sets them apart.

Keywords: *Solidarity, Nudging, Health Incentives, Target Groups, Stigma*

Introduction

The authors of the most prominent book on health incentives, Richard Thaler and Cass Sunstein, define 'nudges' as 'any aspect of the choice architecture that alters people's behaviour in a predictable way without forbidding any options or significantly changing their economic incentives'.¹ Using insights and methods from behavioural economics and psychology² they thus distinguish nudging from coercive or binding measures such as laws or contracts. Smoking prohibitions, for example, are not nudges, because they represent a legally enforceable rule – even if they may make some people stop smoking voluntarily. As **Table 1** illustrates, it is a core feature of nudges that they leave it up to the target group whether or not they let themselves be nudged.

But nudges – at least in the way that Thaler and Sunstein understand them – are not only different from binding

norms. They also cannot 'bribe' people by offering them considerable sums of money. When exactly a nudge turns into a push cannot be determined in general; where exactly the line is depends on the concrete circumstances of the case. For a person living in poverty, a very small economic benefit could already be more than a nudge.

Table 1 highlights several differences between nudges and other instruments. It is important to keep in mind, for example, that nudges are normally destined to benefit the target group, or society as a whole, and not the person or organisation that initiates the nudge. If the nudge benefited solely the incentiviser – e.g. if a person with normal weight were incentivised to lose weight to look 'better' in a billboard campaign organised by the nudger – this would not qualify as a 'nudge' in the Thaler and Sunstein sense. It is noteworthy that one aspect that

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Table 1: Laws, contracts and ‘nudges’

Type of instrument	Laws	Contract	‘Nudge’
<i>Can it be enforced against the will of the addressee?</i>	Yes – binding character	Yes – binding character	No – no binding character
<i>Does the person or entity initiating the instrument benefit directly from compliance?</i>	No direct benefit for the initiator (instrument is geared towards communal benefit)	Direct benefit for the initiator	No direct benefit for the initiator (instrument is geared towards communal benefit)
<i>Does it matter whether the addressee genuinely wants to do what is requested?</i>	Intrinsic motivation is irrelevant (the norm needs to be observed anyhow)	Intrinsic <i>motivation</i> is irrelevant (however, intent, in the legal sense, is relevant)*	Intrinsic motivation may be relevant (scholars do not agree on this point)

Source: Authors

Note: * A person may agree or intend to enter into a legal contract for a number of reasons without necessarily having an intrinsic motivation to do so; e.g. she may enter a new work contract because she has to (or risk losing accumulated benefits) rather than because she inherently wishes.

scholars on nudging are divided about is whether or not the intrinsic motivation of the person who is nudged is important.^{2 8}

Thaler and Sunstein describe and suggest nudges in various areas of public policy making, ranging from changing policies from opt-in to opt-out models, to nudging students to drink less on campus. Some in the public health community have taken up the idea of nudges quite enthusiastically. This is not surprising, since public health planners are trying to get the population to be healthier. In fact, nudges have been used for a long time, even if not under this name; the term ‘nudge’ became associated with health incentives only after the publication of Thaler and Sunstein’s book in 2008. Since then, studies into incentives for healthy behaviour have increased in Public Health, particularly in the US and the UK.^{9 6} At the same time, criticism of the very idea of nudging has been mounting.^{6 7} We argue that the concept of solidarity can help to create health incentives that are sensitive to social inequalities and help to decrease stigma.

Bringing in solidarity

Solidarity has been an important concept in western social theory. Although the exact meanings of the term vary, it always refers to a situation where people share something in common, and alludes to social coherence and often justice.⁸ Solidarity always emphasises what people share in common rather than focusing on what sets them apart. What binds people together can be a common life context, a

common threat, a common goal, or other similarities that become relevant in a specific situation.

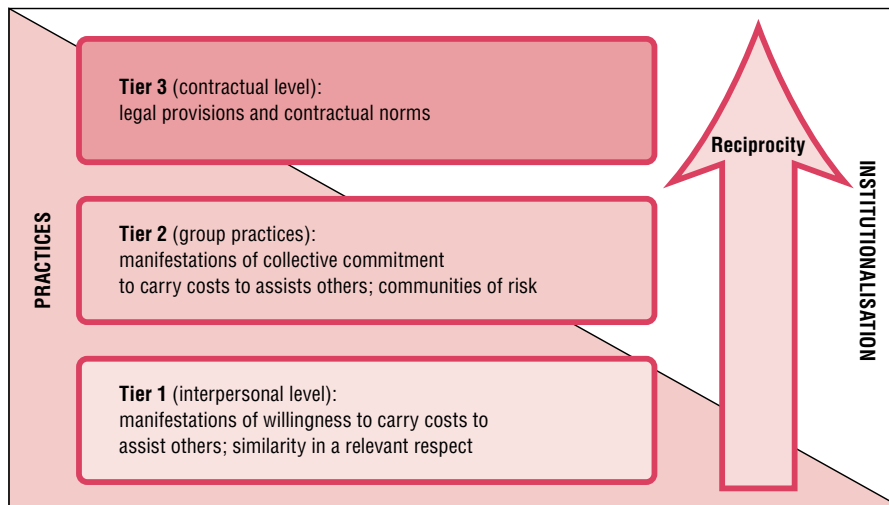
This focus on similarities between people sets solidarity apart from related concepts such as charity. Acts of charity entail that somebody who is in a powerful position gives something to somebody in a weaker position. Charity thus relates to the *differences* in status and needs between people, while solidarity focuses on what they have in common.

Many health care systems include elements that are informed by the principle of solidarity. Welfare state arrangements are a paradigmatic example of this. Of course, they express charitable values as well, with the strong and privileged being expected to support the weaker and less privileged. The basic assumption of solidaristic arrangements, as exemplified by universal health care, however, is that we are all ‘in the same boat’ at least in the one respect that we will all get ill and require assistance at some points in our lives.

Recently, however, these solidaristic arrangements have been under increasing strain from political ideologies, budget cuts and economic crises. One avenue to lower health care costs is to ‘nudge’ people into healthier living. We argue that nudging, in principle, is compatible with a solidarity-based perspective. Before we go into this in more detail, however, we need to have a clear understanding of what we mean when we use the term solidarity in this context.

Literature in the field of health care, political theory and bioethics uses the term in many different ways. In the context of recent work supported by the Nuffield Council on Bioethics we have distilled the key features of solidarity in the wider literature and arrived at a working definition that can be useful for policy-making.⁸ Our approach is strongly influenced by the philosophical tradition of pragmatism, meaning that we understand solidarity as something that is first and foremost enacted, rather than an abstract value or an inner sentiment. In its most bare-bone form, solidarity signifies practices reflecting a commitment to carry ‘costs’ (financial, social, emotional, or otherwise) to assist others with whom those engaging in these practices recognise similarity in a relevant respect. The term ‘costs’, here, includes not only financial costs, but also contributions in terms of time, effort and emotional investments.

‘Similarity in a relevant respect’ means that we share something in common with somebody else *that matters in a specific situation*. What this relevant thing or characteristic is depends on the specifics of the situation. We said earlier that solidarity focuses on what people have in common, and not what sets them apart. However we never have *everything* in common with others. ‘Similarity in a relevant respect’ thus refers to the practical situation that we find ourselves in at the specific moment and place in question.

Figure 1: Three tiers of solidarity

Source: Authors

Note: The authors are grateful to Harald Schmidt [U Penn] for helpful comments on the role of reciprocity for the institutionalisation of solidarity.

Tiers of solidarity

In our work we distinguish between three ‘tiers’ of solidarity (see Figure 1). The first tier of solidarity applies to actions between individuals. If practices of solidarity between people become so common within a group of people that they come to be regarded as the ‘normal’ thing to do, then we speak of tier 2 solidarity. If the values or principles emerging through group or community practices in this manner solidify further and manifest themselves in contractual or other legal norms, then we have an instance of tier 3 solidarity, the most ‘formal’ form of solidarity. Examples include public welfare, or legal arrangements underpinning publicly funded health care systems such as the English National Health Service (NHS) or German Statutory Health Insurance. Other examples include contracts between different private actors and international declarations or treaties, such as virus sharing agreements in the context of pandemics.

This working definition has two advantages: it provides a definition of what solidarity is, and what it is not. Second, it can inform policy making by highlighting the importance of real and/or imagined communities in shaping practices and public attitudes towards solidaristic arrangements.

What solidarity adds

How, then, can drawing upon solidarity contribute to debates on nudging? One thing that a solidarity-based perspective brings to the table is an emphasis on collective responsibility. Because solidarity focuses on similarities between people, it is not so much concerned with ‘chasing the offender’ – i.e. punishing those who engage in ‘bad’ health behaviours¹⁰ – but with ensuring that all of us live in conditions that facilitate healthy lifestyles. Providing secure pavements and reliable public transportation that enable people to leave their cars at home (or even sell them) are illustrations of this; other examples include offering healthy food in schools and work places. All these are typical nudges, aimed at giving an incentive for healthy living.

Another thing that these examples have in common is that they are targeted at the entire population. This is not the case for all nudges, however. Nudges that target only one specific population group can be problematic from a solidarity perspective, because they emphasise what sets these people apart from others. This is particularly troubling in cases where the nudge is targeted at a group whose defining characteristic carries stigma, such as being overweight, frail, ill or a smoker.

Nudging is compatible with a solidarity-perspective in principle. Many nudges that are aimed at everyone, and motivated by community benefits, are very much in line with an idea of solidarity as an underlying principle of health care. At the same time, a solidarity-based perspective urges policy makers to be very careful about how they define target groups. Nudges that are based specifically on differences between people can actually work *against* the sense of shared vulnerability in the face of illness and death within health care systems. They would thus run counter to the overall aim of protecting the broad and inclusive solidarity (still) underlying our embattled health care systems.

“solidarity focuses on what people have in common”

This problem is even more pronounced in nudges where the distinguishing features used for defining the target group carry the risk of stigma, or if the nudge itself is likely to increase existing stigmas. Examples of this would be nudges aimed at groups whose members are seen as deficient in some sense (economically, intellectually, or morally; an example for the latter are smoking pregnant women). In such a case the nudge itself can increase stigma; examples are financial incentives such as vouchers or small cash payments to nudge such women to stop smoking.¹¹ This is not to say that policy planners should not strive to reduce smoking in pregnant women; on the contrary. However, to be in line with an idea of solidarity, nudges would have to be devised in such a way that they avoid setting these women apart from mainstream society, or patronising them. In consequence, such nudges would possibly address a bigger and less specified target group, or use an incentive that focuses on shared characteristics or behaviours. For example, they could give incentives for healthier living to pregnant women, without focusing narrowly only on smoking.

Conclusion

This article has argued that a solidarity-based perspective, in principle, is compatible with ‘nudging’. A focus on solidarity directs our attention to a question that is often side-lined in discussions on nudging, namely on how the target group for the nudge is defined. A solidarity-based perspective mandates that policy makers give careful thought to this. What are the characteristics that define the group? Is there robust evidence that these characteristics correlate very strongly with the problem that is sought to be addressed? Do these characteristics carry stigma in your society? If they do, it may be worth refraining from nudging this specific target group and instead create incentives for a wider group of people that is not associated with stigma (or is less stigmatised). An example would be to create incentives for healthy eating in all schools, instead of only in those in underprivileged areas. Nudges should focus on what people have in common, instead of what sets them apart.

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INFLUENCING LIFESTYLE AND INSURANCE PREMIUM DIFFERENTIATION: THE ETHICAL DEBATE IN THE NETHERLANDS

By: **Marieke ten Have** and **Dick Willems**

Summary: There is debate underway in the Netherlands on the ethical aspects of policies to change lifestyle and differentiation in health insurance premiums. The debate focuses on two specific issues. First is the issue of influencing the lifestyles of individuals to make them more healthy. Does a government that aims to promote healthy lifestyles act paternalistically or is a government that fails to do so guilty of neglect? The second issue explores whether people with an unhealthy lifestyle should pay a higher premium for their health insurance or whether this is unjust. This article argues that mapping the positions in the debate and analysing the arguments can prevent policy that is based on ideological positions rather than on the underlying arguments.

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Note: The Netherlands Centre for Ethics and Health (CEG) is a think-tank for responsible policy, mostly targeted at the government, and in particular, the Minister of Health, Welfare and Sport. It identifies current moral dilemmas in the broad field of health and health care. By clarifying the central issues, the CEG assists policymakers, citizens and professionals with making important choices. The CEG is a joint venture of the Health Council of the Netherlands and the Council for Public Health and Health Care (RVZ).

Keywords: *Lifestyle, Health Policy, Insurance, Differentiation, Paternalism*

Introduction

Implementing taxes on unhealthy foods, forcing people who want to smoke a cigarette to go outdoors, increasing lifestyle insurance premiums for people with a high body mass index (BMI) and organising collective ‘dance and move’ events for office employees are examples of the huge variety of measures being implemented to increase healthy behaviour. Such policies frequently evoke strong ethical debate. The potential ethical pitfalls in this area concern consequences for physical health, psychosocial wellbeing, equality, informed choice, social and cultural values, privacy, the attributions of responsibilities and liberty.¹

Recently, the Netherlands Centre for Ethics and Health (CEG) published two reports to fuel this debate in the Netherlands. The first report² discusses the issue of influencing the lifestyles of individuals to make them more healthy. Does a government (or employer, or insurance company) that aims to promote healthy lifestyles act paternalistically? Or, conversely, is a government or employer who fails to do so guilty of neglecting the health and wellbeing of its citizens/employees? The second report³ discusses the issue of differentiating health insurance premiums based on healthy lifestyles. Should people who smoke, drink, work too hard or exercise too little

pay a higher premium for their health insurance because these lifestyle choices are their own responsibility? Or would this be unjust, for instance, because lifestyle is also subject to external factors such as socio-economic status and environment?

“Should individuals be financially liable for their choices?”

Influencing lifestyles and differentiating premiums based on lifestyle choices are closely intertwined because much of the debate centres around the demarcation between personal responsibility and societal responsibility. However, there is a difference. The first (influencing) can be done in a myriad ways, from providing employees with free fruit during lunch hours to prohibiting smoking in office buildings. The basic issue in the debate about influencing lifestyle and paternalism is whether it is a task of the government, employers, or insurers to do any of these things. The second (differentiating premiums) concerns a very specific way of interfering with personal choices and is not even necessarily meant to influence lifestyles. The basic issue here is whether individuals should be held financially liable for their choices.

Lifestyle influencing

Six situations have recently led to social debate in The Netherlands on the limits to lifestyle influencing by the government, health insurers and employers. The discussions concerned the introduction of a ‘fat tax’; the placing into care of a child who was given only raw food; the ban on smoking in small catering establishments; employer policy on lifestyle; the decision of the Dutch Health Minister to remove courses promoting a healthy lifestyle from public health insurance; and a proposal to make bicycle helmets obligatory in order to reduce injuries.

Within the debate on the limits to lifestyle influencing that these cases evoke, one can distinguish the following three positions:²

(a) Lifestyle influencing is always acceptable when it leads to health benefits.

(b) Lifestyle influencing is always unacceptable because it interferes with individual freedom.

(c) Even when lifestyle influencing leads to health benefits, it is only acceptable under certain conditions.

We conclude that position (a) is too simple. Lifestyle interventions always involve financial and moral costs (e.g. loss of individual freedom) and therefore always require further justification apart from the expected health benefits.

Position (b) is also too simple, because it excludes lifestyle influencing that may be necessary to prevent harm to other people (for instance the health hazards that result from the cigarette smoke of others). However, position (b) also has a strength, that lies in the observation that a measure promoting a healthy lifestyle is not, by definition, in the interests of everyone. The underlying idea in this perspective is that choices regarding what constitutes a ‘good life’ lie within the domain of individual freedom. The objection that lifestyle influencing is unacceptable because it interferes with individual freedom is stronger if the measure heavily encroaches on civil liberty (i.e. is coercive), if it is aimed at adults who are able to give informed consent, and if it is implemented without prior consultation.³

Based on the work and interviews done for the report, position (c) is a broad standpoint taken by most people in the Netherlands. There are three possible justifications of lifestyle influencing within position (c). The first emphasises that if the behaviour to be influenced harms third parties, it is acceptable to influence it. Thus, most people accept that the harmful effects of passive smoking justify banning smoking in some situations. A second possible justification is that if there are strong external factors that stimulate an unhealthy lifestyle, it may be acceptable to counterbalance these factors. Unhealthy behaviour is also influenced by factors beyond the individual’s power, like an unhealthy social environment, the influence of industry, addiction, lack of information or low socio-economic status. This position

argues for the need to strengthen the conditions for choosing a healthy lifestyle, for instance by boosting health literacy and making the social environment healthier. The third possible justification is that if autonomy or freedom is not seriously threatened, lifestyle influencing may be acceptable. Nudging has become a popular concept where certain choices are stimulated, but people can also opt out. Nudging deserves further investigation, both with regard to its potential positive effects and the potential ‘invisible’ crossing of ethical boundaries.

Many questions remain which are instrumental to assessing whether lifestyle influencing is acceptable and advisable in light of possible objections relating to paternalism:⁴

- What are the expected positive effects of the measure and who benefits from it?
- Are there alternative measures that achieve the same goal with less influencing?
- Are third parties harmed by the behaviour to be influenced?
- What external factors stimulate an unhealthy lifestyle?
- Is autonomy or freedom not (too) seriously affected by lifestyle influencing?

Lifestyle differentiation in health insurance

Ethical arguments concerning lifestyle differentiation in health insurance premiums include the following questions. Should people who smoke, work too hard, do not exercise enough, drink alcohol, have unsafe sex, eat too much, play injury-prone sports or have another unhealthy lifestyle pay more in terms of premiums, policy excess or individual contributions for public health insurance? And/or should people who do not do these things be rewarded? The ethical debate on these questions is topical and emotive, such that people have different standpoints and arguments upon which they base their opinion.⁵

The debate on whether lifestyle differentiation should be introduced in public health insurance divides opinions on the following questions:

- Is lifestyle differentiation feasible?
- Is prevention an acceptable motive for lifestyle differentiation?
- Does lifestyle differentiation lead to a fairer distribution of costs?
- Does lifestyle differentiation promote solidarity?

The first point of discussion is the feasibility of lifestyle differentiation, and especially whether lifestyle should be monitored to enable differentiation. Although monitoring unhealthy behaviour is often impracticable or unethical, there could be ways of implementing lifestyle differentiation, for instance by trusting patient self-reports.

Is lifestyle differentiation feasible?

The second point concerns whether prevention forms a convincing motive for lifestyle differentiation. It is uncertain whether lifestyle differentiation in public health insurance has favourable effects on behavioural change and thus promotes better health. In addition, prevention as a motive for lifestyle differentiation raises questions about paternalism.

The third point addresses whether lifestyle differentiation leads to a fairer distribution of costs. Scientists disagree on whether certain unhealthy lifestyles are in fact more expensive for the health system than others. Views also differ on what is fair. On the principle that one should take responsibility for one's choices, it seems fair to make people pay for the costs of their unhealthy lifestyle. But this view is open to the objection of victim blaming: people sometimes cannot be blamed for an unhealthy lifestyle, which is also determined by external factors, such as socio-economic status and an unhealthy social environment (see the article by Mackenbach in this issue).

The fourth discussion point asks whether lifestyle differentiation will promote or at least maintain solidarity. It could be argued that in order to preserve solidarity, the solidarity framework should be restricted to diseases that are independent of lifestyle. For example, when people feel that they have to pay for other people's 'lazy and irresponsible' behaviour, they would (so it is claimed) be less willing to contribute to a system based on solidarity. Therefore, the argument is that in order for solidarity to be maintained the sphere of its application should be restricted to a certain extent. However, the proposition that lifestyle differentiation in insurance premiums makes citizens more willing to help pay for a system of solidarity is a claim that needs to be verified empirically. For example, the Nuffield Council on Bioethics claims that the opposite is the case: that lifestyle differentiation itself undermines willingness to contribute to a solidarity system.⁴ Thus, more research is required on this question.

Conclusion

With the evolving scientific insight that ill health is not just a matter of fate, but that, more often than not, it is to a large extent influenced by lifestyle choices, the way that society looks at lifestyle choices is changing. There are laudable efforts to improve the conditions in which people make such lifestyle choices. At the same time, individuals who engage in unhealthy behaviours are increasingly regarded with disdain and seen as solely accountable for their diseases and the financial costs that come with them.

Current policy in the Netherlands is paying increasing attention to influencing lifestyles. Not only does the government aim to persuade citizens to pursue a healthier lifestyle, but so do other organisations such as employers and insurance companies. Lifestyle differentiation in public health insurance is starting to take place in the Netherlands: insurers are experimenting with positive incentives, for instance by giving clients a discount on their premium when they visit the dentist for an annual preventive consultation or when they go to the gym each week.⁵

Such policies evoke debate with strong emotions and convictions, which shows that lifestyle policy is about deeply held values regarding individual and societal responsibility. It also sometimes leads to policy that is based on ideological positions rather than on the underlying arguments. Future work on mapping the debate and analysing the arguments will contribute to this debate, both nationally and internationally.

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EFFECTIVE POLITICAL STRATEGIES IN PUBLIC HEALTH

By: **Scott L. Greer** and **Denise F. Lillvis**

Summary: Health in All Policies (HiAP) has the potential to improve population health by harnessing the energies of multiple sectors via intersectoral governance. We find that the difficulty of establishing intersectoral governance for HiAP breaks down into two kinds of problems: establishing coordinated actions (coordination); and ensuring that actions endure when political circumstances change (durability). We outline three categories of potential solutions to these problems: manifesting political will; changing bureaucratic procedures; and empowering allies to change policy-making. The three kinds of strategies suggest how policy-makers can, and do, create intersectoral governance that functions and endures amidst changing political winds.

Keywords: *Health Policy, Health in All Policies, Administration, Politics*

Introduction

Key problems in health policy come from outside the health care system, and therefore must be addressed outside the health care system. Whether it is health promotion, health protection, population health, chronic and long-term care, early years investment, promotion of active living, or some other form of wellness, the solution most likely involves long-term collaboration between different sectors and policy tools, from private action to tax codes to physical environments to education. That has logically led to the concept of “Health in All Policies” (HiAP), a newish tag for a long-standing public health objective of promoting intersectoral coordination for better health.¹

But, promoting intersectoral cooperation towards any goal, including health, is hard. Other ministers might not appreciate the

invitation to adopt the health minister’s priorities in place of their own. In recent years, public health advocates have claimed such a broad area of public policy that it’s not so difficult for health ministers to invade another minister’s policy space.² Or, new ministers might not care about the old ministers’ priorities. In such ubiquitous circumstances, it is not enough to have evidence. Nor is it enough to call for more leadership and implicitly blame the leaders we have. Rather, it is important to have a fuller sense of the problem and the strategies adopted to solve it. In a study we conducted, forthcoming in *Health Policy*, we drew on published political science and public administration literature, in health and other policy areas, to identify the challenges and the solutions that creative and effective policy-makers use in many different political systems.³

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The problems

The extensive literature on bureaucracy and politics generally can be read as identifying two different problems facing those who would try any intersectoral policy approach.

Coordination: coming together to improve public health

Coordination is the first problem for HiAP, and indeed policy integration of many sorts from toxins regulation to chronic care to early childhood interventions. Simply put, it is difficult to bring together different people and organisations, each with their own existing priorities, budgets, and accountabilities. They might have professionals who speak different languages, they might have different political objectives, and their leaders' own priorities and ambitions are likely to clash. The result is that an intersectoral priority – and almost any big priority is intersectoral – will create serious coordination challenges.

Durability: staying together to improve public health

While coordination challenges are clear and well known, there is a second problem: the durability problem. Simply put, there is a time limit on the interests and tenure of any single minister appointee, government and party in government. It is easy for reforming energy to dissipate, reformers to move on, and plans to die. Accordingly, opponents remain quiet when they sense strength because they know they will soon sense weakness. While short-lived policies can do good, long-lived policies that become entrenched are probably most likely to produce good effects. That is particularly the case in areas of public health, such as efforts to reduce environmental pollution or promote daily physical activity, where both good and bad policies can take years of constant activity to produce their results.

The solutions

In other words, health policies with the potential to produce good effects face problems of both coordination and durability. It is easy to announce a sensible policy, but much harder to implement it and harder still to entrench it. We found, though, that political scientists have

catalogued a variety of techniques used by politicians and other top policy-makers to solve their problems.⁴

Direct solutions: political will

The simplest solutions are those involving the simple exercise of political will. Policy-makers come into office and announce new policies. These can mean specific administrative circulars, health targets, health plans, or programmatic statements such as White Papers. They attract a great deal of attention, perhaps an inordinate amount of attention, in public health circles. They show a priority and make an argument about how to achieve it, thereby providing a rallying point for advocates and enabling them to argue for the priority in meetings where it might otherwise be forgotten (e.g. if we do not keep a given sum of money in the budget, we will fail to hit our target).

There are a variety of more subtle ways to show political will. Outsiders might not pay much attention to ministerial speeches, but insiders will notice which topics are mentioned, which topics recur, and which topics ministers drop. Prime ministerial or presidential speeches are even more valuable; an occasional paragraph in a speech by a head of government sends a powerful signal that the ambitious and diligent in government should continue to work on the topic. Regular briefings have the same effect. Many politicians enter office intending to seek regular briefings or meetings on a variety of topics, and insiders know to watch which briefings and meetings continue and which ones tail off. If a minister actually does demand monthly progress reports on a topic, that topic will become a priority. If a finance minister or a head of government wants the briefings, that is still more powerful. And if even a few officials or managers are rewarded or punished for supporting or impeding the policy, that communicates a powerful lesson. In each of these cases, powerful politicians are signalling that they care about an issue. That signalling will generally receive a response, whether motivated by personal ambition, or a professional commitment to service.

Political will alone has limitations. It does not always address coordination challenges because those who have the will might not have the power. A well written and

evidence-based health plan might propose a series of intersectoral measures that the finance, economy, transport, urban, education and other ministers and their departments can choose not to follow. Even the most powerful central actors in government, such as finance ministries, have trouble getting their way. A single spending department such as health will always have trouble coordinating other spending departments. It can seem that the health minister is simply inviting his or her colleagues to spend their budgets on solving the health minister's problems.

“health policies face problems of coordination and durability”

Failure to coordinate can be bad, but political will is also extremely vulnerable to the durability problem. A health plan written in the brave early days of a new government might be a dead letter in a year when the minister is gone, let alone in five years when the entire government might be gone. Politicians frequently decline to take marching orders from their predecessors, so even amicable job changes within government can doom the initiatives of the previous minister.

Bureaucratic solutions

What can policy-makers do to make sure that their objectives are actually implemented and persist over time? Part of their solution is legislation – especially in countries where the legislative process is difficult. Precisely because it is difficult to legislate in Germany, or the United States, or the European Union, legislation in those systems is sticky and constraining. Once something is written in law in such systems, it is difficult to change. By contrast, in countries with more parliamentary systems, such as the United Kingdom or Spain, laws are malleable and accordingly are less able to constrain future action. In such systems, though, politicians still have ways to constrain their successors.

One of the most powerful forces in modern life is bureaucracy. A minister or official who can change the direction of a bureaucracy can change thousands if not millions of individual decisions. A minister or official who fails to change the way a bureaucracy works may be much less successful.

One mechanism politicians routinely use is appointments: putting their people into key positions. Most health systems allow this, and even the Whitehall systems, which are notoriously resistant to outsiders at the top, have a variety of important executive posts in agencies whose occupants are chosen by ministers. Rewarding some people already working in the system with more power or resources achieves much the same effect.

A second mechanism, also quite common, is reorganisation. Reorganisation undoubtedly has costs, but it offers the possibility of redirecting organisational priorities—for example, moving the responsibility for sports to the health ministry in Scotland made it clear that sports is to be a public health intervention, just as moving responsibility for pharmaceutical policies in the EU to DG Health and Consumer Protection made it clear that pharmaceuticals are not just another product. Reorganisation can, in fact, be a device to bring in new people with new loyalties; regulatory agencies in the new English NHS bring in people who have consulting or antitrust rather than traditional health management backgrounds.⁵ Likewise, the creation of French Regional Health Agencies was an opportunity for the government to insert people committed to its agenda (e.g. inequalities reduction) into powerful new positions.

A third mechanism politicians use to entrench their preferences in the bureaucracy is to change procedures. Mandatory impact analysis, for example, is a technique to encourage bureaucracies to make some decisions and not others. Obliging government agencies to conduct business impact or regulatory impact analysis creates opportunities for affected business interests to influence, protest and slow the decision;⁶ mandatory environmental impact analysis has the same benefit for environmentalists. Mandatory health impact analysis,

therefore, would be a way to oblige bureaucracies to slow down, inform those concerned with health of decisions, and explain themselves.

Another key procedural change is the creation and manipulation of interdepartmental committees and consultations. These can be important forums for government decision-making (including decision-preventing) and representation on them is important. So, for example, making sure that the health ministry is represented on key committees making intersectoral decisions is a way to make sure that the health ministry is informed and able to participate in decision-making within the committee or in broader government. Equally, keeping other ministries out of key committees is an important way to keep them from blocking decisions.

Indirect solutions

If sheer force of political will is frequently insufficient for coordination and never sufficient for durability; and if bureaucratic change still faces the challenge that it is hard and might be undone by your successor; there is still a third kind of option, one little explored by public health scholars but one well known to political scientists and politicians. That is the indirect approach – changing the political context so it is friendlier in the future when there is a different minister, different direction, and different government.

One way to change the context of future politics in your favour is data – the establishment of regular data releases that highlight issues and that advocates, the press and opposition parties can use to force progress. Data on health care waiting times, or food insecurity, or obesity, or many other topics can put those issues on the agenda regardless of whether the minister wants it. International comparative data can be particularly useful because it can be used to argue that the country is failing in relation to its peers. In some cases, governments have been known to support international organisations' data collection projects in order to have an excuse to collect and release some kind of data at home.

A second indirect solution is to support outsiders – advocates and experts who can generate ideas, highlight problems and press for actions no matter who is in office. This can mean support to civil society organisations, the establishment of independent agencies that can catalogue issues, and support to researchers (such as training journalists in public health, or public health workers in advocacy). In these cases, the idea is to solve the durability problem by creating outside supporters who can press for government action and keep issues on the agenda. Even if (when) such inconvenient agencies are tamed or eliminated, and the non-governmental organisations (NGOs) defunded, the human capital remains; allies have new skills in advocacy and government relations.

A third solution is to make it easier for future allies to challenge decisions by future governments. Ombudsman procedures, for example, can be expanded to allow challenges on health grounds to a variety of public agency decisions. But the most dramatic indirect strategy is to introduce some aspect of judicial review. The much-heralded United States National Environmental Policy Act (NEPA), for example, is best known for mandating environmental impact assessment and inspiring health impact assessment. But its real force lies in the opportunities that it creates for environmentalists to challenge actions in the courts on the grounds of noncompliance with the law.

“Indirect solutions are frequently uncomfortable”

Indirect solutions are frequently uncomfortable. They involve, essentially, solving the durability problem by making ones' successors' lives, and frequently one's own life, more difficult. Introducing more NGO critics, let alone the possibility of legal challenge, means creating stress. But it is a key part of the toolkit of ministers who want to make sure that their agenda continues after they are

gone, regardless of their agenda. Making it easier for outsiders to influence the government, and making sure there are more of the right kind of outsiders, is a political approach policy-makers often use for a variety of reasons, and there is no reason why it should not be used for public health. Anyway, most of the discomfort will be borne by one's successors.

Conclusion

Policy-makers and politicians are more strategic and farsighted than public health writers typically acknowledge. Political scientists have spent decades cataloguing the ways they go "beyond leadership", making direct and indirect bureaucratic and political changes to entrench their policies, allies, and favoured procedures so that future bureaucratic inertia and political arguments promote their goals. Recognising the variety of techniques available, and developing a wider range of public health interventions, might pay off in both our ability to engage with

the political system and help formulate creative solutions to the problems of coordination and durability.

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New Policy Summary on what is the evidence on the economic impacts of integrated care?

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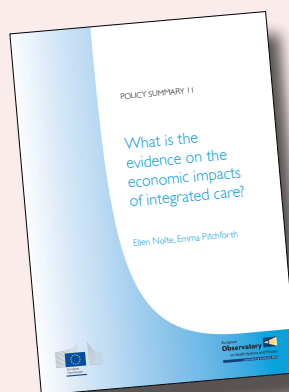
The rising burden of chronic disease, and the number of people with complex care needs in particular, require the development of delivery systems that bring together a range of professionals and skills from both the cure (health-care) and care (long-term and social-care) sectors. Failure to better integrate or coordinate services along the care continuum may result in suboptimal outcomes.

This Policy Summary analyses published reviews on the economic impacts of integrated care approaches. Given the wide range of definitions and interpretations of the concept, it proposes a working definition that builds on the goal of integrated care and which considers initiatives seeking to improve outcomes for those with (complex) chronic health problems and needs by overcoming issues of fragmentation through linkage or coordination of services of different

providers along the continuum of care. The review covers three economic outcomes: utilisation, cost-effectiveness and cost or expenditure and also looks at data on core health outcomes such as health status, quality of life or mortality, as well as process measures.

Available evidence of integrated care programmes points to a positive impact on the quality of patient care and improved health or patient satisfaction outcomes. However, uncertainty remains about the relative effectiveness of different system-level approaches on care coordination and outcomes, with

particular scarcity of robust evidence on the economic impacts of integrated care approaches. In addition, it is important to come to an understanding as to whether integrated care should be considered an intervention or whether it should be interpreted, and evaluated, as a complex strategy to innovate and implement long-lasting change in the way services in the health and social-care sectors are being delivered and that involve multiple changes at multiple levels.



MANAGING THE INTRODUCTION OF NEW AND HIGH-COST DRUGS IN CHALLENGING TIMES; THE EXPERIENCE OF HUNGARY AND POLAND

By: Danica Kwong, Alessandra Ferrario, Jakub Adamski, András Inotai and Zoltán Kaló

Summary: Hungary and Poland are currently facing budgetary pressures to reduce health and pharmaceutical spending. However, they still must ensure that valuable innovative medicines are made available to patients. Risk-sharing schemes (RSSs) are a mechanism to achieve access, particularly for high-cost innovative medicines that payers might be reluctant to fund because of uncertainty around their cost-effectiveness in real life. RSSs can be designed to distribute financial risks, risks relating to health outcomes or a combination of both. Due to fiscal imperatives and complexities linked to the implementation of health outcome-based schemes, both countries have focused mainly on financial RSSs.

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Keywords: *Pharmaceutical Cost Containment, Risk-Sharing Schemes, Innovative Medicines, Hungary, Poland*

Introduction

In the recent difficult economic climate, many governments are cutting health and pharmaceutical budgets as part of wide-ranging austerity measures. Expenditure on drugs is particularly viewed as a major driver of health spending¹ and thus an attractive target for spending cuts.

These pressures have compelled payers to implement a wide range of cost containment measures on pharmaceuticals. In Europe, a number of countries reported the immediate implementation of policies

such as enforced price cuts, as well as changes in co-payment levels, VAT rates on medicines and distribution margins.²

On top of the difficult economic circumstances all of Europe is facing, Central Eastern European countries such as Hungary and Poland must simultaneously deal with additional challenges. These include manufacturers imposing the same pharmaceutical price levels as for higher-income European countries as a tactic to avoid low prices spilling over through international

reference pricing and parallel import practices,¹ in addition to pressures to reduce overall deficit.

An additional consideration is that the increasing proportion of the non-working population (including the unemployed, older people and disabled) in these countries also has implications for their social health insurance financing structures; shrinking payroll contributions could result in fewer available funds to spend on health.

“Both countries employ a swathe of payback measures

Against this backdrop of austerity, however, payers and health ministries maintain a responsibility to provide access to valuable innovative medicines² for patients in need, even if these medicines are costly. To address this need, payers are increasingly employing mechanisms that require pharmaceutical manufacturers to share the risk of reimbursing and making available these new medicines, particularly with regards to high-cost new oncology and immunomodulating medicines.

These mechanisms are aptly known as managed-entry schemes (or sometimes more narrowly defined as risk-sharing schemes, though not all of them include a risk-sharing component).

Reimbursement structures and processes

The Hungarian and Polish reimbursement systems share many similarities.

The financing of new innovative medicines rests respectively with the Hungarian National Health Insurance Fund (NHIF) and the Polish National Health Fund (NHF). The decisions on whether to publicly fund them are made by the Reimbursement Department at the NHIF and the Polish Ministry of Health.

Health technology assessments (HTAs) are mandated as a prerequisite to the reimbursement negotiation process of new medicines in both countries; these are conducted respectively by the National Institute for Quality and Organisational Development in Health Care and Medicines in Hungary and the Agency for Health Technology Assessment in Poland (AHTAPol). Of note, the published cost-effectiveness thresholds in both Hungary (2–3x Gross Domestic Product (GDP) per capita/Quality Adjusted Life Year (QALY)³) and Poland (3x GDP per capita/QALY or Life Year Gained⁴) are intended as soft reference points. Manufacturers may apply for reimbursement at any price that they feel to be justified; but in practice, applications should be submitted with a cost-effectiveness claim deemed ‘acceptable’ (acceptability being loosely based around the threshold) to enhance the likelihood of the medicine being accepted for positive reimbursement. In reality however, Hungary and Poland, like many other countries, tend to consider budget impact more strongly than cost-effectiveness in reimbursement decision-making.

Later we discuss risk-sharing schemes as a mechanism to achieve access, particularly in the case of high-cost innovative medicines that payers might be reluctant to fund because of perceived uncertainty around their cost-effectiveness.

Pharmaceutical cost containment strategies

Both countries have recently enacted drastic economic reform plans with significant implications for pharmaceutical expenditure. In 2011, the Hungarian government introduced a structural reform plan (*Széll Kálmán plan*) with the intention to meet obligations from the European Union relating to the country’s excessive deficit. Within this plan, the stated aim is to reduce public pharmaceutical spending by over 35% during 2012–2014.⁵

In 2012, Poland introduced the latest Reimbursement Act to fully implement the European transparency directive as well as to alleviate budgetary pressures. To that effect, the Act introduced several mechanisms to decrease pharmaceutical expenditure – most notably: basing

statutory prices on mandatory negotiations; setting price limits for generic drugs and drugs which have lost their marketing exclusivity (both at 75% of the original price); and introducing adjusted fixed wholesale and retail mark-ups. To date, the Act seems to be serving its purpose by providing savings to the Polish NHF, both by applying downward pressures on prices as well as reducing the level of reimbursement to the pharmacy sector paid by the NHF; however, it is noteworthy that NHF spending on high-cost hospital drugs did increase under the Act. The Act also made progress on increasing access to medicines, introducing measures such as mandatory bi-monthly reviews of the reimbursement lists which resulted in 13 updates to the list in 2012 and 2013 (compared to the 13 updates that occurred during the entire period of 2005–2011).

Both countries employ a wide swathe of payback measures to contain pharmaceutical spending which are either implemented in relation to individual products (e.g. clawback) or therapeutic groups (payback based on market share). A general pharmaceutical budget ceiling is also designated in both countries as an additional safety measure; when expenditure exceeds the ceiling, industry is required to pay back a certain proportion. In Hungary, the ceiling is designed so that when it is exceeded by 10% or more, industry must pay back 100% of the excess consumption. In Poland, pharmaceutical companies must cover 50% of the overspend if the ceiling (17% of NHF’s total health budget⁶) is exceeded. The payback is shared across companies that have received a larger reimbursement amount in comparison to the previous year; the distribution among these companies is calculated on a ‘per product’ basis taking into account the ratio of each company’s price to the product which sets the reimbursement limit in the group. Thus far, the effectiveness of other cost-containment measures in both Hungary and Poland has meant that the ceilings have never been reached.

It is salient to note that across both countries, engaging in a risk-sharing scheme exempts manufacturers from general paybacks.

Table 1: Financial risk-sharing schemes in Hungary and Poland

	Hungary	Poland
Price-volume schemes	Yes; generally applied for all new pharmacy drugs	Yes
Confidential discounts	Yes	Yes
Dose/volume capping	Yes	Yes

Utilisation of risk-sharing schemes in Hungary and Poland

Risk-sharing schemes (RSSs) are a relatively novel mechanism available to payers for financing innovative medicines that are high-cost. While RSSs have been implemented by a number of countries in recent years, there is not yet a consensus amongst policy-makers on their appropriateness or their utility relative to administrative burden. This is in part due to the diversity of RSS types and their varied implementation across countries; but above all, it is due to a lack of data suitable for evaluation. However, as an alternative to pure cost containment strategies (for example, mandatory price reductions), RSSs have potential advantages as a longer-term, more sustainable framework that distributes risk between the payer and the manufacturer to further their mutual goal of facilitating patient access to new medicines. RSSs can be designed to distribute financial risks, risks relating to the outcome or performance of the treatment not being as expected in real life, or a combination of both financial and performance uncertainty.

Financial schemes aim to minimise the risks to the payer in making a positive reimbursement decision and publicly financing the new medicine. Examples of commonly used financial RSSs in the two countries include:

- price-volume schemes: a volume of sales related to a target population is negotiated; the manufacturer will offer a rebate or discount on any sales exceeding the predetermined threshold
- confidential discounts: manufacturers agree on discounts independently with reimbursement authorities in each country without having to reduce the official list price of the drug
- dose/volume capping: manufacturers offer discounts or even full rebates after

an agreed spending or volume threshold is reached; thresholds can be set on overall levels or per patient.

While information about the number or details of RSSs is held in commercial confidence in the two countries, some information is available.

“confidential discounts comprise the majority of schemes proposed in Poland”

In Poland, the most commonly proposed RSSs in reimbursement applications in 2012 were confidential discounts (34.61%), various price-volume schemes (11.54%) or payback schemes (23.08%) and others (26.92%).¹⁴ Confidential discounts comprise the majority of schemes, serving both as a way to diminish cost to the payer and as a counter-measure for manufacturers against external reference pricing. Such conditions are most commonly concluded for drugs purchased directly by hospitals or used in drug programmes; payers want a discount from the high cost of these products and manufacturers benefit from the ease of concealing the price in the purchases through tenders. The paybacks are settled directly between the companies and the NHF. Due to the specifics of inpatient hospital treatment (a relatively small number of patients and health service providers allowing for effective

monitoring of the treatment and gathering of data), it is reasonable to predict that most future schemes will be concluded for inpatient medicines.

It is worth noting that the Minister of Health recognises the value of RSSs, and tries to incentivise pharmaceutical companies by allowing an exemption from general payback schemes if companies propose and engage in such schemes. At the same time, companies may be fined by the Minister of Health if the risk-sharing conditions are not met.

Within the Hungarian context, price volume schemes are mandatory for all innovative drugs reimbursed from the pharmacy budget of the NHIF. Different volume restrictions are applied for hospital products, so that risk is shared not only with pharmaceutical companies, but also with hospitals. Of note, volume restrictions have not always been successful in meeting patient needs; the volumes reimbursed are often insufficient, leading to unequal access across the country.

Further potential for RSSs in the future

To date, both countries have focused mainly on financial RSSs. Stakeholders cite lack of administrative capacity, infrastructure and political will as obstacles to attempting outcomes-based RSSs.

In comparison to financial schemes where the overarching objective is to manage budget impact with limited consideration of the real-life added value of introducing the drug, outcomes-based schemes aim to achieve true risk sharing between the two parties by linking current, or future, reimbursement to real-life effectiveness. Coverage with evidence development (CED) schemes recognise that efficacy data from clinical trials is often insufficient to accurately gauge

utilisation or cost-effectiveness in real-life clinical practice. In CED schemes, real-life data are collected during the initial reimbursement period, after which the reimbursement status may be adjusted based on the drug's performance and utilisation in real life.

“Price volume schemes are mandatory for all innovative pharmacy drugs

In an outcome guarantee (also commonly known as payment-by-results) scheme, the manufacturer would offer a rebate or a discount if the drug does not achieve a predetermined outcome level. As yet, few countries have fully embraced health outcomes-based risk sharing. This is certainly understandable within the current economic climate; payers are compelled to focus on containing budget impact and certainly would face difficulties in setting up and maintain resource-intensive data collection registries. In Hungary, a framework for such schemes was actually developed in 2010 but application of the framework has been stalled. Poland's capacity to monitor outcomes-based schemes is limited at the moment. In 2012, 3.85% of the 26 RSS proposed included a payment by result element.⁶ There are some isolated registries maintained privately or by non governmental organisations (NGOs) for certain diseases, but there have not been efforts from public institutions to coordinate data-sharing. There is some push to set up electronic prescribing and registries, but bureaucratic delays are undermining timely implementation.

As RSSs are a relatively new mechanism, there is certainly room for creativity and innovation. In recognition of the political constraints on governments in the current economy, manufacturers could propose risk-sharing arrangements and offer to set up and fund monitoring registries for outcomes-based schemes. Such arrangements would especially appeal to health ministries if manufacturers were to set up registries that integrate into and strengthen existing data collection systems (rather than standalone drug-specific monitoring projects). Outcomes-based routes could prove advantageous to the manufacturer rather than yielding to discounts or other financial arrangements.

There is not yet a general consensus within the policy community on whether RSSs are a good method to achieve the mutual goals of payers and industry, nor has there been a systematic evaluation of their impact. In the case of Hungary and Poland, governments are facing budget constraints and patients are facing reduced access to medicines; thus new policy tools such as RSSs that potentially allow for rational spending, while ensuring patient access to new medicines, should be attempted implemented, evaluated and considered in a committed manner.

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NEW JOINT HOSPITAL PROCUREMENT PROGRAMME IN CROATIA

By: Luka Vončina and Anna Sagan

Summary: In 2012, faced with budget cuts and pressures to rationalise health care costs, the Croatian Ministry of Health initiated its joint hospital procurement programme. State-owned hospitals, which previously procured all goods and consumables individually, were directed to form joint purchasing bodies for items that made up the highest expenditure, e.g. medicines, medical devices, energy, etc. They adopted a decentralised approach where each hospital was delegated to procure several categories for all participating hospitals. Despite substantial opposition from manufacturers and retailers, the reform was successful as it standardised the quality of procured goods and reduced prices by an average of 27%.

Keywords: Procurement, Hospitals, Medicines, Medical Devices, Croatia

Introduction

Croatia spends around 7% of its GDP on health care, which, although slightly higher than the European Union (EU)-12 average is much lower than the EU15 average of 10.4%. Over 80% of total health spending comes from the public sector. Established in 1993, the Croatian Health Insurance Fund (CHIF) is the single insurer in the mandatory health insurance system and the main purchaser of health services, accounting for over 90% of public health expenditure.¹

A number of changes were made in the financing and delivery of health care in the 1990s, after Croatia gained independence from the Federal Republic of Yugoslavia. Despite the improvements, the health system continued to face a variety of financial and structural

problems, such as the imbalance between revenues and expenditures, excess infrastructure and low efficiency, and a number of measures were introduced in the first decade of the 2000s in response to these problems.¹ These reform efforts culminated in the so-called ‘2008 reform’. The reform encompassed a broad range of measures aimed at: (a) increasing revenues (e.g. by reducing exemptions from co-payments or earmarking certain tax revenues for health); (b) reducing expenditure (e.g. by introducing centralised procurement of medical equipment such as CT and MRI scanners and linear accelerators); and achieving operational improvements (e.g. through modification of hospital and primary care payment models).^{2 3} Although the reform was launched to address the longstanding problems of deficits in the

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Table 1: Examples of prices achieved for identical devices marketed by the same manufacturers through individual hospital tenders in 2010 and 2011

Item	Hospital/price in HRK	
Femoral head for the total endoprosthesis of the hip	Clinical hospital centre Rijeka	General hospital Sibenik
	250	750
Femoral head for the partial endoprosthesis of the hip	General hospital Varazdin	General hospital Dubrovnik
	545	690
Press fit acetabular cup	Clinical hospital centre Sisters of mercy	General hospital Bjelovar
	2400	4050
Uncemented ace-tabular cup	General hospital Cakovec	General hospital Varazdin
	3900	6500
Proximal femoral nail for the total endoprosthesis of the hip	Clinical hospital Lovran	General hospital Cakovec
	3090	4600
Standard acetabular plate for hip replacement revision	General hospital Varazdin	Clinical hospital Lovran
	1479	3420
Screws for acetabular plates	Clinical hospital centre Rijeka	Clinical hospital centre Zagreb
	200	800
Intraocular lens type X	Clinical hospital centre Rijeka	General hospital Pula
	320	376
Intraocular lens type Y	Clinical hospital centre Zagreb	General hospital Cakovec
	350	621
Stent type A	Clinical hospital centre Rijeka	General hospital Zadar
	4500	11500

Source: ¹⁰

health care system and was planned before the start of the economic crisis, since its launch coincided with the deterioration of the economic situation, the reform was promoted as part of an antirecessionary package.⁸

“ joint procurement for all state-owned hospitals

The effects of the financial crisis started to unfold in Croatia from mid-2008, when the costs of foreign borrowing increased.⁹ Gross Domestic Product (GDP) growth turned negative in 2009 and both the government deficit and gross debt started to increase rapidly.⁹ Initially, only limited measures were taken in response to the growing fiscal problems. They included reductions of public

infrastructure investments, an increase in the general VAT rate and the imposition of stringent fiscal expenditure targets (Law on Fiscal Responsibility, effective from 1 January 2011). The health care sector was largely unaffected by the austerity measures, as the health system's contribution to the fiscal deficit was relatively small compared to other sectors (such as pensions).⁹ At the same time, the effects of the 2008 reform were expansionary: overall health care funding increased in 2009–10, in spite of the increase in unemployment (and thus a decrease in the total number of active workers contributing to compulsory health insurance and a reduction in CHIF revenues).⁹

The new centre-left government that took office in January 2012 initiated stronger fiscal adjustment strategies (mainly to avoid a downgrade in the country's credit rating) and austerity efforts focused on the rationalisation of the public sector, reduction of public sector benefits, cuts to non-discretionary

welfare spending, and faster privatisation of state property. In addition to tackling long-overdue structural reforms of the pension system and the labour market⁷ radical measures were also implemented in the health sector. The 2012 health budget decreased by over 2% compared to 2011⁹ and the hospital sector was singled out to achieve significant savings, particularly after rationalisation of staffing and the implementation of centralised procurement.⁹

Joint hospital procurement

Until 2012, all hospitals procured medical products and most other goods individually through public tenders (centralised procurement of medical equipment was introduced by the 2008 reform; see above). This practice resulted in substantially different prices achieved for similar or even identical goods produced by the same manufacturer (see Table 1). In addition, as purchasing was not standardised, patients could not have been guaranteed the same quality

Table 2: Delegated central authorities for public procurement and procurement categories

Delegated central authority for public procurement	Procurement categories
Clinical hospital centre Zagreb	All medicines that have generic parallels, products for ophthalmology and neurosurgery, pacemakers
Clinical hospital centre Osijek	Postal services, laboratory diagnostics and microbiology products
Clinical hospital centre Rijeka	Reagents, tests and supplies for pathology and cytology, cleaning and maintenance supplies (including antiseptics and disinfectants), textiles
Clinical hospital centre Split	Groceries
Clinical hospital Dubrava	Products for cardiac surgery, vascular surgery, plastic surgery, gastroenterology, anaesthesiology, sterilisation, transfusion and haemodialysis
Clinical hospital Merkur	Medical gases
Clinical hospital centre Sisters of Mercy	Devices for interventional radiology and interventional cardiology, nuclear medicine, other medical supplies (bandages, needles, syringes, plaster, infusion systems, gloves, catheters)
Hospital for Infectious Diseases	Fuel
Clinical hospital Lovran	Products for orthopaedics and trauma surgery
Croatian Health Insurance Fund	Electricity and telephony (fixed and mobile), Internet, office supplies (including toner and ink)

Source: Authors

of medical products and consumables regardless of where they received treatment, although they were all insured by the same public health insurance fund that financed all hospitals.

“
Estimated
savings
amounted to
HRK 449 million
(€59 million)

Due to the substantial differences in prices (as much as fourfold for identical products) that suggested ample scope for savings through economies of scale, the Ministry of Health issued a decree introducing mandatory implementation of joint procurement for all state-owned hospitals.¹⁰ In addition, county (local administration) owned hospitals were invited to participate if they so chose. The large majority decided to do so.

Decentralised approach

A decentralised approach to organising joint procurement was adopted in order

to increase the speed of the reform and to efficiently utilise staff already employed in hospital procurement units. Centralising procurement in a single purchasing body would have entailed substantial and lengthy administrative procedures that would have delayed implementation.

Nine state-owned hospitals and the Croatian Health Insurance Fund were delegated as central authorities for public procurement and were each assigned a scope of products that they would procure for all participating hospitals (see Table 2). The distribution of joint procurement categories was decided by analysing historical results i.e. hospitals that previously achieved best value for money for a certain procurement category were assigned as central purchasers. Distribution of the administrative burden (considering the complexity of tendering procedures) was also taken into account as the government requested speedy implementation. Procurement categories were determined based on financial consumption.

Each delegated central authority was given the task to collect and analyse required quantities of all products from the procurement categories it was assigned, as well as quantities and prices at which these were purchased annually from 2009 to 2011. The reform process did not require lengthy legislative changes as the

Croatian Public Procurement Act (aligned to EU requirements during the accession process) already entailed the necessary legal basis for joint procurement for public institutions that choose to do so.

Transparency

In October 2012, a total of 45 public tenders worth HRK 2.3 billion (€306 million) were prepared and presented for public discussion to all interested parties on the Ministry of Health website in order to increase the transparency of the procurement process.¹¹ A committee consisting of representatives from the Ministries of Health, Finance, Internal Affairs, Regional Development and EU Funds, as well as representatives of the National Agency for Market Competition and the State Office for Public Procurement discussed the received comments with the hospitals that prepared the tendering documents. Subsequently, after modifications, all tenders were released consecutively from January to April 2013.

Unsurprisingly, manufacturers invested substantial efforts in challenging joint procurement tenders through a variety of legal means. Their efforts were only partially successful as by February 2014 a total of 33 tenders were successfully concluded resulting in 112 two-year framework agreements for procurement

items with various manufacturers worth HRK 1.2 billion (€156 million). The only exception to the length of the framework agreements was for medicines that have generic equivalents. This agreement was concluded for a one-year period due to the large number of new generic equivalents that enter the Croatian market annually and stimulate further market competition through price decreases. The remaining twelve tenders that were legally challenged are expected to be finalised later in 2014.

Savings

Estimated savings from the concluded tenders amounted to HRK 449 million (€59 million) or 27.2% compared to expenditure on the same items in the year preceding joint procurement. The largest savings have been achieved for medicines that have generic equivalents (44.7%), products for transfusion (45.8%), office supplies (39.4%), products for ophthalmology (37%), and electricity (35.4%).¹⁰

Expansion of joint procurement programme

Encouraged by the successful results, in July 2013 the Ministry of Health decided to expand joint procurement to further procurement categories. The nine state hospitals that implemented the tendering procedures in 2012 and 2013 were again designated as central authorities for public procurement due to the experience they accumulated in the first round of joint tendering. New procurement categories include products and consumables used in electro surgery, endoscopy, dentistry, in-vitro fertilisation, laparoscopic instruments, surgical instruments and knot kits. These additional procurement categories were chosen in consultations with hospital directors and the tenders should be finalised by Autumn 2014.

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NEW PUBLICATIONS

Health professional mobility in a changing Europe. New dynamics, mobile individuals and diverse responses

Edited by: J Buchan, M Wismar, IA Glinos and J Bremner

Copenhagen: World Health Organization 2013.
Observatory Studies Series No. 32, 2014

Number of pages: xx + 387 pages; **ISBN:** 978 92 890 5025 8

Freely available for download: http://www.euro.who.int/__data/assets/pdf_file/0006/248343/Health-Professional-Mobility-in-a-Changing-Europe.pdf?ua=1

Health professional mobility in Europe has become a fast-moving target for policy-makers. It is evolving rapidly in direction and



magnitude as a consequence of fundamental change caused by European Union enlargement and the financial and economic crisis. Health professional mobility changes the numbers of health professionals in countries and the skill-mix of the workforce, with consequences for health-system performance.

Countries must factor in mobility if they are forecasting and planning their workforce requirements. To this end they need clarity on mobility

trends and the mobile workforce, and effective interventions for retaining domestic and integrating foreign-trained health workers.

This book is the second volume of the PROMeTHEUS project and presents practical tools such as a yardstick for registry methodology, a typology of mobile individuals, qualitative tools for studying the motivation of the workforce and a set of concrete policy responses at EU, national and organisational level including bilateral agreements, codes and workplace responses.

Contents: Part I – Setting the scene, key finding and lessons; Part II – The changing dynamics of health professional mobility; Part III – the mobile individual; Part IV – Policy responses in a changing Europe; Lessons from retention strategies outside Europe.

Regulating Long-Term Care Quality: An International Comparison

Edited by: V Mor, T Leone and A Maresso

Cambridge University Press: 2014

Number of pages: 519; **ISBN:** 978 1 107 66535 4

Available for purchase at: www.cambridge.org/9781107665354

The number of older people relying on formal long-term care services is dramatically increasing year after year, and the



challenge of ensuring quality and financial stability of care provision is one faced by governments both in the developed and developing world.

This book is the first to provide a comprehensive international survey of long-term care provision and regulation, built around a series of case studies from Europe, North America and Asia. The analytical framework allows different approaches that countries

have adopted to be compared side by side and readers are encouraged to consider which quality assurance approaches might best meet their own country's needs. An introductory chapter sets out important themes and trends to highlight wider issues underpinning the need to regulate the quality of long-term care, while the final chapter summarises and analyses all the country-specific case studies to highlight policy options and their advantages and disadvantages. This timely book is a valuable resource for policymakers working in the health sector, researchers and students taking graduate courses on health policy and management.

Contents: Foreword; A framework for understanding regulation of long-term care quality; Country case studies for Australia, Austria, Canada, China, England, Finland, Japan, Germany, the Netherlands, New Zealand, the Republic of Korea, Spain, Switzerland and the United States; Regulating quality of long-term care – what have we learned?

NEWS

International

Informal meeting of EU Health Ministers: economic crisis, e-health and migration

The effects of the economic crisis on health and the safeguarding of health systems' resilience, migration and its effects on health care, and e-Health, with an emphasis on e-Prescription and m-Health, were the focus of discussions at a two-day informal meeting of EU Health Ministers in Athens on April 28 and 29.

The meeting was chaired by Greek Health Minister Spyridon-Adonis Georgiadis, who stressed, in his opening remarks that "as Europeans respecting human rights, we should aim at finding the way to provide health services for all citizens in the best possible way, even during the present economic crisis, which we are determined to overcome. We should always remember that the EU is the best place to live in today".

With regard to the effects of the economic crisis on health care, there was a broad consensus on ensuring access for all to health care and on further systemic improvements. It was pointed out that a new reality has been introduced by the economic environment and therefore, health systems need to be adapted accordingly. The core of this new reality consists of enhancing cooperation, exchanging best practices and information among member states, in order to secure health systems' resilience, in a number of fields including: (a) the cost and pricing of pharmaceutical products, (b) the basket of basic health care services mainly covering most vulnerable groups, (c) investing in prevention and health care cost reduction, and (d) health systems performance assessment. Finally, "the deeper involvement of health ministers, as well as health in the framework of the European Semester [a European cycle of economic policy coordination] were also issues of discussion", added Minister Georgiadis.

In relation to migration and public health, ministers agreed on: (a) promotion of access to health care for all migrants; (b) the development of guidelines and methodology for the control of communicative diseases; (c) the need for special health services for particularly vulnerable migrant groups, such as pregnant women and small children; (d) the creation of a Special Working Group in the framework of the Health Security Committee to effectively address issues at hand; (e) enhanced member state cooperation for the exchange of best practices and mutual support, and (f) better information diffusion and exploitation of structural funds' resources, including the new Asylum, Migration and Integration Fund. The meeting also highlighted the interests of ministers in using e-health solutions for cost containment and improved health care provision.

EU Health Commissioner Tonio Borg stressed, regarding health reform in Greece, that "no health system is sustainable unless reformed", further adding that "the introduction of ePrescriptions has created one of the most advanced systems in Europe". The Commissioner underlined, regarding migrants, "let us not treat them as a disease, but treat the diseases of migrants", noting, in particular, the potential of the new Asylum, Migration and Integration Fund. He further thanked the Greek Minister on his support to the European Commission's proposal for a Joint Procurement Agreement on Vaccines.

Videos from the informal meeting are available at: <http://tinyurl.com/np4b3a6>

New Tobacco Products Directive

On May 19 a new Tobacco Products Directive came into force. The goal is to reduce the number of smokers in the European Union by at least 2% by 2020. The directive was approved by the Council of the European Union in March following a first-reading agreement reached with the European Parliament in December. Member states now have two years to transpose the directive into their national

laws, and will have to apply the new rules from the end of this period.

The main objective of the directive's revision was to make tobacco products less attractive, especially to young people, by strengthening the rules on how tobacco products can be manufactured, presented and sold. It includes a ban on the placing on the market of cigarettes and roll-your-own tobacco with flavours such as fruit flavours, menthol or vanilla within two years after the entry into force of the directive. This is to make sure that tobacco products taste and smell like tobacco products. For those tobacco products with characterising flavours whose EU wide sales in their product category represent more than 3% (e.g. mentholated cigarettes), the ban will apply only six years after the entry into force of the directive.

Tobacco products containing additives in quantities that increase in a significant or measurable manner toxic or addictive effects, or carcinogenic, mutagenic or reprotoxic properties, will also be banned. The directive also means that mandatory combined (picture and text) health warnings will have to be placed at the top edge of both sides of the pack of cigarettes and roll-your-own tobacco. These warnings must cover 65% of the front and back of packaging. There is also a ban on "lipstick-style" packs aimed at women – all packs must now have at least 20 cigarettes to leave room for health warnings. It will also ban promotion elements such as saying a product is free of additives or is less harmful than other brands.

The directive also allows member states to prohibit internet sales of tobacco and related products, and sets out safety and quality requirements for consumer electronic cigarettes, including a maximum concentration level for e-cigarettes. It obliges manufacturers to notify novel tobacco products before placing them on the EU market. It also introduces EU-wide tracking and tracing to combat illicit trade in tobacco products.

The new directive is available at: http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf

Monitoring the safety of medicines: European Medicines Agency report

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce their risks. In May 2014 the European Medicines Agency (EMA) presented the European Commission with its first report on the tasks it undertook during the first year of application of the EU's new pharmacovigilance legislation. Responsibility for implementing the new legislation is shared between the European Commission, the national competent authorities and the EMA. The report, covering the year from July 2012, highlights activities that contribute to the EU system of pharmacovigilance being one of the most advanced and comprehensive systems in the world.

It reveals positive results for ensuring the main objectives of the new legislation, i.e. better collection of key information on medicines, improved analysis and understanding of data and information, improved timeliness of procedures and greater transparency. The report found nearly 25,000 patient reports of suspected adverse drug reactions – an increase of more than 60% compared to the previous 12 months. There have also been product information changes for medicines following assessment of signals of new or changing safety issues. For example, hearing disorders associated with medicines containing roxithromycin and the risk of hypoglycaemia associated with medicines containing tramadol. A number of major public health reviews were also initiated including reviews on all combined hormonal contraceptives and venous thrombo-embolism and Codeine-containing medicines used for pain relief and overdose in children. The agency has also been involved in training individuals in pharmacovigilance, and has published a catalogue with training material for the implementation of the new pharmacovigilance legislation.

The EMA's full report is available at: http://ec.europa.eu/health/human-use/pharmacovigilance/developments/index_en.htm

More information on pharmacovigilance in the EU at: http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm

Council of Europe launches guide on end of life care

On May 5 in Strasbourg the Council of Europe launched a 'Guide on the decision-making process regarding medical treatment in end-of-life situations' at a special conference. The conference was held by the Committee on Bioethics, under the auspices of the Austrian Chairmanship of the Committee of Ministers of the Council of Europe. The Council of Europe has recognised that advances in medical knowledge and developments in technology bring with them ethical challenges. The Committee on Bioethics was established to address legal and ethical challenges in the medical field.

The Guide presents an informative summary of principles to be applied to the decision-making process in specific end of life situations. This takes the form of a process for ethical decision-making rather than a list of actions to take in specific situations. Although aimed mainly at medical professionals, the authors of the guide suggest that it could form a basis for discussion among "patients, their family and close friends, all those providing support, and associations dealing with end-of-life situations."

The guide notes that, in addition to aiming to cure disease, that doctors "also have a duty to take care of their patients, ease their suffering and provide them with support," while going on to recognise that "the prolonging of life must not in itself be the sole aim of medical practice, which should attempt just as much to relieve suffering."

It covers issues such as dialogue between health professionals and patients; attendance to patients' previously expressed wishes; unnecessary or disproportionate treatment; artificial nutrition and hydration and equity in access to health care. On the topic of equity, the guide states that "it is now generally accepted that palliative care is an integral part of health care, as asserted in Recommendation Rec(2003)24 of the Committee of Ministers of the Council of Europe on the organisation of palliative care. In this context, it is therefore for governments to guarantee equitable access to such care for anyone whose state of health requires it."

The guide is available at: <http://tinyurl.com/lx6qflp>

67th World Health Assembly

On May 24, the 67th World Health Assembly closed after adopting more than 20 resolutions on public health issues of global importance. These included the approval of a resolution on antimicrobial drug resistance in response to growing concern, recognition of the need to do more to address global violence, make better use of health technology assessment, help implement the Minamata Convention on Mercury and plan for health in the post 2015 development agenda.

Antimicrobial resistance

This resolution urged governments to strengthen national action and international collaboration. This requires sharing information on the extent of resistance and the use of antibiotics in humans and animals. It also involves improving awareness among health providers and the public of the threat posed by resistance, the need for responsible use of antibiotics, and the importance of good hand hygiene and other measures to prevent infections.

The resolution also urged member states to strengthen drug management systems, to support research to extend the lifespan of existing drugs, and to encourage the development of new diagnostics and treatment options. As requested in the resolution, the World Health Organization (WHO) will now develop a draft global action plan to combat antimicrobial resistance, including antibiotic resistance for presentation to the World Health Assembly for approval next year.

The global challenge of violence

Member states agreed to work to strengthen the role of the health system in addressing violence. WHO will develop a global plan of action to strengthen the role of national health systems within a multi-sectoral response to address interpersonal violence, focusing on women and children in particular.

Across the world, each year, nearly 1.4 million people lose their lives to violence. Women and girls experience specific forms of violence that are often hidden.

Globally, one in three women experiences physical and/or sexual violence at least once in their lives. For every person who dies as a result of violence, many more are injured and suffer from a range of adverse physical and mental health outcomes.

Health intervention and technology assessment in support of universal health coverage

Wasteful spending on medicines and other technologies has been identified as a major cause of inefficiencies in health service delivery. Following the adoption of a resolution on health technology assessment at the Health Assembly, the WHO will support capacity-building for health technology assessment in countries. It will provide tools and guidance on health technologies and intensify networking and information exchange among countries to support priority setting.

Public health impacts of exposure to mercury and mercury compounds

The World Health Assembly also requested the WHO Secretariat to provide expert advice to help health ministries implement the 2013 Minamata Convention on Mercury. This aims to "protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds". The legally binding convention will enter into force when 50 countries have ratified it. Most mercury is released through burning coal and waste and mining for mercury, gold and other metals. The Convention encourages countries to identify and better protect people who are at particular risk from mercury and highlights the need to provide effective health services for everyone who has been exposed to mercury.

Polio eradication

Monaco made an intervention on behalf of the European Union (EU) to support the Director-General's decision (on 5 May 2014) to declare the current international spread of polio a public health emergency of international concern. In addition to high-quality surveillance of acute flaccid paralysis, the EU suggested setting up evidence-based standards for environmental surveillance of polio, following recent experience

in Israel, where poliovirus was isolated in sewage as a result of surveillance. Monaco also noted the strong link between conflict, insecurity and the spread of poliovirus and called for the necessary measures to be put in place to ensure the widest vaccination coverage under secure conditions for the population and health workers.

More information on the World Health Assembly at: <http://www.who.int/mediacentre/events/2014/wha67/en/>

Country news

Scotland – Alcohol Minimum Unit Price case referred to European court

In May 2012, the Scottish Parliament passed The Alcohol (Minimum Pricing) (Scotland) Act 2012 setting a £0.50 minimum unit price as part of an effort to tackle alcohol misuse. According to National Health Service figures, Scottish deaths from chronic liver disease are among the highest in Europe, while alcohol kills the equivalent of 20 people a week in Scotland. Under the plan the cheapest bottle of wine would be £4.69 and a four-pack of lager at least £3.52.

The legislation has been subject to legal challenge, with the Scottish Whisky Association (SWA), whose members account for more than 90% of the Scottish alcohol industry's production, appealing against a ruling of Scotland's Supreme Court – the Court of Session – that the minimum alcohol pricing policy was within the powers of Scottish ministers and not incompatible with EU law. The appeal hearing focused on what the aim of minimum unit pricing is, whether this aim could be achieved using alcohol excise duties which would be less distortive to the free movement of goods (article 34 of the Treaty on the Functioning of the European Union–TFEU), and whether the policy was proportionate to protect public health and therefore justifiable under article 36 of the TFEU. The SWA also maintain it will be ineffective in tackling alcohol misuse and say it will penalise responsible drinkers and damage the industry. Two major European wine and spirit organisations also support the SWA's appeal.

In response, on 30 April, the Court of Session referred the Scottish Alcohol Minimum Unit Price for a preliminary ruling to the EU Court of Justice (ECJ). Scottish Health Minister Alex Neil welcomed the referral from the courts and stressed that it was right this "precedent-setting case" was considered by the ECJ, the highest authority on EU law. He added that "the evidence shows that minimum unit pricing is an effective way to tackle alcohol-related harm. This is because it targets heavy drinkers in particular as they tend to drink the cheap, high strength alcohol that will be most affected by the policy."

David Frost, SWA chief executive, said that the SWA "believed minimum unit pricing was contrary to European Union law and that it was likely in the end to go to the European Court. We also believe that minimum unit pricing would be ineffective in tackling alcohol misuse and would damage the Scotch Whisky industry in the UK and overseas."

Before the case can be heard by the European Court of Justice the questions it will be asked must be decided. This will involve another hearing in Edinburgh at which the Scottish government, the SWA and other parties to the case will give their views. It could take two years before a ruling will be given by the European Court. Even then it may not be possible for the Scottish government to implement the policy, as the SWA could appeal to the UK Supreme Court, a process which would take several months. The UK government previously abandoned plans for minimum pricing in England and Wales, after Prime Minister David Cameron cited concerns over evidence it would not work and possible legal challenges.

The Opinion of the Court of Session is available at: <https://www.scotcourts.gov.uk/opinions/2014CSIH38.html>

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7th



EUROPEAN
PUBLIC
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CONFERENCE

Mind the gap:

Reducing inequalities in health and health care

SECC, Glasgow
19 – 22 November 2014



- How can we reduce inequalities in health and health care?
- What more can and should we do to promote the health of the public in European countries?

Share and learn from experiences

Exchange knowledge, build your capacity

To promote population health in all countries, understanding the causes underlying inequities in health and discovering which interventions or policies may reduce inequalities and under what circumstances is critical. Due to current economic circumstances in many countries, it is more important than ever for researchers, policymakers and practitioners to learn from each others' experiences rather than constantly reinventing the wheel.

For detailed information and online registration please visit www.ephconference.eu

The EPH conference is an initiative of the European Public Health Association (EUPHA) and aims to contribute to the improvement of public health in Europe by offering the means to exchange information and a platform for debate to researchers, policymakers and practitioners in the field of public health, health services research and public health training and education. The conference covers a broad range of health issues, has a high political relevance, a large involvement of European networks and organizations and attracts a major audience of public health professionals and students.

Next year
14–17 October 2015,
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EUPHA is an independent international scientific umbrella organization for public health associations and institutes in Europe to encourage a multidisciplinary approach to public health.



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The European Parliament elections, the elections for the President of the European Commission and the new College of Commissioners in **2014 will earmark an important year** for European politics in general and for health

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