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- Industry engagement

- NHS view: Clinical Trials Directive
- Medicines innovation
- European reference networks
- Kazakhstan: health system reform

Volume 18 | Number 4 | 2012

European Observatory on Health Systems and Policies
a partnership hosted by WHO

EUROHEALTH

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Article Submission Guidelines
Available at: http://tinyurl.com/eurohealth

Published by the European Observatory
on Health Systems and Policies

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

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The European Observatory on Health Systems and Policies is a partnership between the World Health Organization Regional Office for Europe, the Governments of Belgium, Finland, Ireland, the Netherlands, Norway, Slovenia, Spain, Sweden and the Veneto Region of Italy, the European Commission, the European Investment Bank, the World Bank, UNCAM (French National Union of Health Insurance Funds), London School of Economics and Political Science and the London School of Hygiene & Tropical Medicine.

Design and Production: Steve Still

ISSN 1356-1030

LSE Health

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EDITORIAL OVERVIEW

Since the health of a population is affected by policies and programmes originating beyond the health sector, governments need to employ a strategy that fosters intersectoral action. Health in All Policies (HiAP) is a dual process – it consists of fostering health considerations in other policy areas and taking into account the potential impact of other sectoral policies on the health of the population (the wider social determinants of health) – thus leading to several policy coordination challenges and the need for targeted intersectoral governance mechanisms.

When successfully implemented, HiAP can contribute positively to key aims in promoting public health, such as ameliorating population health status and it can also help to diminish health inequalities both within countries and throughout the wider region. It is not surprising therefore, that recently intersectoral governance and HiAP have gained high level attention as a priority of WHO's Health2020 strategy, while the EU is also promoting it as a strategic policy tool.

The first article in the **Eurohealth Observer** section explores key intersectoral structures used by governments, parliaments and the civil service to promote HiAP. The authors also identify which structures can trigger different governance actions or outcomes and summarise some key conditions for their successful implementation. We then present four case study articles which focus on specific intersectoral governance structures – parliamentary committees, inter-departmental units and committees, joint budgeting and industry engagement. These articles explore in greater detail how such intersectoral mechanisms operate in practice and their strengths and weaknesses in achieving HiAP objectives.

In the **Eurohealth International** section, Willy Palm and colleagues discuss the concept of European reference networks to connect health centres to share knowledge and expertise in diagnosing and treating specific health problems. They contend that under the Cross-border Care Directive, such networks can work to improve patient care, but should build on existing practices in Member States to be successful. In her article, Elizabeth Zanon identifies the deficiencies with the current Clinical Trials Directive, analyses the proposals for new EU legislation and argues that an improved and streamlined EU regulation on clinical trials is essential. Next, Jim Attridge and David Nutt approach the topic of innovation in medicines for severe mental illness. They argue that unless the tide of declining investment for these types of medicines turns, this area may be the next innovation desert.

In this issue's **Eurohealth Systems and Policies** section, Alexandr Katsaga and colleagues discuss health system reforms in Kazakhstan. Since 2005, two comprehensive national reform programmes have endeavoured to change health care financing and provision, while improving prevention and quality of care. The article then identifies areas of the Kazak health system still in need of further development.

Finally, the **Eurohealth Monitor** section draws attention to three new HiT (Health Systems in Transition) profiles for Northern Ireland, Scotland and Wales and a new book called *Intersectoral Governance for Health in All Policies,* while the news section keeps you up to date on health policy developments across Europe and beyond.

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

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

Cite this as: ***Eurohealth*** 2012; 18(4).

INTERSECTORAL GOVERNANCE FOR HEALTH IN ALL POLICIES

By: Matthias Wismar, David McQueen, Vivian Lin, Catherine M Jones and Maggie Davies

Summary: Many policies with important consequences for the health of the population are outside the health sector and the remit of ministries of health. If we want to address the health consequences of these policies we need to reach out. To this end, intersectoral governance can help to build bridges and facilitate dialogue and collaboration between other ministries, sectors and stakeholders. This article presents key intersectoral structures used by governments, parliaments and the civil service. It also presents intersectoral structures for managing funding arrangements and engagement beyond government. In addition, we summarise some key conditions for the successful implementation of intersectoral governance.

Keywords: *Intersectoral Governance, Health in All Policies, Intersectoral Structures, Governance Actions, Health2020*

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Introduction

Intersectoral governance for health in all policies (HiAP) is a policy practice in many European countries that aims to tackle major health issues by aligning health and non-health objectives and policies. These may include housing, consumer protection, environment, land use, transport, taxes, waste management and working conditions.[1] A great deal of scientific progress has been made to understand the social causes of ill health and health inequities and the relationships between policies in these areas and population health, and also with regard to effective interventions.[2] But without a particular focus on intersectoral governance structures, actions and contexts, implementation will remain sluggish and HiAP will fall short of its potential. This is not a marginal issue, it is central to the implementation of public health strategies.

A current example of the importance of intersectoral governance in the implementation of public health strategies comes from England. The Department of Health announced in November 2012 that the cabinet sub-committee on public health (known as the Public Health sub-Committee) will be abolished after only two years in existence. According to Whitehall sources, it had proven difficult to get ministers from departments other than health to attend the sub-committee meetings and it had met only a few times.[3] The aim of the cabinet sub-committee was to have an important and leading role in the implementation of the public health strategy in England. The central government was aiming to establish a framework so that local action in public health and on the social determinants of health could be most effective, and to do nationally only the things that need to be done at that level. To this end, the cabinet sub-committee was meant to work

Table 1: Overview of how intersectoral governance structures may address governance action to support Health in All Policies

			Governance actions								
			Evidence support	Setting goals & targets	Coordination	Advocacy	Monitoring & evaluation	Policy guidance	Financial support	Providing legal mandate	Implementation & management
Intersectoral governance structures	Government level	Cabinet committees and secretariats		√	√	√					
	Parliament level	Parliamentary committees	√			√	√	√		√	
	Bureaucratic level/(civil service)	Interdepartmental committees and units	√		√	√	√	√			√
		Mega-ministries and mergers			√						√
	Managing funding arrangements	Joint budgeting			√				√		√
		Delegated financing			√	√			√	√	√
	Engagement beyond government	Public engagement	√	√		√		√			
		Stakeholder engagement				√		√	√	√	
		Industry engagement			√				√		

Source: [4]

across multiple departments to address the wider determinants of health. The issues to be tackled were laid out in the public health strategy and included mental health, tobacco control, obesity, sexual health, pandemic flu preparedness, health protection and emergency preparedness.[5] In order to fulfil its role, the membership of the cabinet sub-committee was composed in a truly intersectoral manner. It was chaired by the then Secretary of State for Health and composed of nineteen cabinet ministers and junior ministers, including those for Employment, Energy and Climate Change, Families, Decentralisation, Agriculture and Food, the Treasury, Home Office, Equalities, Transport, Sport and the Olympics. The chief medical officer could also be invited as required.

Public health doctors, practitioners and activists have expressed their dismay at the scrapping of the cabinet sub-committee. Concerns have been voiced that this could be a U-turn in the government's pledge to make public health a priority. Unless the sub-committee is replaced by another well or better functioning intersectoral governance structure, a devoted high-level mechanism for cross-departmental dialogue and collaboration will be absent.

The governance challenges of HiAP

The centrality of dialogue and cooperation across departments to the success of HiAP can be illustrated by the example of alcohol control policy. There are many policies, other than health sector ones, linked to the social determinants of alcohol consumption, and as such they provide multiple entry points for an alcohol control policy. However, most of the entry points are within the remit of the ministries responsible for taxes, retail, transport, education, economic development, criminal justice and social welfare. These ministries may pursue different objectives: they want to stimulate economic activity; enhance mobility; or provide security. Some of these objectives may be conducive to the aim of curbing alcohol consumption, whereas others are indifferent or even detrimental. Without a strong intersectoral governance structure ensuring common orientation and implementation across departments, public health strategies will make limited progress.

Despite occasional political fluctuations, there is a high level of sustained interest in tackling the social determinants of health. In September 2012, the Member States of the World Health Organization (WHO) European Region adopted a new European health policy, *Health2020**. The policy posits public health as a major societal asset and pursues two strategic objectives: stronger equity and better governance. At the heart of these intertwined objectives is a firm commitment to intersectoral governance using a variety of structures.[6]

What are those intersectoral structures? What intersectoral action can they facilitate and under what circumstances and for what issues do they work best? These questions are raised in the four case studies included in this issue of *Eurohealth*. They deal with parliamentary committees, inter-departmental units and committees, joint budgeting and industry engagement. These case studies are abridged versions of longer chapters developed for a recently published study, which has dealt with nine intersectoral governance structures.[4] As in the study, here we use a matrix as a conceptual framework to understand which

* Moreover, the *8th Global Conference on Health Promotion*, to be held in Helsinki in 2013, and co-organised by WHO and the Finnish Ministry of Social Affairs and Health, will focus on HiAP. In support of this event and under the leadership of the Finnish Ministry, a new study on implementing HiAP will be published. See: http://www.hiap2013.com/ for details.

governance structures can trigger different governance actions (**see Table 1**). We discuss each structure in turn.

> Without strong intersectoral governance, public health strategies will make limited progress

Cabinet sub-committees, such as the aforementioned cabinet sub-committee on public health, either standing or ad hoc, are an intersectoral structure that facilitates dialogue and collaboration at government level. Health or certain aspects of health may be pursued by cabinet sub-committees that do not bear health in their name – for instance 'sustainability sub-committees'. While it is difficult to trace the work of these cabinet committees due to confidentiality issues, emerging evidence underscores their importance in setting the context for policy change by developing a common understanding of issues and solutions.[7]

The ***role of parliamentary committees*** is analysed in this issue of *Eurohealth* through a case study on the United Kingdom's House of Commons Health Select Committee inquiry into health inequalities. It shows that parliament can be an important advocate for intersectoral governance and HiAP. As the example illustrates, a clear assessment of policy development and the results of policy-making can inform better governance. This parliamentary committee's work also went beyond partisan boundaries and prepared the ground for cross-party consensus and policy.

Intersectoral committees are one of the most commonly used intersectoral governance structures. There is plenty of literature on how these committees may be run, including appropriate terms of reference, the adequate level of seniority and the suitable frequency for meetings. While this technical view is indispensable when running intersectoral committees, it only tells part of the story. Intersectoral committees are often derided and unpopular among their members, and they can be ineffective or even used as a mechanism for delay or sabotage. They are only operative under very specific circumstances; while useful on bureaucratic issues, they cannot resolve political ones. They work best for important issues with wide consensus, and worst when this consensus is absent or when the issue is not considered a priority (see case study article in this issues).

Mega-ministries and ministerial mergers are often introduced to enhance the efficiency and coherence of political and administrative work in government and administration. One example is the Hungarian Ministry for National Resources which comprises six ministries that may be found in other countries as individual ministries. Theoretically, the argument seems to be striking, but putting theory into practice is more problematic, and the evidence on increasing intersectoral coherence is somewhat unclear. Positive effects, if they take place, seem to be very modest and temporary, making it difficult to assure returns on the investment that these mergers represent.[8]

Joint budgets are an intersectoral structure that can facilitate the funding of health-related activities. The pooling takes place within the government and the funds come from different sources for joint projects. England has utilised this tool, and Sweden is piloting several projects as well. A particularly difficult hurdle is assigning accountability, which can prevent ministries developing joint budgets (see case article in this issue).

Delegated finance is an intersectoral governance structure that pools monies outside the ministry and therefore allows for input sources outside of government. Examples include the health promotion foundations operating in Switzerland, Austria, Australia and Thailand. However, plans for a similar health promotion foundation in Germany were scrapped, after it failed twice to secure support in parliament. Some of the active foundations are co-financed from tax revenues, sin taxes or health insurance contributions, and they can operate as matching-fund financing projects to a certain percentage. Often criticised as institutional duplications that undermine the established health promotion agencies, these foundations have in fact been shown to raise the amount of health promotion spending.[9]

Public consultation is utilised to reach out and engage with wider civil society. There are different ways of doing this. For instance, Austria used a public consultation process to communicate and discuss its new intersectoral public health policy. With inputs from almost 4500 citizens, NGOs and stakeholders,[10] it was considered a relatively well-populated consultation. In addition, the European Commission, as part of its general decision making process, submits all legislative and major proposals to a public consultation process.[11]

The analysis of ***stakeholder engagement*** in the study[4] focuses on health conferences organised by national, federal or regional governments. Health conferences help to reach out to a range of stakeholders. Examples can be found in Austria, Germany and France. The best analysed system is in North Rhine Westphalia, where the state health conference is mirrored by health conferences in the municipalities. Evaluation has been favourable, confirming its relevance in agenda setting, coordination and joint implementation.[12]

The last form of intersectoral structure is ***industry engagement***. In the case study included in this issue, the authors have analysed the EU Platform on Diet, Physical Activity and Health that was set up to facilitate joint action between the European Commission, industry and a large number of NGOs. Some countries have mirrored the EU-based activities by similar national Private-Public Partnerships. The structure is a relatively new one and while evaluations are rather limited, current experiences highlight the challenges of this type of governance

structure, particularly with regard to dealing with asymmetries in the resource capacities of the participating stakeholders, managing potential conflicts of interest and reputational risks and engendering mutual trust and real cooperation across the sectors represented (see case study in this issue).

> HiAP needs to be firmly embedded within general policy imperatives

This list of intersectoral governance structures is not exhaustive. Some countries, for example, have employed public health ministers to improve dialogue and collaboration at the cabinet table and between different departments. Other countries have introduced strong ministerial linkages that lead to more policy consistency and alignment of policy objectives. There are examples where health ministries post some staff in other ministries to ensure that the health perspective is always taken into account and that policy developments are monitored early. In addition, there is health impact assessment, a decision support tool that helps to assess the health consequences of pending decisions and feeds this information back into the decision-making process.

Successful implementation

It is important to note that the governance structures discussed above are context-dependent and that institutional settings between countries in Europe differ widely. Interpreting the results of the study also requires some caution since the evidence base varies widely. For some of the intersectoral governance structures there is plenty of literature available, while others were covered for the first time in the form of a collection of case studies. Despite these variations, a few observations can be made with regard to the conditions under which these intersectoral governance structures work best. Apart from the considerations outlined below, policy-makers can ask themselves a series of questions to help them assess which intersectoral structure suits their needs and has the best chance of working well (**see Box 1**).

- ***Political will*** plays an important role in the effectiveness of many intersectoral structures. Cabinet committees, intersectoral committees and many other structures do not work or work only with serious limitations if the bureaucracy is left alone without political backing.
- Most intersectoral governance structures rely on the consideration and integration of ***partnerships' and constituents' interests***. If the chemistry between stakeholders does not work, or if stakeholders cannot manage to mutually align their interest, the chances of achieving effective intersectoral governance are slim. The quality of partnerships is essential for effective governance; this is equally true with regard to partnerships beyond government where the composition of the partners plays an important role. For example, industry engagement works better if there is also community engagement and participation from civil society. Functioning partnerships need to deal with power asymmetries, conflicts of interest and the hidden agendas that come with it. If these asymmetries prevent some partners from making a vital contribution and having their specific interests acknowledged the partnership will not function.
- *The **political importance** of the policy issue* is a key consideration in selecting the most appropriate governance mechanism.
- *The **immediacy** of the problem* needs to be taken into account: some of the governance structures are more suitable for addressing short to mid-term issues while others work well with long-term developments.
- Strong ***leadership***, and if possible from the head of government, is required in cabinet committees. Similarly, mergers and mega-ministries require the strong leadership of a minister who can facilitate change. For stakeholder engagement strong leadership is the single most important condition to successfully manage tensions and mediate conflict; the leadership may come from sources other than the government.
- Intersectoral governance structures need to not only respect but also actively use the given ***context*** to create or benefit from windows of opportunities. In the example of the UK's parliamentary Health Select Committee, context assisted its scrutiny process as it took place at the same time as the media picked up on several other influential reports into health inequalities, helping to promote health inequalities as a mainstream political

Box 1: Questions that can help policy-makers to choose or improve the use of intersectoral governance structures

- What is the general political context for policy change? What has been tried previously? What other external factors are at play (i.e. growing public interest, landmark report released, policy disaster/event)?
- Who is driving the desire for HiAP?
- Is there political will? Or, who else is "on board"?
- Is there strong leadership? By whom?
- Which stakeholders are engaged?
- What are the resourcing requirements? How much money, if any, is there to contribute?
- What is the timeframe? Is this a long-term solution, or a one-off?
- Is the timing appropriate – for the political climate, phase of the political cycle and constituency interest?

issue. Another example is the creation of mega-ministries that take advantage of perceived policy failures.

- ***Resources*** constitute a critical condition for effective intersectoral governance because recognising the direct and indirect costs of supporting structures is an important commitment to be made to ensure their effectiveness.
- There is a range of ***implementation practicalities*** that need to be taken into account when implementing and using intersectoral governance structures.

Conclusion

Based on the analyses of these structures and the critical conditions identified, four issues need to be raised. First, while we often speak indiscriminately of intersectoral governance, the evidence and the case studies presented in this issue show that each governance structure has its own profile in terms of the intersectoral actions (**see Table 1**). Therefore, the choice of intersectoral governance structures must follow the desired intersectoral action. Second, the evidence we have collected shows that intersectoral governance structures rarely work in isolation. There are other intersectoral governance structures working in parallel. Third, there is a need for action at various levels and strong leadership (political, bureaucratic or both), particularly within the broader policy environment where the concept of HiAP is less familiar. Fourth, HiAP needs to be firmly embedded within general policy imperatives. Well-functioning intersectoral governance structures must pursue their goals in a way that is tangible and understandable to all partners and that feed into overarching societal goals.

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New HiT for Cyprus

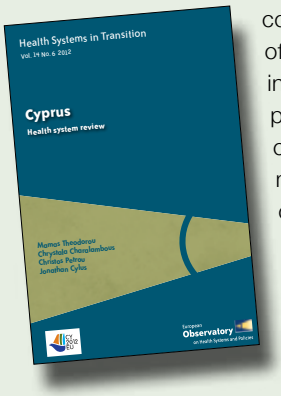
By: M Theodorou, C Charalambous, C Petrou and J Cylus

Copenhagen: World Health Organization 2012 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

Number of pages: 128, ISSN 1817-6127 Vol. 14 No. 6

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0017/174041/Health-Systems-in-Transition_Cyprus_Health-system-review.pdf

Cyprus has a dual health care system, with separate public and private systems of similar size. The public system, which is financed by the state budget, is highly centralized and tightly controlled by the Ministry of Health and entitlement to receive free health services is based on residency and income level. The private system is almost completely separate from the public system and for the most part is unregulated and largely financed out of pocket. In many ways there is an imbalance between the public and private sectors. The public system suffers from long waiting lists for many services, while the private sector has an overcapacity of expensive medical technology that is underutilized. To try to address these and other inefficiencies, a new national health insurance scheme, funded by taxes and social insurance contributions, has been designed to offer universal coverage and introduce competition between the public and private sectors through changes in provider payment methods. However, implementation of the scheme has been repeatedly postponed mainly due to cost concerns. Despite the low share of economic resources dedicated to health care and access issues for some vulnerable population groups, overall Cypriots enjoy good health comparable to other high-income countries.



THE ROLE OF **PARLIAMENTARY SCRUTINY** IN PROMOTING HiAP

By: Ray Earwicker

Summary: This article explores the contribution of parliaments to an intersectoral governance framework that promotes Health in All Policies (HiAP) by drawing on the system of parliamentary scrutiny in England, using as a case study the House of Commons Health (Select) Committee inquiry into health inequalities in 2009. The Committee's report contained practical suggestions and recommendations which are now part of the wider discussion about promoting effective governance in HiAP to tackle health inequalities and to reduce the health gap. It also encouraged a more consensual approach between the political parties by drawing on the evidence, helped win wider support for an approach recognising the wider causes of health inequalities, and demonstrated the scope for action across a range of policies needed to address them.

Keywords: *Health Inequalities, Health Select Committee, Parliamentary Scrutiny, Health in All Policies, England*

Introduction

While intersectoral governance usually is seen as the realm of government ministers, policy-makers and other stakeholders, including regional and local government, and voluntary and private sector agencies, parliaments also have a role to play through agenda setting, promoting a cross-government approach and wider political ownership, and providing practical suggestions that can improve the quality of policy-making and the focus of implementation and action.

This article explores the contribution of parliaments to an intersectoral governance framework that promotes Health in All Policies (HiAP) by drawing on the system of parliamentary scrutiny in England, using as a case study the House of Commons Health (Select) Committee (HSC) inquiry into health inequalities in 2009. It will also look at the links between this inquiry and the wider health inequalities perspective provided by the review published by Sir Michael Marmot in 2010 (the Marmot Review).[1]

The role of the HSC

In the Westminster Parliament, each department of state is 'shadowed' by an all-party parliamentary select committee, with a minimum of eleven members, and whose membership usually reflects the relative strength of each party in parliament. All select committees are formal parliamentary institutions that can influence and shape policy-making through reports and recommendations. Select committees decide on lines of inquiry and gather written and oral

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Box 1: Topics included in the HSC enquiry written evidence

- Extent to which the National Health Service (NHS) can contribute to reducing health inequalities;
- Distribution and quality of general practitioner services;
- Effectiveness of public health services;
- Effectiveness of specific interventions;
- Success of the NHS in coordinating its activities;
- Effectiveness of the DH;
- Whether the government was likely to meet its health inequalities targets.

Source: [5]

evidence, including expert witnesses. All evidence is published and an inquiry report requires an official response and is followed by a parliamentary debate to which the relevant government minister responds.

The HSC is the relevant select committee for the Department of Health (DH) in England. Its role is to apply effective scrutiny of the department's expenditure, administration and policy, and by extension that of the government. The HSC's inquiry into health inequalities took place from 2007 to 2009 and demonstrates how this process can enable parliament to play a part in tackling health inequalities and promoting a HiAP approach.

The HSC inquiry and report

Tackling health inequalities has been a priority area in England since 1997. It now has bi-partisan support since its status as a priority was reaffirmed by the coalition government that took office in May 2010. Over the past ten years, there have been a series of initiatives, including a national target, a national strategy that promoted intersectoral collaboration and encouraged an HiAP approach across twelve government departments,[2] and the annual monitoring of a number of performance targets on the wider determinants of health through a series of reports and other updates.[3] The rising profile of health inequalities attracted the attention of the HSC at the end of 2007 and, in particular, whether the health inequalities target would be met. The HSC was concerned that the target was unlikely to be met under the current framework of policies and indeed, was worried that the gap was actually widening.

While the link between policy action and its impact was complicated by time lags in the data, it was clear that effective action required a balance between the wider social determinants of health, for example housing, child poverty and education, as well as health service and lifestyle factors. The Committee began receiving written evidence and invited views on a broad range of related factors (**see Box 1**). One hundred and fifty-four pieces of written evidence were submitted by stakeholders during the enquiry, ranging from pharmaceutical and food manufacturers to the medical Royal Colleges, academic experts and the DH. The Committee proceeded to clarify the issues raised in the written evidence and other material by taking a number of expert or interested witness statements (oral evidence) in eleven sessions over eighteen months. These witnesses were drawn from a wide range of interest groups, including scientific and other experts, groups representing a wide range of health and related issues, officials and ministers.

The Committee's report, published on 15 March 2009, found that the causes of health inequalities were complex. These causes included lifestyle factors, as well as the wider social determinants of health, but access to health care seemed to play a less significant role.[4] While support was given to government efforts in tackling health inequalities nationally, these positive aspects had to be offset against the continued scarcity of good evidence and lack of proper evaluation of current policy that had hindered the design and introduction of new policies. In particular, apart from calling on the government to reaffirm the health inequalities targets for the next ten years, the HSC Report highlighted the need for effective coordinated action across government through a HiAP approach as many of the direct causes of health inequalities lay outside the health sector and beyond health policy. It called for the DH to lead action on health inequalities across all sectors and government departments, and to promote joined-up working. In addition, the report noted that the findings of the forthcoming Marmot Review on health inequalities[1] would provide a unique opportunity for the government to show its commitment to introducing rigorous methods for evaluating policy initiatives.

The impact of the HSC report

In its formal response to the HSC report, published in May 2009,[5] the government emphasised its determination to reduce health inequalities and outlined a series of direct actions across government departments, and at regional and local level. The government response emphasised that it had learned from the growing volume of evidence, noting that a decade ago there was little evidence about what to do and how to do it. The response also focused on the national target to identify priorities for action, understand what works, and develop evidence-based resources for local use.

A more general impact of the Report may be seen from its role in keeping health inequalities on the policy and public agenda. This was evident from the parliamentary debate that followed its publication and through media coverage. It also helped to shape policy in conjunction with other reports that were published either around the same time or shortly afterwards, particularly the Marmot Review.

It is clear that the HSC report helped to set the policy agenda, notably through its recognition of the high importance of action on health inequalities, the value of a cross-government approach, the use of a target as a catalyst for action and the underlying need for a scientific and evaluative approach. Public interest in the Committee's work is perhaps best illustrated by the decision of the BBC to devote virtually the whole of its half-hour lunch-time news programme (*The World*

at One) to health inequalities to coincide with the opening of the inquiry's oral evidence sessions on 13 March 2008.

The systematic debating of select committee reports in the House of Commons has increased their influence and their ability to set the wider agenda by engaging government directly and requiring relevant ministers to respond to their findings. The HSC inquiry debate on 12 November 2009 was no exception. The role of the social determinants of health and a HiAP approach were a prominent aspect of the debate, particularly in light of one of the HSC's key findings – that lack of access to good health services did not appear to be the major cause of health inequalities. This highlighted that greater focus on local programmes and local actions, such as Sure Start children's centres, was required. The role of adequate housing, cutting crime and improving access to jobs, education, as well as health services, were also raised by Members of Parliament. The complexity of factors that contributed to health inequalities was emphasised in the public health minister's reply to the debate.

> "the HSC report helped to set the policy agenda

At a broader level, the appointment of the independent Marmot Review on health inequalities in November 2008 and the publication of its influential report in 2010,[1] gave new impetus to the debate and offered a way of embedding health inequalities in mainstream policy and political agendas, including the government's white paper on public health.[7] Health inequalities were increasingly recognised as a major concern and addressing them was part of the way that business was done in the NHS and other public services, including through planning, delivery and performance processes, and in fostering better governance and the promotion of a HiAP approach.

The scrutiny exercise provided by the HSC report contributed to the wider debate that informed the Marmot Review and also directly shaped the Review's thinking on several key points, including the use of evaluation. Other shared focal points included concern over the scale and timing of policies, the need to reconcile long-term goals with short-term gains, and the need to pay better attention to the planning process as a way of integrating action on the social determinants of health, including through linking planning, transport, housing, environment and health systems.

Conclusion

The impact of the parliamentary scrutiny process on raising the key issues around the health inequalities agenda is shown by the work of the HSC. The Committee's report contained practical suggestions and recommendations which are now part of the wider discussion about what happens next in promoting effective governance in HiAP to tackle health inequalities and to reduce the health gap. The HSC also encouraged a more consensual approach between the political parties by drawing on the evidence and the data, helped win wider support for an approach recognising the wider causes of health inequalities, and demonstrated the scope for action across a range of policies needed to address them.

The HSC report's findings also remain relevant in the context of the new coalition government's explicit commitment to fairness and social justice, mirrored by the establishment of new social justice and public health cabinet committees. In conjunction with the Marmot Review's findings and recommendations, the HSC's work has helped health inequalities remain a priority. This was reflected, among other things, in the government's decision to create a new duty on the Secretary of State for health and the NHS to have regard for the need to reduce health inequalities in their decisions from 1 April 2013.[8]

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INTERSECTORAL PROBLEM SOLVING BY **INTERDEPARTMENTAL UNITS AND COMMITTEES**

By: Scott Greer and Anna Maresso

Summary: Interdepartmental committees and units can expect to have different degrees of success in providing potential solutions to coordinating government policies and operating intersectorally. There is variable scope for them to contribute to a range of governance outcomes, including evidence, coordination, advocacy, monitoring, guidance development and implementation. The appeal of interdepartmental committees and units is that they work within the government bureaucracy, do not require significant costs or reorganisation, can work with departments over time, and can apply sustained pressure. They can work in multiple situations but are less useful in resolving political conflict.

Keywords: *Interdepartmental Committees, Interdepartmental Units, Intersectoral Governance, Health in All Policies*

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Introduction

Both interdepartmental committees and interdepartmental units are intersectoral governance structures that try to reorient existing government ministries around a shared, intersectoral priority. Both of these mechanisms operate within the bureaucracy and their fundamental justification is that they can move the bureaucracy to engage in such intersectoral priorities. Their vigour, though, depends on their ability to persuade other bureaucrats to engage with them, which is much more likely if they have strong political backing.

The role of interdepartmental committees and units

Interdepartmental committees are made up of representatives from the civil service (or possibly political appointee) level of departments. They might shadow a ministerial committee or be serviced by an interdepartmental unit. Such committees appear throughout the history of modern public health. Today, there are many examples of interdepartmental committees within European administrations, such as the Public Health National Committee in France (designed to improve coordination and information among the main ministries whose policies may have a health impact, particularly prevention and health security); the Traffic Safety Committee in Slovakia (whose narrower remit and detailed tools have contributed to a dramatic decrease in road fatalities); the Interdepartmental Public Health Committee in Hungary (which assisted the implementation of the National Public Health Programme) and several permanent

Table 1: Conflict, salience and coordination challenges

	High Political Importance	Low Political Importance
High conflict	*Situation 1.* Interdepartmental committees and units might clarify issues but resolution depends on political will.	*Situation 2.* An interdepartmental committee or unit with strong political support could impose a solution. Risk of departmental sabotage.
Low conflict	*Situation 4.* Optimal for interdepartmental committees and units – strong political backing and few political conflicts.	*Situation 3.* Interdepartmental committees and units very useful – committees can clarify problems and solutions while units can add missing energy to the issue.

Source: [5]. Note: A high conflict situation is one in which there is little or no basic agreement. Political importance is the extent to which an issue matters to the government, especially its senior politicians.

inter-ministerial committees coordinated by the Finnish Ministry of Social Affairs and Health that focus on aspects of health promotion such as occupational health, rehabilitation, gender equality and child and adolescent health.[1] Moreover, nearly every European Union (EU) Member State has some kind of committee structure responsible for coordinating EU policy.

The virtue of interdepartmental committees is that representatives of the different relevant units use them as a forum for problem solving. Committees lower the costs of a decision by maximising the relevant information made available, and lower the costs of implementation by involving the affected interests (departments) in the decision. Regular committee meeting schedules can also be a stimulus to action: they allow participants to review new information, actions and progress, which thereby creates deadlines capable of forcing some information provision, action, and progress.

The weakness of interdepartmental committees is that they may fall prey to a number of pitfalls. One is depleted energy: the committee ceases to meet or high-ranking members send low-ranking deputies and thus its mission is forgotten. A second is irrelevance: departments might send representatives but do not actually feel committed to the agenda or its implementation. A third is sabotage: departments may use the committee solely as a way to spy on people who might ask them to do things that they dislike.

Interdepartmental units are groups of civil servants, deployed and organised specifically to pursue a particular policy issue or agenda. They are typically delegates of somebody (ministerial committee or a central government minister) and they differ from agencies in that they are not responsible for delivering any services. Rather, they are creatures of the need to coordinate policy rather than autonomously deliver a service as agencies are generally created to do.[2] Such units also often attract scholars, consultants and policy entrepreneurs as outsiders who can provide new ways of thinking.

In the UK, most attention recently has gone to units such as the Prime Minister's Delivery Unit (charged with monitoring delivery on a broad range of key goals such as shorter elective surgery waiting times)[3] and the Performance and Innovation Unit (responsible for identifying ways in which the government could organise itself to deliver better services.[4] Another experiment was a unit to deal with the homeless living on the streets that focused on the joining up of relevant aspects of local government, housing, social work and health services,[5] as well as drug harm reduction programmes.

The virtue of interdepartmental units, above all else, is that they have staff which can dedicate their time and energies to intersectoral work, a task that often takes place outside the rhythms of established bureaucracies and the frenzies of daily politics, which can redirect government activity and the focus of ministers. A unit can continue to carry out the political mission of intersectoral governance when the politicians have been called away to other tasks, acting as a delegate for a minister who can be distracted by politics or sucked into administration.

The potential weakness of interdepartmental units is that they may be side-lined as being too intellectual, too impractical or too distant from the preoccupations of the bureaucracy. Three broad kinds of responses can meet this challenge. One is that political will ultimately does matter and that a unit has a chance of being effective if it is known that it 'belongs' to a senior minister who will advocate and defend it if necessary. The second is that personnel matters, making it imperative that the unit be staffed to combine technical competence, energy and a sense of the relevant bureaucratic and political issues. The third is strategy, whereby the unit makes itself a credible ally for at least some of the interests within affected sectors, rather than being solely an in-house critic alienating departments and their ministers.

> a forum for problem solving

Problem solving

Intersectoral governance often must face coordination problems that have a political rather than simply a bureaucratic source; that is, the government does not agree within itself. There are four quite common situations which highlight the nature and extent of this problem, both in terms of the level of conflict between ministries and the political importance of the issue that needs coordinated action. Consequently, interdepartmental committees and units can expect to have different degrees of success as the potential solution to the coordination problem. The four situations are:

1. Two ministries refuse to agree because their ministers refuse to agree. A common example would be conflict between the ministries of health and finance over tobacco control.
2. Two ministries refuse to agree about some minor problem and no senior official or minister thinks the issue is a priority. An example here would be disputes over the role and cost of health care in schools or prisons.
3. Two ministries do not have particular disagreements but need to iron out the details and do not necessarily get around to fixing the problem. An example here might be implementing a policy that allows home care visitors to older people to carry out multiple tasks such as health visiting, checking smoke detectors, and helping with official paperwork, which in practice is difficult to coordinate.
4. Two ministries basically agree on the need to cooperate because it is an important government agenda item, they do not disagree much, and senior ministers want cooperation. For example, this was the case with the English task force on helping the homeless sleeping on the streets, mentioned above.

Based on a framework by Page,[5] Table 1 presents these four situations in a grid, along with the potential role of interdepartmental committees and units. In general, the worst situation for a unit or committee is Situation 1 when they are as likely to be damaged in a conflict between top politicians as to be effective in mediating high-level political conflicts. This was basically the situation of the New Zealand Public Health Commission, which managed to offend so many high-level politicians and affected interests that it was abolished only three years after it was created. Situation 4 is the best scenario for units and committees as they can bring their respective advantages to bear on an intersectoral task that the government supports and that does not involve too many interdepartmental conflicts.

Governance outcomes

Using the map of situations outlined in Table 1 one can see the scope for interdepartmental committees and units to contribute to a variety of governance outcomes:

Evidence: An interdepartmental committee is a forum for aggregating information; this could include information from around government but as a structure for this purpose, it might be inefficient. A unit is more commonly found in this role, with tasks ranging from collecting existing information to commissioning or performing research, engaging in public debates or simply informing ministers. In principle, evidence is a function that a unit or committee could fulfil in any of the four situations, although higher conflict makes information harder to gather and creates more risk that evidence will be ignored or incur retribution.

Coordination: This administrative 'holy grail' means having the processes necessary to promote intersectoral working, including allocating responsibilities and making sure that bureaucracies carry out their tasks. Also, coordination can resolve differences and even build trust, and ideally should be carried out by experts in bureaucracy. Therefore, a committee is the logical choice and it can carry out the task in low-conflict situations. An interdepartmental committee is only likely to coordinate in high-conflict situations, for example, if there is a very clear political demand to resolve the issue or if it is backing a ministerial committee or other political process designed to resolve the issue.

Advocacy: The virtue of a unit is that it can add energy. Advocacy requires energy and a unit should be well suited to this role as long as it is either working on relatively non-contentious issues or has strong political support (or both). A unit in a high-conflict, politically salient situation probably needs the backing of the most senior politicians to survive, let alone win. A unit in low-salience situations can be particularly useful, particularly if energy is lacking from other quarters. Finally, a unit in a high-salience, low-conflict situation is likely to be very successful.

Monitoring: Monitoring is best done by a unit, though in theory, a high-functioning committee could co-opt member departments' resources. The UK Prime Minister's Delivery Unit was a success in this regard because monitoring requires energy and it was able to deal with the conflict that monitoring engenders. It is more likely to work in low-conflict situations but can work in high-conflict ones.

Guidance development: Done by a committee it can be reduce conflict but paradoxically this is more likely in situations where there are already low levels of conflict. Done by a unit, guidance development can reduce transaction costs in formulation but requires diplomacy and political support to be implemented. This means that it works best in situations 3 and 4 where the problem is technical rather than political.

Implementation and management: While departments and agencies implement policies, the monitoring and evidence activities of interdepartmental committees and units may feed into implementation.

While interdepartmental committees and units can achieve these goals, they should not distract from the fact that existing units and committees frequently are low-cost established mechanisms as well. Interdepartmental committees, in particular, do not capture all bureaucratic interdepartmental coordination within government; nor should we think that only those committees and units led by health specialists are of special interest to health policy. Service on committees and units led by other departments, and participation in their consultation mechanism, is ubiquitous and, if used well, a vital technique for intersectoral governance.

Conclusion

The appeal of interdepartmental committees and units is that they work within the government bureaucracy, do not require significant costs or reorganisation, can work with departments over time, and can apply sustained pressure. They can work in multiple situations but are less useful in resolving political conflict. There are two summary lessons. First, political support is helpful for committees and units to work best. Second, a combination

is a good idea – a unit to provide energy and a committee to resolve technical issues, as well as political leadership such as a ministerial committee to channel and contain political disputes. Such a combination should be powerful and effective.

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CAN **JOINT BUDGETING** FACILITATE INTERSECTORAL ACTION?

By: David McDaid

Summary: The importance of looking beyond the health sector when promoting health is a core mantra of public health, but too often there are organisational and financial factors which hamper the achievement of this goal. Potentially the use of some form of joint budgeting mechanism may help overcome some of these barriers and promote collaboration on health-related actions within and across the work of different sectors and agencies. This article provides an overview of different approaches to joint budgeting and experience to date. Factors that have influenced the success or failure of schemes are highlighted, including the crucial need to identify non-health benefits arising from health promotion interventions implemented and/or funded outside the health care sector.

Keywords: *Joint Budgeting, Intersectoral Action, Public Health, Health Promotion, Health In All Policies*

Introduction

Good horizontal relationships between health and other sectors are critical to the implementation of actions for better Health in All Policies (HiAP). While this is by no means a new idea, nonetheless it is an issue that often is either neglected or has been challenging to implement, with a focus therefore on actions that take place within different departmental fiefdoms and budgetary silos. Moreover, health promotion is unlikely to feature prominently as a key goal for most departments and non-health sector budget holders.[1] Thus, opportunities to realise substantial health, non-health and other economic benefits may be missed.[2]

In practice, mechanisms by which services are funded act as catalysts or barriers to action. The long-term nature of many health promotion and public health initiatives, requiring actions and funding across different sectors, has long been vulnerable to resource constraints and uncertainties. Multiple short-term funding streams, often with tight restrictions on how funding can be used and subject to different financial incentives and cost containment concerns,

can act as major impediments to the efficient use of resources for Health in All Policies (HiAP). For example, despite a growing evidence base supporting the effectiveness of interventions in the first years of school to tackle bullying and conduct problems, the education sector may be reluctant to invest its limited resources in school-based mental health promotion programmes rather than on core education-related activities. However, changing funding arrangements could actually help to overcome some of these narrow sector-specific interests. Cross-sectoral collaboration could be fostered through establishing one single budget for the provision of school-based health promotion.

Creating a dedicated budget for a non-health sector health-promoting activity, bringing together resources from the health sector and beyond, provides health policy-makers with a direct means of influencing policy in other sectors. For instance, the approach might be used to ensure that adequate funding and priority is given to road safety measures by ministries of transport, or to address health concerns in new urban housing developments. It has also been argued that funding across sectors could help to eliminate unnecessary gaps and duplications in services.[3] Pooling funds may help to reduce administrative and transaction costs, generating economies of scale through sharing of staff, resources and purchasing power, while also facilitating rapid decision-making.[4]

> joint budgeting covers different mechanisms

Implementing joint budgeting

The term 'joint budgeting' can itself cover a number of quite different mechanisms, involving two or more government departments and/or tiers of government, in order to help achieve one or more shared goals. They can range from fully integrated budgets for the provision of a service or policy objective to loose agreements between sectors to align resources for common goals while maintaining separate accountability for the use of funds (**see Box 1**). Agreements on joint budgeting can be mandatory or voluntary and may operate at a national, regional and/or local level. This may be accompanied by legislation and regulatory instruments. There may be very detailed agreements between sectors on how budgeting mechanisms will work; for instance, they may include identification of any host partner, clarity on functions, agreed aims and outcomes and the levels of contributions, as well as the relevant accountability issues. Such agreements may also deal with the ownership of common premises and equipment, as well as how any surpluses or liabilities are dealt with. The temporal nature of joint budgeting arrangements also varies – they can be time-limited, short-term initiatives, particularly when receiving grant funding from central government, or envisaged as a longer-term, more permanent organisational change.

Box 1: Different approaches to joint budgeting

Budget alignment: Budgets may be aligned rather than actually joined together. For instance, a commissioner of health services can manage both a health budget and a separate local government budget to meet an agreed set of aims.

Dedicated joint funds: Departments may contribute a set level of resources to a single joint fund to be spent on agreed projects or delivery of specific services. This may often be a time-limited activity. There is usually some flexibility in how funds can be spent.

Joint-post funding: There may be agreement to jointly fund a post where an individual is responsible for services and/or attaining objectives relevant to both departments. Theoretically, this can help to ensure cooperation and avoid duplication of effort.

Fully integrated budgets: Budgets across sectors might become fully integrated, with resources and the workforce fully coming together. One partner typically acts as the 'host' to undertake the other's functions and to manage all staff. To date, this largely has been restricted to partnerships between health and social care organisations or for the provision of services for people with mental health needs.

Policy-orientated funding: Central or local government may set objectives that cut across ministerial and budget boundaries and the budget system. Money may be allocated to specific policy areas, rather than to specific departments, as has been seen in Sweden and England.

Source: [5]

Experience in joint budgeting

Examples of joint budgeting and discussion in policy documents in the health sphere can be identified in a number of countries, including Australia, Canada, England, Italy, the Netherlands and Sweden.[5] A feature of many of these initiatives is that they focus on easily identifiable population groups that have a clear need not only for health care services but also support from services such as social care, education, housing and employment. Continuity of care and support for these population groups requires a coordinated approach across sectors and schemes. Initiatives often have been set up with the explicit aim of overcoming the fragmentation of funding and service provision that has hindered the development of seamless care pathways.

The four countries that make up the United Kingdom, as well as Sweden, have been particularly prominent in the joint funding of services and programmes to support older people who may be frail, as well as those who have physical disabilities or chronic health problems, including mental health needs.[4] Pooled budgets also have been used to help develop joint

Box 2: Factors that can aid implementation of joint budgets

- Identify rationale, potential health and non-health benefits and added value to sectors pooling resources
- Establish clear outcomes to be achieved
- Speak the languages of all sectors, not just that of the health sector
- Determine how current funding and legislative frameworks are operating across sectors
- Move towards flexibility in legislative and regulatory frameworks governing joint budgeting
- Engage in sustained efforts to build cross-sectoral trust, and training in common skills and competencies
- Consider use of performance-related incentives
- Identify economic costs and benefits of joint budgets
- Consider using financial instruments to ensure that where budgets are aligned rather than shared all sectors can benefit equally from any efficiency gains made.

Source: [5]

approaches to rehabilitation and return to work for individuals with chronic health problems, as is the case for those with musculoskeletal health problems in Sweden, where the health, social insurance and social work sectors have worked together to address this issue.[7] In England, Scotland and Wales, road safety initiatives also have brought together partners from the health, transport, child and safety sectors.[2] In the Netherlands, joint budgets have been used for research and policy activities in connection with the national action programme on environment and health, funded by the ministries of environment and health,[8] while in New Zealand, 'clustering projects' bring together relevant government agencies to pool budgets and resources.[9]

Effectiveness of joint budgeting

The evidence on the effectiveness of joint budgeting arrangements is limited and at times rather equivocal. Despite the formal advantages of overcoming narrow sectoral interests and promoting flexible funding, as yet there is no strong evidence that joint budgets have made a difference to final outcomes and little is known about their cost-effectiveness compared to previous arrangements.[10] Exceptions can be noted, as with some experiences in transport safety in the United Kingdom where the impact of jointly funded actions on casualty rates can be identified as a key indicator of success.[11] In Sweden, cross-sectoral initiatives have been the subject of much evaluation. One example is the SOCSAM scheme which allowed social insurance and social services to voluntarily move up to 5% of their budgets, along with a matched contribution from health services, to a pooled budget to jointly manage rehabilitation services to help individuals on long-term sick leave to return to work. It was evaluated in eight localities and compared with experiences elsewhere in the country where schemes were not introduced. The evaluation found that interdisciplinary collaboration between health and social care professionals improved compared to control areas.[12] This Swedish experience also suggests that joint funding arrangements and collaboration at local or regional level, where institutional structures are closer to stakeholders and have a better understanding of local problems, can be effective.

A number of factors that can aid the implementation and effectiveness of joint budgets have been identified (**see Box 2**), a fuller discussion of which may be found in the chapter on joint budgeting in the recently published book on intersectoral governance.[5] It is clear that the process must begin by carefully defining health and other policy issues that may benefit from joint budgeting, considering what actors and stakeholders need to be involved and understanding their priorities and goals. Crucially, partners need to perceive any pooling of resources and structures as being in their own interests, adding value to what they can achieve in isolation.

Conclusions

Experience from several high income countries of intersectoral work with some form of shared or aligned budgets indicates that when it comes to joint budgeting arrangements, no one approach is ideal in all circumstances. While the legal frameworks under which joint budgeting operates may be established at national level, there appears to be a greater likelihood that schemes will be more successfully implemented at a very local level. The implication is that the need to tailor joint budgeting arrangements to meet different contexts and institutional arrangements may mean that above a certain geographical or budgetary size, schemes become too difficult to manage.

Careful consideration must also be given to the design of any joint budgeting initiative, taking account of context and resource, and whether schemes are mandatory or voluntary. In the short-term, the mandatory pooling of budgets and *de facto* requirements that different sectors collaborate may help to facilitate HiAP and will provide opportunities for mutual learning across sectors. However, the imposition of these schemes from above may mean that there is resistance from different sectors, which may not augur well for their long-term sustainability. On the other hand, approaches that are voluntary will take more time to establish. They rely more heavily on securing the buy-in of different stakeholders by demonstrating the potential added value of collaboration, both in terms of health and objectives of importance to other sectors.

Where they are well implemented, measures to bring budgets together can help embed health impacts in all policies. In the longer-term, if such initiatives and partnerships are sustained, then a common working culture can be established, reducing potential distrust and misunderstanding between partners. It should be stressed though, that joint budgeting arrangements are more likely to be successful when complemented by other actions to facilitate intersectoral actions and improved partnership working.

ENGAGING INDUSTRY IN INTERSECTORAL STRUCTURES

By: Monika Kosińska and Leonardo Palumbo

Summary: The EU Platform for Action on Diet, Physical Activity and Nutrition is an intersectoral structure that aims to reach out to industry as well as other non-governmental stakeholders to achieve common actions on obesity. Members of the Platform are required to submit 'commitments' to the European Commission which are monitored through the submission of annual reports. Overall, since 2005, about 300 commitments have been submitted, with 56% in the traditional 'health promotion' area, tackling lifestyle modifications and educational activities and the remainder focussing on marketing or advertising, reformulation and labelling. The increase in formal relationships between industry and the public sector in health promotion clearly raises challenges for health governance, requiring that such partnerships be well managed, with clearly defined roles, responsibilities and expectations.

Keywords: *Industry Engagement, Private-Public Partnerships, Public Health, EU Platform for Action on Diet, Physical Activity and Nutrition*

Introduction

The EU Platform for Action on Diet, Physical Activity and Nutrition is a flagship example of a private-public partnership (PPP) aimed at tackling rising rates of obesity. As such, it is an intersectoral structure that aims to reach out to industry as well as other non-governmental stakeholders to establish and achieve common actions on a complex and important public health issue. With governments and public sector actors looking for innovative ways to face modern challenges, the involvement of industry, through the development of PPPs, has become increasingly common, as has the impact of PPPs on our understanding and framing of traditional public health questions. Despite this, the relatively recent nature of joint ventures by public and private actors in health means that their impact, relationships and governance questions are still new, and to some extent uncertain. Furthermore, some PPPs in health have been received with controversy and high expectations, as well as scepticism.

Role and aims

The Platform was established in 2005 and gathers together food and health

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stakeholders from across Europe. Its creation was spearheaded by concern over one of the biggest modern public health challenges – the obesity epidemic. The Platform is not a traditional PPP because there is involvement from non-governmental organisations (NGOs), there is no direct partnership with the food industry, and it is a forum to discuss practices and commitments to activities on healthy nutrition, physical activity and tackling obesity.[1]

The Platform became an implementation tool for the European Commission's Strategy for Europe on Nutrition, Overweight and Obesity-related Health Issues, launched in 2007, and remains a high-profile element of the Commission's stable of policies targeting overweight and obesity. There is no formal leadership or management mechanism, and membership is voluntary. The initiatives are set by the public sector and currently five formal fields of action have been identified: consumer information (including food labelling); education (including lifestyle modification); physical activity promotion; marketing and advertising; composition of foods (reformulation), availability of health food options and portion sizes. An additional area of advocacy and information exchange is also included.

The Platform was a unique concept as it facilitated a structured public discourse bringing together the public sector, industry and NGOs. The theory behind its creation is that it allows for action to be taken within the private sector/industry voluntarily and faster than through legislation. If the results are not satisfactory there is still the alternative of regulation. Members of the Platform are required to submit 'commitments' to the Commission which are monitored through the submission of annual reports. Examples of commitments include McDonald's providing nutritional information on packaging throughout Europe and the Union of European Soft Drinks Association's pledging not to market directly to children under twelve across the EU.

Pros and cons for stakeholders

For economic actors (i.e., industry), their participation in what is in effect a self-regulatory process provides two 'wins': firstly, in the continued absence of direct regulation in this area; and secondly as their actions can be used to promote their image via public relations activities or branded as examples of corporate social responsibility. The benefit for the Commission can also be seen as twofold: achieving action, arguably quicker than through direct regulation, in an area with little political will within Member States; and enabling a setting where the issues and arguments can be debated directly between economic actors and public health NGOs; whereas previously, this had taken place bilaterally between the stakeholders and the Commission, with antagonistic behaviour between the two sets of stakeholders. The benefit for participating NGOs is less immediately obvious as the process is time-consuming, resource intensive and some have argued, also distracting from other political discussions or advocacy activities. However, some have remarked that it does benefit their work by maintaining political attention on the issue of obesity, which is complex from a policy perspective, particularly during periods of low levels of political will.[2,3]

The distribution of resources within the work of the Platform has been a topic of debate amongst participants and highlights the difference in resources and abilities of the actors. While both NGOs and economic actors are obliged to provide commitments on action to tackle obesity, and to participate in meetings and discussions, the resource burden on NGOs is much heavier given the difference in resourcing between the two. Many feel that industry is better able to commission expertise in legal, academic, scientific and public relations fields whereas non-profit making organisations depend mainly on the goodwill and volunteering of experts.

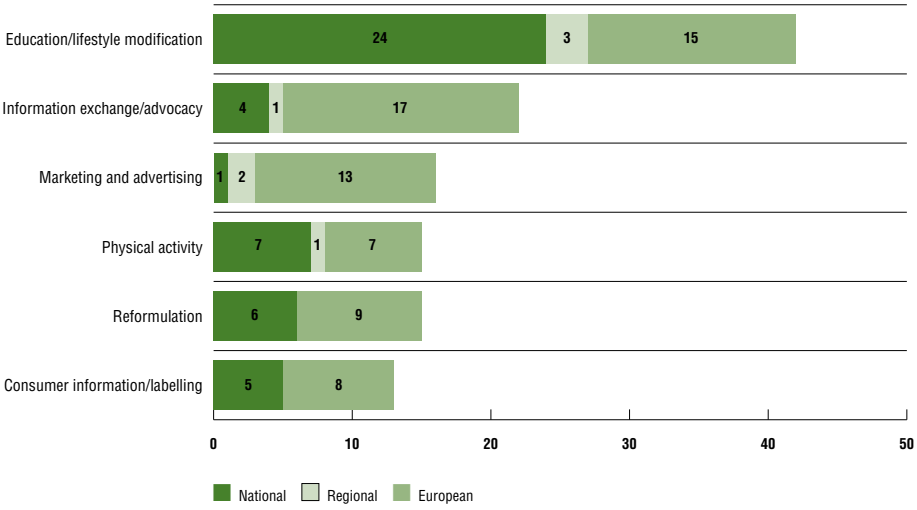
Lastly, the Platform has also been criticised because commitments and actions of the industry tend to favour investing in information and education rather than making healthier food choices available or regulating advertising, labelling and health claims. In this regard, there is no 'quality monitoring' of the commitments, on either their appropriateness or effectiveness according to public health evidence. However, the Platform could be considered successful in terms of its engagement of economic actors, both in terms of attribution of responsibility as contributors to the obesity crisis, as well as driving responsibility and action in tackling obesity.

> The Platform has facilitated a structured public discourse

Participation in the Platform also raises a number of wider governance issues, not only in terms of what are considered as the 'proper' responsibilities of the state or the public sector in health protection and public health promotion, but also in terms of ensuring 'well-governed' PPPs and their legitimacy, representativeness, accountability, transparency and efficiency. These are discussed in greater detail in our chapter in the recently published book on intersectoral governance.[4] However, here we briefly mention two key issues – reputational risk and conflict of interest – and how they potentially impact on participants of the Platform.

Particularly for NGOs, there are reputational issues that need to be managed carefully. For many participating NGOs there are strict guidelines on the nature of partnerships that can be undertaken with economic actors. Even so, for NGOs working on population health, simply participating in a process that can be construed as delaying action to tackle obesity, acting as a distraction from regulatory approaches or 'approving' commitments that may be seen as marketing exercises masked as corporate action to tackle obesity, can be damaging in other contexts, especially where their primary role as 'watchdogs' are central to their constituency and, at times, financial supporters. In terms of conflict of interest,

Figure 1: Number of Platform commitments by geographical coverage and type of action, 2011



Source: [6]. Note: N=123.

at times commercial actors could use their PPP interaction to gain political and market intelligence in an attempt to gain political influence or a competitive edge over companies who are not seen as government partners.[5] Moreover, as relatively new entities, little is known in the literature on how PPPs operate and what they achieve.[7] This potential conflict of interest is raised frequently during the Platform, particularly in discussions on the role of economic actors in providing promotional or educational campaigns on healthy living. Thus, the balance between corporate support for public health messages and the need for robust, evidence-based public health promotion strategies is a fine one that needs to be navigated carefully in practice.

PPPs as a lever for health change?

The traditional model of public sector responsibility for the health and wellbeing of populations could be considered to have led to a fragmented approach to tackling health issues; that is, activities are health sector-led in isolation from other sectors and organisations. In this sense, the increased engagement of the private sector in health promotion can be seen as an extension of the realisation of the Health in all Policies (HiAP) approach, in using the drivers and resources outside the health sector. It could also be seen as risk-sharing, where the industry actors involved are themselves the producers of products leading to poor health outcomes. However, this presumes a willingness of industry to take responsibility for the outcomes of the consumption of its products and that it does not use PPP involvement for cynical purposes – for example, using it merely as a delaying tactic to prevent robust regulation.

Overall, since 2005, about 300 commitments have been submitted under the Platform, with 56% in the traditional 'health promotion' area, tackling lifestyle modifications and educational activities and the remainder of the commitments focussing on marketing or advertising, reformulation and labelling, the latter being what NGOs would consider the 'real' action to tackle obesity.[8] In 2011 there were 123 commitments whose application according to geographical area and topic was quite varied. The majority of actions promised in 2011 are education and lifestyle modification commitments, followed by initiatives in information exchange and advocacy, and those tackling marketing and advertising (**see Figure 1**).

In particular, NGOs have been concerned about the large number of health promotion actions that are put forward by the economic actors on the basis that many of the commitments target the employees of the economic actors themselves and thus are not sufficiently within the spirit of the Platform's objectives. In addition to this, the economic actors may not be the most competent of actors to put forward evidence-based health promotion activities. Finally, there may be conflicts of interest when the producers, manufacturers or retailers of products that are high in fat, salt or sugar (HFSS) are also involved in providing educational campaigns on healthy eating.

Regarding marketing and advertising to children, there is already a regulatory framework with the EU Audiovisual Media Services Directive[9] which provides guidance on the protection of minors. However, the economic actors largely attribute the Platform in their adoption of commitments for self-regulatory approaches in this area. Although it is difficult to prove or disprove to what extent the extension or continuation of existing activities have been strengthened due to their participation in the Platform, the evaluation of the Platform found that in the context of these commitments, the exposure of children to marketing of HFSS foods has decreased. However, due to factors such as the limited number of products chosen for the commitment and the definition and threshold age of the target audience, this decrease was over-reported by economic actors.[8]

In contrast, reformulation does not have any corresponding 'hard' EU regulatory framework. Reformulation makes up about one quarter of the total Platform commitments and can be considered to be largely successful. These commitments were taken up by multinationals on a wide range of products, or a significant share of HFSS products, affecting both existing new products and affecting a significant number of products in general, with 25–50% (but up to 80%) reduction in fat, salt or sugar.[8]

The multi-stakeholder model has also been exported to national levels, forming part of initiatives in a number of countries including Germany (to combat obesity), Poland (to promote good diet and physical activity), Portugal (salt reduction and school fruit programme), and Hungary (educational programmes on salt).

Conclusion

Given the complexity of the political context and regulatory framework, as well as the multiplicity of challenges raised by the prevalence of obesity in Europe, it is hard to draw a simple conclusion on the Platform's success overall. Certainly, it has acted as an innovative process to bring together actors with very different interests. Dialogue within the Platform has become more constructive and less confrontational over the years, although it still retains a clear divide between the economic and non-economic participants. Moreover, joint actions between the two sets of actors are rare.

The increase in formal relationships between industry and the public sector in health promotion clearly raises challenges for health governance, requiring that such partnerships are well managed, with clearly defined roles and responsibilities as well as expectations, something that is, by and large, achieved successfully in the context of the Platform. It is clear that more research is needed on the use of PPPs to increase the accountability of industry for poor health outcomes. Currently, the literature does not reflect on whether PPPs are more or less effective in different industries – pharmaceuticals over food, for example – nor on how the political importance or the potential for public controversy surrounding a topic can affect the drive for, and implementation of, a PPP on an issue.

However, despite the questions that remain and the clear need for more research, it is important not to lose sight of the fact that often PPPs, such as the Platform, are put forward where regulation, the traditional government tool, is not achievable for political or financial reasons. In addition, throughout its existence as a discipline, public health has always trod the line of trade-off and working across sectors and groups.

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New HiT for Republic of Moldova

By: G Turcanu, S Domente, M Buga and E Richardson

Copenhagen: World Health Organization 2012 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

Number of pages: 151 pages, ISSN 1817-6127, Vol. 14 No. 7

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0006/178053/HiT-Moldova.pdf

The reform of health financing in the Republic of Moldova began in earnest in 2004 with the introduction of a mandatory health insurance (MHI) system. Since then, MHI has become a sustainable financing mechanism that has improved the technical and allocative efficiency of the system as well as overall transparency. This has helped to further consolidate the prioritisation of primary care in the system, which has been based on a family medicine model since the 1990s. Hospital stock in the country has been reduced since independence as the country inherited a Semashko health system with excessive infrastructure, but there is still room for efficiency gains, particularly through the consolidation of specialist services in the capital city.

The rationalisation of duplicated specialised services, therefore, remains a key challenge facing the Moldovan health system. Other challenges include health workforce shortages (particularly in rural areas) and improving equity in financing and access to care by reducing out-of-pocket (OOP) payments. OOP spending on health is dominated by the cost of pharmaceuticals and this is currently a core focus of reform efforts.

The publication was launched on 22–23 November 2012 in Chisinau at the National Health Forum: "Healthy Moldova: Policies, Achievements and Opportunities". The aim is for the Forum to become an annual event to support intersectoral working to bring health into all policies.

REVISING THE **CLINICAL TRIALS DIRECTIVE**: A VIEW FROM THE ENGLISH NATIONAL HEALTH SERVICE

By: Elisabetta Zanon

Summary: The Clinical Trials Directive has been highly criticised for contributing to a significant drop in the number of clinical trials conducted in the European Union (EU), with associated costs and the time taken to launch a trial almost doubling. To remedy these unintended consequences, the European Commission recently released proposals to amend the existing regulatory framework. The proposal for a new EU Regulation on clinical trials promises significant improvements to the current legal framework and is a clear attempt to streamline the rules in order to reduce the administrative burden and speed up time for the authorisation of new clinical trials.

Keywords: *Clinical Trials, Research, Medicines, European Commission, NHS*

Introduction

Clinical trials are studies on humans aimed at testing the safety and efficacy of medicines. They are essential to the development of new medicines, and also have a role in the improvement of medical care more generally, for example, through trials comparing treatments or aiming to improve the use of medicines already on the market.

Many clinical trials involve multiple sites, including in several countries but historically, different Member States have developed diverse approaches to regulating clinical trials. The Clinical Trials Directive[1] aimed to address this by simplifying and harmonising the administrative requirements for clinical trials, while ensuring the protection of the health and safety of clinical trials' participants, the ethical soundness of the trials, as well as the reliability and robustness of data generated.

While the Directive has significantly improved the safety and ethical soundness of clinical trials in the European Union (EU), the harmonisation objective has only been achieved to a limited extent, as Member States have interpreted the Directive differently and have taken varied approaches to implementation. This has contributed to a considerable increase in the administrative burden and costs associated with clinical trials and, ultimately, has resulted in a significant drop in the number of clinical trials applications in the EU. This has, in turn, restricted innovation and reduced the competitiveness of clinical research in the EU, with knock-on effects for patients' access to new medicines and treatments.

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Table 1: Number of clinical trials applied for in the EU, 2007–2011

2007	2008	2009	2010	2011
5028	4627	4619	4400	3490

Source: [3]. Note: The data for 2011 is forecast on the basis of data available on 18 October 2011.

Table 2: Number of planned subjects in clinical trials in the EU, 2007–2010

2007	2008	2009	2010
544,287	410,568	367,036	408,294

Source: [3]

To address these shortcomings, following extensive consultation with stakeholders on how to improve the EU law, the European Commission published legislative proposals to amend the existing Directive in July 2012.[2]

> most heavily criticised piece of EU pharmaceutical legislation

As clinical studies become increasingly important to the National Health Service (NHS) in England, and to other health care systems around Europe, this article looks at the impact of the Clinical Trials Directive and at how some of the proposed changes could help to boost life sciences research and improve patient care.

Trials and tribulations

As the European Commission has recognised, the Clinical Trials Directive is arguably the most heavily criticised piece of EU pharmaceutical legislation. Criticisms have been articulated by a broad range of stakeholders and political actors such as patients, industry, academics, Member States and EU institutions for several years.

One of the main criticisms has been that the costs of conducting clinical trials have increased significantly. The European Commission itself has recognised that the number of staff needed for industry sponsors (i.e., the organisation responsible for the trial) to handle the clinical trial authorisation process has doubled, while for non-commercial sponsors the increase in administrative requirements has led to a 98% increase in administrative costs. In addition, the average delay in launching a clinical trial has increased by 90% to 152 days, while insurance fees have increased by 800% for industry sponsors.[2]

These difficulties have contributed to making the EU a less attractive location to conduct clinical trials, which, in turn, has resulted in a fall in clinical trial activity in the EU. According to figures quoted by the European Commission in its own impact assessment on the revision of the Directive, and shown in Table 1, the number of clinical trials applications fell by around 25% from 2007 to 2011. In terms of the number of participants in clinical trials, as Table 2 shows, 2010 saw over 135,000 fewer subjects planned to be enrolled in a trial compared to 2007, a fall of around 25%.[3]

Regulating for change

As mentioned previously, to respond to these difficulties, the European Commission has released a proposal for new EU legislation. The proposal takes the form of a Regulation, meaning that once agreed, the EU law will apply directly in each Member State, without the need to be transposed into national law, and thereby ensuring that the rules for conducting clinical trials will be consistent across Europe.

The proposed Regulation represents a significant improvement to the current regulatory framework and is one that should be widely welcomed. It is a clear attempt to streamline the existing rules to reduce the administrative burden and speed up time for the authorisation of new clinical trials.

The NHS has been pressing for a revision of the existing Directive for a number of years and is pleased to see that the proposed Regulation reflects a number of changes it has recommended.

Below we look in more detail at some of the proposed changes:

Simplifying the authorisation process
The first significant amendment concerns the application and authorisation process before a clinical trial can start. Current rules require the submission of separate application dossiers for each of the countries involved in a trial, often resulting in a disproportionate administrative burden and delays in the launch of clinical trials. The new Regulation proposes that a single application dossier would be submitted via an EU portal. While all countries in which the sponsor intends to conduct the trial will be involved in the assessment of the application, they will have to cooperate in several areas of the process with one Member State leading and coordinating on their behalf. These changes are important and should reduce the bureaucratic burden, speed up the authorisation process and reduce the lengthy delays that have hindered many clinical trials applications.

A lighter regime for 'low risk' trials
Another positive proposal is the recognition that trials which pose no or very limited additional risk to participants compared to normal clinical practice should be subject to a lighter regulatory regime. The proposed Regulation identifies a new category of clinical trials, called 'low interventional', which would be subject to more proportionate rules for different aspects of the clinical

trial process, including timelines for authorisation, monitoring, reporting, and insurance requirements. This is a positive step forward especially for non-commercial bodies, such as universities and hospitals, which often sponsor non-commercial trials that aim to compare the efficacy of medicines which are already authorised and for which there exists extensive knowledge of their safety and tolerability.

Enabling co-sponsorship
The explicit introduction of the concept of co-sponsorship is also a very positive development, particularly for non-commercial sponsors like universities and hospitals. These bodies often are unable to lead clinical trials on their own due to different regulatory and practical difficulties and, therefore, decide to share the sponsor's responsibilities with partner organisations to overcome these obstacles.

Compensation for damages
The proposed Regulation seeks to simplify the insurance compliance requirements for clinical trials. Current requirements have created difficulties especially for organisations sponsoring multinational trials in terms of their ability to obtain insurance cover for clinical trials sites outside of their Member State. The new proposal attempts to tackle this by exempting from these requirements those trials that pose only negligible additional risk compared to treatment in normal clinical practice. More controversially, it proposes that each Member State sets up a national indemnification mechanism, working on a not-for-profit basis, to help sponsors comply with insurance requirements. This proposal is particularly welcome by non-commercial sponsors.

Simpler safety reporting
Researchers and ethics committees have long complained that the existing reporting arrangements for clinical trials are both onerous and inconsistent across Europe. Presently, all reports of suspected unexpected serious adverse reactions (SUSARs) related to a substance under investigation have to be reported to the national authorities and ethics committees in all the countries where a trial looking at that substance is running. Each country is also responsible for ensuring SUSARs are reported to the European database. The proposed Regulation aims to streamline and simplify these reporting procedures by enabling direct reporting of SUSARs by the sponsor to the European database and the possibility to exclude investigator-level reporting to sponsors if the protocol allows. Again, this proposal is certainly a welcome one, though more could be done to further streamline reporting requirements.

> "clinical trial applications fell by around 25% from 2007 to 2011

The proposed Regulation will now pass through the EU legislative procedure, with negotiations between EU decision-makers expected to last for several months before the Regulation can be agreed.

Conclusions

The reform of the Clinical Trials Directive was long overdue and after extensive efforts by many health and research bodies, including the NHS, it is encouraging to see that the European Commission has listened to many of our concerns and proposed a way forward. An improved and streamlined EU regulatory framework for clinical trials is essential not only to boost Europe's competitiveness but, most importantly, to improve the quality of health care which is provided to patients.

Research and innovation are becoming increasingly important for health care systems. Looking at the English NHS specifically, NHS hospitals currently sponsor around 500 clinical trials and virtually all our hospitals are involved in some clinical research and recruit patients for clinical trials.

This Directive itself has been on trial for much of the last decade. The English NHS is committed to making the most of the opportunity offered by this revision and to ensure that the new EU law is fit for purpose by maintaining patient safety while promoting high quality research and improved patient care.

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MEDICINES INNOVATION IN SEVERE MENTAL ILLNESS – THE NEXT INVESTMENT DESERT?

By: David J. Nutt and Jim Attridge

Summary: The societal burden of mental illness in Europe exceeds that of either cancers or cardiovascular diseases. Depression, anxiety and schizophrenia seriously impact upon the working age population and labour productivity. Despite past progress in developing effective medicines, many patients still do not respond and there are high levels of unmet need. Emerging basic science and product development technologies suggest that much scope exists for further incremental innovations. However in Europe, the 'new economics' of biopharmaceutical innovation and intense pressure on health budgets are driving a substantial decline in rewards for innovators. Unless more is done to protect funding of purchases of innovative medicines in this disease sector, the decline in investment will continue, creating another innovation desert analogous to that already seen for antibiotics.

Keywords: *Medicines, Severe Mental Illness, Innovation Incentives*

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Gustavsson et al. estimated in 2010 that the cost of mental illness in Europe was €798 billion, consisting of 37% direct health care costs, 23% direct non-medical costs and 40% indirect costs and productivity losses.[1] The EU per capita cost of brain disorders on average was €1,550. This paper is limited primarily to depression, anxiety and schizophrenia, which constitute a substantial part of this cost and there is a growing literature showing the high negative impact of these illnesses upon labour productivity.

Enormous progress has been made in clinical models of severe mental illnesses and biochemical brain mechanisms, leading to the development of effective new drug treatments. However, investment in research and development (R&D) in better drugs for these conditions in Europe is weakening.[2] This article reviews past progress and offers a prognosis of exciting scientific advances confronted with growing short-termism in rewarding innovation, driven by economic austerity.

Innovation models for medicines in severe mental illnesses

The balance between static and dynamic competition determines the incentives to invest in R&D; government regulation of markets sets this balance by providing 'economic shelters', such as patents. Biopharmaceutical innovation involves three competitive races:

The **Research Race** to discover new disease mechanisms and novel patentable agents for modifying them.

The **Development Race** to convert the patent knowledge into safe and effective products.

The **Market Diffusion Race** to bring these products into general use to benefit both patients and reward the innovators.

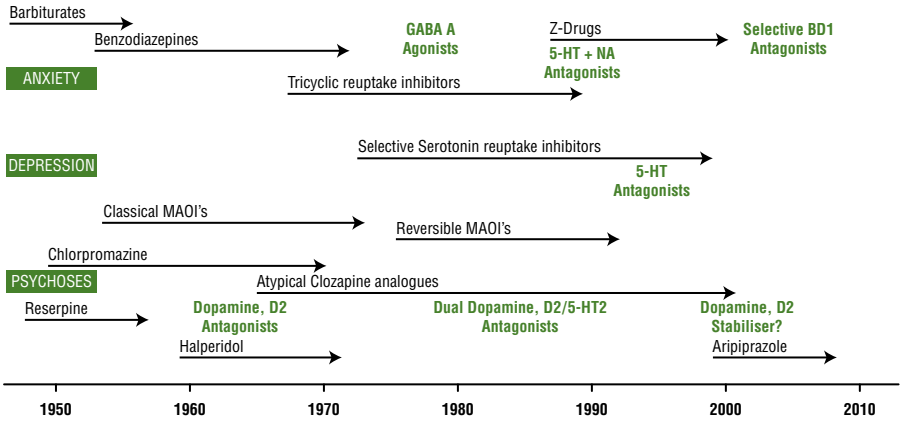
Innovation theories distinguish between radical innovations and incremental ones. The first to market of a new class of treatment appears to be a radical innovation and follow-on products are 'incremental' followers, but it may be one of these later entrants that offers the best treatment. This analysis reaffirms the reality that in practice innovation is an incremental process and that classification of medicines as either 'breakthrough' or 'me-too' is a gross and unhelpful distortion.

Progress in medicines for serious mental illnesses

Up until the 1970s, concepts of disease states were vague, the numbers of people living with them greatly underestimated, and there were few treatments. Furthermore, those whose condition deteriorated, or experienced psychotic conditions, were incarcerated, sometimes for life. Innovative progress in three domains – clinical research, laboratory studies and development of new classes of medicines, in conjunction with more widespread availability of psychotherapeutic interventions, has transformed outcomes.

Effective therapy for depression began with the monoamine oxidase inhibitors, which have serious side effects. Later the tricyclic class of antidepressants (TCAs) were developed which had much improved activity to side effect profiles. However, individual patient responses varied greatly and many did not respond at all. Better definitions of disease states led to more accurate diagnoses and the selective deployment of this new choice of therapies. The selective serotonin reuptake inhibitors (SSRIs) which followed were both highly effective and safe and became established as the first line treatments for depression. Given they are exceptionally safe in overdose, SSRIs are preferred to the TCAs in the treatment of patients with suicidal tendencies. Later clinical studies of manic and depressive episodes led to the definition of the new diagnostic sub-class of 'bipolar disorders'.[3]

Figure 1: Classes of psychotropic medicines and their modes of action



Source: the authors.

Anxiety is a normal emotion, but when excessive, inappropriate or prolonged it can cause profound distress and functional impairment. The benzodiazepines, discovered in the 1960s, were the first effective anti-anxiety agents and research on them continues even today. Not all novel structural types blossom into successful drug families. The novel partial agonist buspirone has value in treating patients with general anxiety disorders, but substantial investment failed to find more selective analogues.

The phenothiazine class of medicines were the first effective antipsychotic agents, but they cause 'Parkinsonian-like' side effects. Clozapine was patented in 1963, but it was twenty years later, when its exceptional efficacy in schizophrenia was recognised. It works exceptionally well, but has a very poor side effect profile. Despite many years of study, we still have little idea as to how it works; identifying this mechanism remains a major research goal. However, improved analogues, such as risperidone, olanzapine and quetiapine, have become widely used. The latest developments in antipsychotics are the dopamine receptor partial agonists, the first of which, aripiprazole, does not cause Parkinsonism.

> dominant paradigm is one of incremental improvements in treatments

In summary, common patterns of progress across the basic research, clinical research and product development domains provides a choice of effective therapies along with psychological interventions, from which one, or more can be selected to suit individual patients, as shown in Figure 1.

The dominant paradigm is one of incremental improvements in benefit to risk ratios for new disease states and patient sub groups. Clinically, there remain significant cohorts of patients that are resistant to all current treatments, or which, once stabilised, relapse, or become resistant to them. Figure 2 summarises the complex relationships between clinical conditions, modes of action and therapeutic agents.

Innovation incentives

Future investment will depend upon 'technology push' factors, technical regulatory standards and 'market pull' factors.

Technology push factors

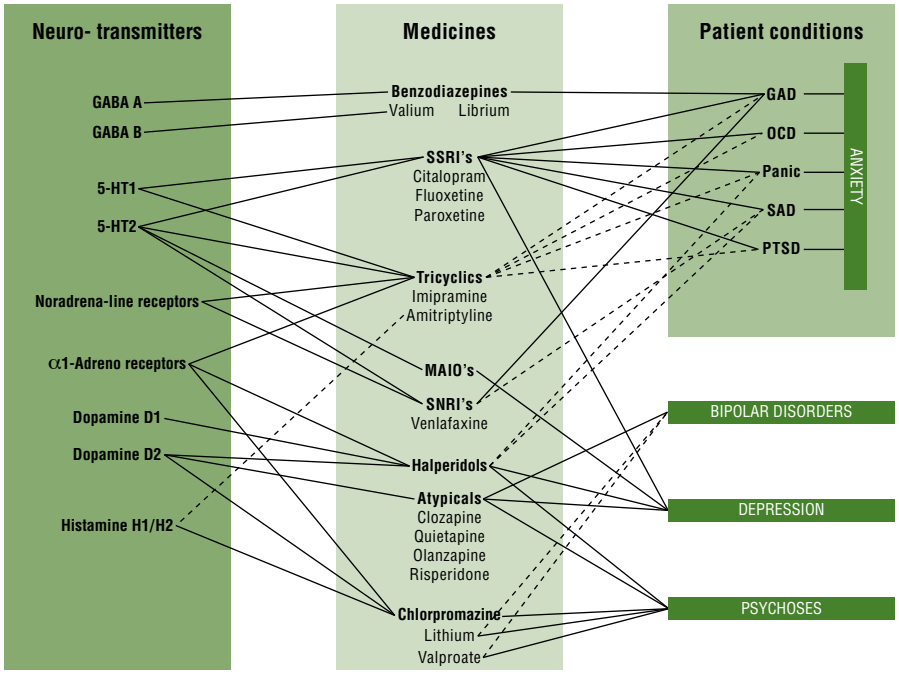
There are new small molecule treatments for anxiety and depression, for psychoses and for bipolar disorders in phase II and III clinical development. However, if, due to poor prices most of these fail in EU markets, it appears likely that there will be an even sharper downturn in longer-term investment. Scope for further innovation exists in the following three areas:

Variants of dopamine receptor partial agonists in schizophrenia and mania and modified reuptake blockers in depression could offer improved efficacy or tolerability, which are likely to improve patient outcomes through greater population uptake and sustained adherence to treatment. Such developments could reduce the adverse effects of nausea and sexual dysfunction. In anxiety, improving understanding of the role of the GABA-A receptor should lead to drugs with less sedating and amnestic effects.

> prices are being levelled down to those of the cheapest generics

The discovery of neurotransmitters, which regulate 'sleep-wake' cycles by promoting arousal/awakefulness – the orexins – is leading to the invention of novel orexin antagonists as sleep-promoting agents. High levels of stress hormones, especially cortisol receptor (crf), corticotrophin and cortisol are found in many depressed people and new crf receptor antagonists targets are emerging for these disorders. A remarkable discovery has been that the anaesthetic ketamine produces a rapid elevation in mood in 'treatment-refractory' patients. Its mechanism of action may involve switching off memory circuits for bad memories in depression. We have known for many years that glutamate systems are dysregulated in the schizophrenic brain, but only recently have glutamate-acting drugs for schizophrenia become safe enough to use.

Figure 2: Relationships between, neurotransmitters, classes of medicines and disease states



Source: the authors.

The search for genetic or physiological biomarkers for psychiatric disorders has been on-going for many years. Brain imaging, particularly magnetic resonance imaging (MRI), has contributed much to our understanding of the brain regions involved in depression. Currently, there is great excitement that the brain changes responsible for the action of antidepressants can be observed in normal volunteers, providing a way of screening compounds at phase I clinical trials, allowing pruning out of candidates earlier, with major cost savings.[4] Several molecular and structural abnormalities have been reported for schizophrenia, but no diagnostic test or other clinical application has yet emerged.[5] European biomarker research may yield 'diagnostic-therapeutic' combinations for mood disorders.[6]

Technical regulatory standards

Future innovations in mood disorder medicines will depend critically upon whether less costly and time consuming approval pathways are feasible. Concerns regarding the wide variation in Member States' approaches to valuing innovations has led to suggestions that the European Medicines Agency (EMA) should play a more prominent role at the outset by issuing with the product licence an EU assessment of the 'relative efficacy' of a new product, to improve the consistency of national cost-effectiveness assessments.

Market pull factors

Self evidently, there is a strong market pull effect from patients with mood disorders for better treatments, but the EU economic crisis has led to multiple cost saving interventions by health systems, through price cuts, sweeping away the hoped for transition to a more orderly, Health Technology Assessment (HTA) – based approach to pricing and reimbursement. Prices are being levelled down within countries close to those of the cheapest generics, upon which are superimposed cross-market price comparisons, which

now exploit the falling prices in poorer countries. In effect it is becoming a 'race to the bottom' for EU medicines prices across the EU Member States.

Future European policies and regulation

Across EU health systems there is a convergence of thinking on rewarding innovation around three precepts:

- *Does it address an area of high unmet medical need?*
- *To what degree is it a therapeutic innovation?*
- *Is it cost-effective today relative to current therapy at the price on offer?*

For severe mental illness drugs, exceptionally high uncertainties in predicting outcomes resulting from difficulties in making accurate diagnoses, patient relapses, non-adherence and non-responders makes it difficult to determine what are the areas of unmet need, but health systems are signalling to innovators, that only if they achieve step-change advances in therapy in areas of high unmet need will they be well rewarded. This is incompatible with an incremental innovation process.

However it is the third consideration, cost-effectiveness, that heralds the most significant driver of change. Innovation is a continuous process and real world experience in clinical practice plus further product developments commonly transforms the potential value during the early years of a product's market life. Comparative HTA methods can seriously disadvantage new medicines for mental illnesses, because building quantitative models, with high levels of indirect costs and uncertain patient responses, is exceptionally challenging. Innovators bringing forward incremental advances for anxiety, depression and schizophrenia must either concede that the product is derivative of an existing class and then justify a massive price uplift over the cost of existing generic therapies, or they have to persuade purchasers that it should be exempt from such clustering methods and negotiate a 'managed entry' contract.

Across Europe, cheap generics have saved health care systems billions of euros, dramatically reducing revenues for innovative companies. Projections suggest globally a further decline in revenues of circa €23–31bn, which will only be partially offset by new products amounting to circa €15–23bn. Revenues may decline by as much as 27%, while only 13% of new product revenues may be generated from central nervous systems medicines.[7] Three factors are reducing investment in innovation; allowing generic competition from imported Indian and Chinese copy products, supporting EU Member State cost containment and lowering R&D productivity.

For health care systems more cost savings will accrue from generics, but with greater risks of supply shortages.[8] Loss of some product development capabilities may increase exposure to resistant organisms, pandemics and new disease states. In mood disorders, valuable inventions will not be translated into useful products. The implications for EU competitiveness are likely to be an export of more manufacturing and services jobs to Asia due to the upsurge in generic sales. Competition from Asia and the USA for inward investment in innovative activities will intensify and EU biopharma sector employment could fall by 50–100,000 jobs.

Conclusions and recommendations

Public health systems and industry business models are at a point of discontinuity.

Health policies implicitly assume that if there are established treatments for diseases, such as anxiety and depression, this is synonymous with them having relatively low levels of unmet need. Popular rhetoric persists in naive distortions that new products are either true innovations of great value, or worthless me-too's. When a broader view is taken of the economic, as well as clinical consequences of unmet need in mental illness in the working population, this is a faulty judgement. The full added value of innovative medicines can only be understood in retrospect. For example, the SSRI's antidepressants have made, and will continue to make, an immense social and economic contribution, which dwarfs the cost of these drugs.

> more severe cost saving measures will seriously damage incentives for innovation

The exciting new 'push' factors have the potential to drive a renaissance in mental disorder medicine innovation, but, if the advances now in late development are not reimbursed at reasonable prices, investment in further product development could dry up altogether by 2015, in a manner similar to that observed for antibiotics in the 1990s.

There are three domains in which policy interventions might be made:

1. Invest more money in research to strengthen the 'technology push'
2. Lighten the regulatory burden in development by streamlining processes.
3. Protect innovators from yet more arbitrary price cutting initiatives

A holistic view of *all three* of these is needed in formulating future policies. It is not enough to frame EU policies solely upon supply side factors. The EU Innovative Medicines Initiative (IMI) and collaborative 'government-industry' schemes are making a valuable contribution. The Orphan Drug programme has strengthened investment in drugs for rare diseases but the future burden of 'relative efficacy' assessments at the EU level and national cost-effectiveness assessments militate against faster, less costly pathways to market. Further 'push' incentives and streamlining of EMA processes alone will not reverse the decline in investment for

mood disorders, in particular, without a more concerted pan-European initiative to address damaging demand side policies.

Successful innovative industries are the key to restoring competitiveness and growth for Europe, but more severe cost saving measures will seriously damage the incentive for innovation investment and drive investment out of Europe to the USA and Asia. Máire Geoghegan-Quinn, EU Commissioner for Research, Innovation and Science recently emphasised [9]:-

> *'All Member States are currently working to reduce their budget deficits and to keep public debt levels under control. While this process is necessary, it is critical that budget cuts be implemented in a way that supports sources of future growth'.*

The question has been posed, 'Can Europe Afford Innovation'? [10] In the face of the escalating social and economic costs of mental disorders in Europe and the promising technological advances described here, we would conclude with the question, 'Can Europe afford not to invest in, and reward well, innovation to improve the mental health of its citizens'?

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New HiT for Kazakhstan

By: A Katsaga, M Kulzhanov, M Karanikolos and B Rechel

Copenhagen: World Health Organization 2012
(acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

Number of pages: 154, ISSN 1817-6127 Vol. 4 No. 4

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0007/161557/e96451.pdf

Since becoming independent, Kazakhstan has undertaken major efforts in reforming its post-Soviet health system. Two comprehensive reform programmes were developed in the 2000s: the National Programme for Health Care Reform and Development 2005–2010 and the State Health Care Development Programme for 2011–2015 "Salamatty Kazakhstan". Changes in health service provision included a reduction of the hospital sector and an increased emphasis on primary health care. However, inpatient facilities continue to consume the bulk of health financing. Partly resulting from changing perspectives on decentralisation, levels of pooling kept changing. After a spell of devolving health financing to the *rayon* level in 2000–2003, beginning in 2004 a new health financing system was set up that included pooling of funds at the oblast level, establishing the oblast health department as the single-payer of health services. Since 2010, resources for hospital services under the State Guaranteed Benefits Package have been pooled at the national level within the framework of implementing the Concept on the Unified National Health Care System.

Kazakhstan has also embarked on promoting evidence-based medicine and developing and introducing new clinical practice guidelines as well as facility-level quality improvements. However, key aspects of health system performance are still in dire need of improvement. One of the key challenges is regional inequities in health financing, health care utilisation and health outcomes, although some improvements have been achieved in recent years. Despite recent investments and reforms, however, population health has not yet improved substantially.

DEVELOPING **REFERENCE NETWORKS** FOR EUROPE: MOVING PATIENTS OR KNOWLEDGE?

By: Willy Palm, Irene A. Glinos and Bernd Rechel

Summary: After more than ten years of heated debate a European directive was finally adopted in March 2011 that established a legal framework for cross-border health care within the European Union. In addition to setting out rules for providing and reimbursing cross-border health care, the Directive also aims to promote cooperation between Member States, including through the development of European reference networks. With less than one year until the entry into force of the Directive in October 2013, the European Commission is preparing criteria and conditions for such reference networks.

Keywords: *Cross-border Health Care, Cooperation, Reference Centres and Networks, EU Law, Specialised Care, Rare Diseases*

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An old idea, a broad concept

The idea of creating – or rather identifying – centres of clinical excellence in Europe was already raised many years ago when the phenomenon of patient mobility started to make its way onto the EU health agenda. It was not only seen as an interesting avenue for developing a conscious, proactive policy towards cross-border care but also as a way of saving costs and improving quality for complex medical interventions or indications by sharing resources between Member States.[1] In an era of increasing clinical specialisation, hospitals were also self-proclaiming their excellence in specific areas to extend their catchment areas, even beyond national borders.

In 2003, the High Level Reflection Process (HLRP) on patient mobility and health care developments in the European Union (EU) recommended that existing initiatives be mapped and their scope further explored, along with the use of cohesion and structural funds. Not surprisingly, the first policy initiatives were taken in the field of rare diseases. It was the Task Force on Rare Diseases that produced the first overview in 2005 and defined a range of criteria that centres of reference should comply with to obtain European recognition. This was followed by various pilot projects on specific rare diseases, which received financial support under the EU's public health or research framework programmes.[2]

To some extent, the initial focus on rare diseases contributed to another significant development: the gradual shift from identifying individual European centres of reference (ECRs), which, based on their specific equipment and/or expertise could treat patients from all over Europe, towards the creation of European reference

networks (ERNs) which would connect different centres to share knowledge and expertise in diagnosing and treating complex cases. This accommodated the idea that the EU, rather than organising the mobility of patients through labelling expert centres, should instead promote mobility of knowledge and information.

> Improve access to highly specialised care

Despite these developments, the concept of European reference networks (or centres) was never meant to be restricted to the particular area of rare diseases nor was it focused entirely on moving knowledge instead of patients. The HLRP noted that any system of ECRs should be flexible, objective, transparent and leave choices as to its use open to the responsible authorities. Even if the EU promoted the idea that expertise rather than patients should travel, it was recognised that both aspects could not – and should not – be dissociated from each other. Partners within the networks, by disseminating information and developing guidelines on state-of-the-art treatment for specific conditions, would particularly attract patients from countries where this expertise is lacking.

European reference networks under the Directive

The concept of ERNs as specified under the Cross-border Care Directive[3] follows this broad approach. In its preamble, the Directive suggests that "all patients who have conditions requiring a particular concentration of resources or expertise" could benefit from providers networking to improve access to high-quality and cost-effective care (Recital 54). Cooperation in the field of ERNs and rare diseases is developed in Articles 12 and 13.

Article 12 rather than providing a real definition for the concept of ERNs, lists their objectives and the criteria they should fulfil. It leaves room for different types of networks pursuing different objectives or motivations by specifying a range of eight different objectives of which ERNs need to embody at least three (Article 12.2). Whereas initially the idea of ERNs seemed to be inspired by the objective of improving cost-effectiveness through concentrating resources across borders, it increasingly became motivated by the desire to improve safety and quality through concentrating cases, raising standards and even integrating care. Equity also plays a role, since reference networks might give Member States, whose limited patient numbers or resources make investing in the necessary equipment and infrastructure difficult, access to highly-specialised services for their populations outside of the national territories.

In setting the framework within which the Commission is now requested to define a more detailed list of criteria and conditions for ERNs and providers wishing to join them (Article 12.4), the Directive also applies an open and integrative approach. Rather than exclusively focusing on the clinical excellence that is naturally expected from ERNs in the actual diagnosis and treatment of patients, the Directive recognises that expertise should also be reflected in a broader range of aspects: a multidisciplinary and coordinated approach; special attention to evaluating outcomes and controlling quality; strong links with medical training and research, and an active role in developing standards and best-practice guidelines. In addition, good communication skills and the involvement of patients and patient groups are regarded as key features for recognising reference networks, as well as their willingness to collaborate closely with other centres and networks.

In fact, by focusing on networks rather than centres and by emphasising the multifaceted approach and openness to sharing and collaborating, the Directive avoids the trap of being dragged into a spiral of competition between clinical institutions to become the top reference centre in Europe. On the contrary, networking supports the goals of benchmarking, mutual support and knowledge transfer between Member States and centres in the same clinical field.

Building on national practices

In order to be successful, ERNs need to reflect and build on existing practices in Member States. Although the concept of reference centres and networks is known in most European health care systems, a review of experiences in 20 EU Member States and Norway found substantial variation, not only in the scope and motivations for developing them, but also in their state of progress and political importance.[4]

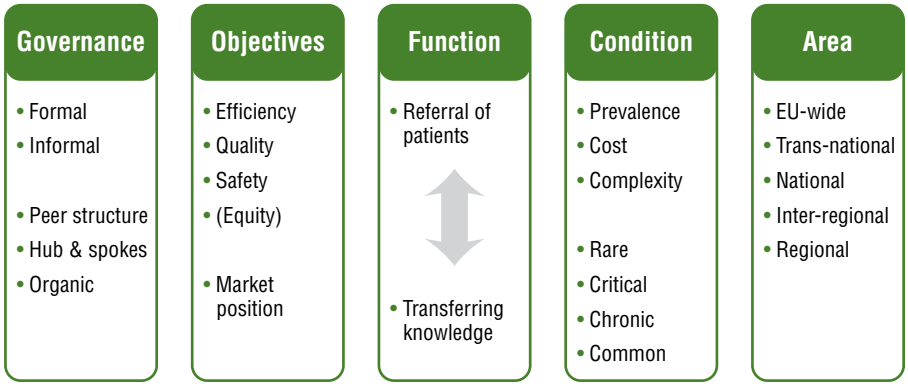
Based on the review five key dimensions can be distinguished in the establishment and functioning of reference centres and networks (**see Figure 1**):

- The way they are organised and governed;
- The purpose or motivation for their development;
- Their function (what they do);
- Their material scope (what type of patients/conditions/care they focus on);
- Their geographical scope.

While several European countries have not yet officially embraced the concept of reference centres or networks, a growing number of countries have in recent years initiated specific regulation and frameworks for establishing reference centres or networks, sometimes under the direct influence of the Cross-border Care Directive. Most often, this was motivated by the need to concentrate the provision of highly specialised services in a limited number of medical institutions. Some countries also have "*de facto*" systems, in which certain hospitals or departments – mostly teaching hospitals – have become the leading centres to which the most complex and severe cases are referred because of their traditional position or recognition among professionals. However, proper referral rules, designation criteria and systematic quality assessment are often lacking.

Gradually, in many countries more formal systems are being set up. Partly due to the

Figure 1: Dimensions to define reference centres and networks



Source: Palm W, Glinos I A, Rechel B, Garel P, Busse R, Figueras J (Eds.) Building European Reference Networks. Exploring concepts and national practices in the EU. Observatory Studies Series 28; (forthcoming 2013).

effects of the financial crisis, countries have stepped up efforts to rationalise and reconfigure hospital care, categorising their hospitals into distinct levels that specify their remit both in geographical terms and in the types of care to be provided. Although the need for a more centralised and structured provision of specialised hospital services is generally justified in view of benefits for efficiency, cost-effectiveness, quality and equity, it sometimes also faces criticism and distrust.

In Central and Eastern European countries, centralisation efforts may evoke memories of the old Shemasko model, which provided only limited choice for patients. In decentralised systems, centralisation may be perceived as an attempt by the central level to gain more control over the health system. In some cases, it is even argued that the designation may actually impede collaboration between hospitals. Whereas such negative perceptions most often come from providers who are questioning or challenging the designation, providers are sometimes also the biggest proponents. Obviously, their interest in the concept may not always be in accordance with health system objectives, but based on more business-oriented motivations and the need to seek a return on investment for highly specialised equipment through consolidating their market positions or even extending their catchment areas. The danger here is that without any clear framework the concept is used to increase patient expectations, as well as the scope and prices of provided services, giving rise to provider-induced demand. Therefore it is important to establish objective, detailed and transparent procedures, with the involvement of all relevant actors.

Some European countries have developed well-established systems and procedures for defining and designating reference centres and networks, as well as for monitoring their activities and outcomes. A good example is Spain. Since 2006 the country has elaborated a joint planning system for concentrating specific specialised services in reference centres, departments and units (RCDUs) of the National Health Service (SNS). Under the supervision of the SNS's Interterritorial Council, a special designation committee, in which the Autonomous Communities and the Ministry of Health are represented,* identifies the priority diseases and procedures for which concentration is desirable. This can be either motivated by the use of very advanced technologies (e.g., total skin electron radiation), the involvement of a high level of specialisation or the low prevalence of cases (rare diseases, transplants). Reference services can only be established for treatments that are part of the publicly funded basket of health care services. With the help of a group of experts the designation criteria are defined for each area of specialisation. The actual selection of RCDUs is made on the basis of centres proposed by the autonomous community governments. Following a qualification process in which each centre is audited by the SNS's Quality Agency, the designation committee proposes the centres for nomination to the Ministry of Health. The designation is awarded for a maximum period of five years. The RCDUs are monitored annually. An information system gathers data on the procedure and the outcome indicators included in the designation criteria.

To date, 46 priority diseases and procedures have been identified and the designation criteria for thirteen areas of specialisation have been defined. Up to 2011, 132 reference centres, departments and units of the SNS had been designated for 35 diseases and procedures. Nearly 90 of them are monitored through the information system. The care provided by the RCDUs is mainly funded through a national cohesion fund.

However, not all approaches to reference networks require a general planning process. Concentration of specialised services and referral of patients can also be achieved through minimum activity thresholds, as for instance applied in Germany, or through special agreements or contracts between statutory health insurance bodies and a range of reference centres that specialise in the treatment of specific rare or chronic diseases, as in the case of Belgium. In addition, quality standards and certification processes can be used as tools to define and impose the level of expertise and multidisciplinary approach that is expected from reference centres and networks for the treatment of rare and complex cases.

For what conditions?

One of the important challenges that EU and national regulators are facing is how to define the scope for reference centres and networks. Similar to the EU policy processes described above, rare diseases are clearly a prime focus for developing the concept of reference centres and networks also at Member State level. Several countries recognise centres for specific rare diseases and have established national networks, often built around a central coordination centre. The Italian National Network for Rare Diseases,

* In Spain, the regions, known as Autonomous Communities, are responsible for managing the regional health system and delivering health care.

established in 2001, is coordinated by the National Centre for Rare Diseases (part of the National Health Institute) and links certified care providers who were mandated by regional authorities. France adopted a National Plan for Rare Diseases in 2004, which included a designation procedure for reference centres for specific or groups of rare diseases. The Czech Republic, Belgium and Malta are developing similar strategies.

Furthermore, in areas of critical and complex conditions similar plans for centralising and networking are being implemented. Examples can be found in the fields of transplants, burns, trauma and stroke care. The concept also has considerable appeal in the field of cancer. Countries are setting up reference centres in oncology, not only to address some rare cancers but also to improve the quality of care and to ensure speedy uptake of new therapies. In some cases, these networks are less focused on the actual provision of care but rather on the idea of sharing knowledge and best practice, as well as the coordination of training and research.

This further extends the scope to chronic conditions (e.g., diabetes) as they can also benefit from this kind of networking. In Germany, the Competence Networks in Medicine, initiated at the end of the 1990s, promote horizontal collaboration between research institutions to stimulate innovative medical therapies in specific areas of disease (e.g., mental health, Parkinson's disease, dementia, specific cancers, rare diseases), as well as vertical integration with medical specialists to accelerate transfer into practice. Another good example are the five Hospital-University Institutes (IHU) in France, a collaboration mechanism between tertiary care hospitals and universities, involving teams of renowned biomedical researchers involved in education and translational research. Smaller interesting examples include the Dutch ParkinsonNet, coordinating regional networks of closely cooperating specialised professionals, and the Alliance for Heredity Issues (VSOP), also in the Netherlands, which is run by organisations of parents and patients with rare, genetic and congenital disorders, aimed at improving care through information, research and patient participation.

> "goals of benchmarking, mutual support and knowledge transfer

This wide variety of national practices illustrates that prevalence of conditions is just one, and not necessarily the most relevant, indicator that justifies the setting up of ERNs. The question of whether there is sufficient critical mass within a country or a region to address rare diseases depends not only on the size of the country (after all, the European definition of rare diseases still results in about 30,000 cases in the UK alone): available expertise and treatment capacity are also highly relevant. Prevalence alone fails to indicate the type of disease; how well established treatment options are; what is required in terms of interventions and support; or whether it involves a short period of treatment or ongoing care.

Next steps

From the national experience, it is clear that also at EU level there are important challenges to ensuring that the various (potentially competing) regional, national and international concerns are reconciled, not least when it comes to selecting the potential centres to be part of the ERNs. In addition to involving national and regional health authorities in reviewing and assessing candidate centres, it is equally important to use detailed and, objective criteria, as well as having good monitoring and information systems in place. Since on some occasions the expertise and willingness to share knowledge can be specifically linked to the presence of certain individual specialists, it is important to perform periodical re-assessments of designated centres and networks. Moreover, given the financial implications that the labelling of centres as part of ERNs may have,[5] it could be important to constrain their scope and expectations and develop a gradual approach in designating European reference networks.

To enable the development of ERNs, the European Commission is required to adopt a Delegated Act that defines the criteria that ERNs and health care providers wishing to join them have to fulfil. To support and advise the Commission, a Cross-border Health Care Expert Group was established with representatives from Member States. In addition, in late November 2012 the Commission launched a public consultation, inviting stakeholders to give their views on the criteria for selecting diseases or conditions suited for creating ERNs, and for determining which centres can join them.[6] In a next phase the Commission will adopt an Implementing Act for establishing and evaluating the ERNs as well as facilitating the exchange of information and expertise.

To come up with a system of criteria that is clear, pertinent and perceived as fair and that can work in 27 different national settings is not an easy task. After all, the difference in Member States' approaches to reference networks and centres is just a reflection of the diversity between health systems in Europe.

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FINALLY ON TRACK? HEALTH REFORMS IN KAZAKHSTAN

By: Alexandr Katsaga, Maksut Kulzhanov, Marina Karanikolos and Bernd Rechel

Summary: Since 2005 Kazakhstan has embarked on two comprehensive national reform programmes. These have aimed to change the provision and financing of care, place more weight on prevention, and improve the quality of care. Key changes to health care provision included the standardisation of health services and the development and implementation of clinical practice guidelines. Health financing reforms have seen the introduction of pooling at the national level (for hospital services under the State Guaranteed Benefits Package) and the oblast level (for primary health care services). However, there are still challenges in the implementation of reforms and population health indicators lag behind those of most other former Soviet countries.

Keywords: *Health System Reforms, Health Care Financing, Health Care Delivery, Kazakhstan*

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Introduction

Due to its booming energy sector, Kazakhstan is by far the richest of the Central Asian states that became independent with the dissolution of the Soviet Union in 1991. Despite a reduction in Gross Domestic Product (GDP) between 2008 and 2009 resulting from the global economic crisis, Kazakhstan's economy has rebounded and its GDP per capita in 2011 was at least four times higher than that of the poorest Central Asian countries – Kyrgyzstan, Tajikistan and Uzbekistan – and 50% higher than in Turkmenistan.[1]

Yet, paradoxically, many of Kazakhstan's health indicators lag behind those of other countries in the former Soviet Union. Life expectancy at birth in 2010, at 68.6 years, was one of the lowest in the WHO European Region.[1] These numbers already highlight the enormous challenges faced by Kazakhstan's health system. Our article, based on the recently published health system review,[2] aims to provide an overview of recent health reforms in the country and of the challenges that remain for the future.

Recent reforms

Similar to other countries in the region, Kazakhstan inherited an oversized and inefficient health system from the Soviet period, with too much emphasis on bed and staff numbers.[3] Initial health reforms in the country after independence were chaotic and volatile. Factors that impeded progress in health reforms included a general lack of trained administrative and health management personnel and frequent organisational changes. Beginning in 1996, the Ministry of

Health changed its internal structure several times, with Ministers of Health and their teams changing on average every two years. In 1999 the Ministry of Health was abolished as an independent administrative body and subsumed under larger ministries, only to be restored in 2002.

> “out-of-pocket payments constitute 40.1% of health expenditure

Major changes in the structure and regulation of the health system were initiated in the mid-1990s, ranging from attempts to devolve power to the *rayon* (local) level to the introduction of mandatory health insurance and the restructuring of primary health care. However, not all of these envisaged changes were implemented and some, such as the experiment with mandatory health insurance, were reversed. More consistent and coherent reforms only came about in the second half of the 2000s, when two comprehensive reform programmes were adopted: the National Programme of Health Care Reform and Development for 2005–2010 and the State Health Care Development Programme for 2011–2015. These programmes greatly stabilised the previously fluid health policy environment.

In 2009 two key health policy documents were adopted that aimed to underpin further reforms: the Code on People’s Health and the Health Care System[4] and the Concept on the Unified Health Care System.[5] Both documents envisage country-wide measures for improving the health of the population, with a particular emphasis on prevention and the shared responsibility of the state and individuals for health. The Concept on the Unified Health Care System envisages the free choice of providers, the introduction of performance-based payment mechanisms, and a strengthening of continuous quality improvement processes.[6]

Health financing reforms

Initial health financing reforms in the 1990s and early 2000s were erratic. In 1996, the national Mandatory Health Insurance Fund was set up, operating as a parallel structure along with the previous system of funding health organisations through the state budget, which resulted in the vertical fragmentation of pooling. Due to revenue shortfalls, corruption, and the impact of the Russian financial crisis in 1998, the national health insurance system was discontinued the same year and Kazakhstan returned to budgetary financing. However, problems of horizontal fragmentation emerged in 2000–2003, when, in line with broader administrative decentralisation, health financing and administration were decentralised to the *rayon* level. These changes resulted in the creation of inefficient and poorly manageable micro-health systems, negatively impacting on the overall efficiency of the health system and the population’s access to health services.

Beginning in 2004, a new health financing system was set up that, following similar reforms in neighbouring Kyrgyzstan,[7] allowed pooling of funds at the oblast (regional) level, establishing the oblast health department as the single-payer for health services. Health purchasing mechanisms were also reformed, establishing capitation payment for primary health care, a case-based payment system for hospital care, and a partial fund-holding system for outpatient specialty care. Since 2010, resources for hospital services under the State Guaranteed Benefits Package have been pooled at the national level.

However, as in other countries of the region, out-of-pocket payments (coming from official user fees and informal under-the-table payments) are another important source of revenue, constituting 40.1% of total health expenditure in 2010.[1] Recognising that this presents a major barrier to accessing services, an outpatient drug benefit has been introduced that entitles children, adolescents up to 18 years old and women of reproductive age to free outpatient pharmaceuticals. Insufficient financial protection is an issue for part of the population, with 7.4 % not using health services in 2008 because of high costs.[2]

Health service provision reforms

Similar to other countries of the former Soviet Union, the provision of health services in Kazakhstan has evolved on the basis of the legacy of the Soviet health system, with its overemphasis on hospital services and its neglect of primary health care, disease prevention and health promotion. This delivery system is still in the process of being reorganised.

Health care provision and financing have been largely devolved to the oblast administrations and their health departments. The 14 oblast and Almaty and Astana city health departments are the key bodies administering health services in Kazakhstan and run most hospitals and polyclinics. In addition, parallel health systems run by some ministries and government agencies have been inherited from the Soviet period and are still largely in place.

Although Kazakhstan was the setting of the Alma-Ata Declaration of 1978, which emphasised the centrality of primary care to the operation of effective, efficient and equitable health services,[8] this principle was neglected for a long time, with a higher priority allocated to inpatient facilities. In the 1990s a dramatic reduction of outpatient services occurred, following the introduction of user fees for most diagnostic services and the necessity to purchase outpatient pharmaceuticals. This situation changed significantly in the 2000s, when primary health care facilities were legally and financially split from hospitals, providing them with greater autonomy to manage their resources and increase efficiency. Furthermore, the infrastructure of primary health care was upgraded, particularly in rural areas. However, the shortage of qualified personnel remains one of the major problems in this sector. Rural and remote areas continue to experience a shortage in primary care personnel, while larger cities are much better staffed. There

is also an imbalance towards specialist services, to the detriment of primary health care facilities.

In the hospital sector, Kazakhstan has significantly reduced the number of hospitals and hospital beds and also started to renew its health infrastructure, but the ratio of hospital beds per capita is still high and also differs greatly across oblasts. Furthermore, inpatient facilities continue to consume the bulk of health financing. In 2008 public expenditure on hospital care was 2.6 times higher than expenditure on outpatient services and only 0.17% of oblast health expenditure was devoted to health promotion.[2]

Quality of care was another focus of reform efforts. After 2005 the principles of evidence-based medicine were increasingly introduced to policy-makers, academics and health care providers, leading to a gradual recognition of evidence-based medicine as a core prerequisite of clinical practice, education and research, and of the importance of its institutionalisation and implementation. The Health Care Development Programme 2011–2015 envisages a comprehensive set of measures to improve the efficiency and quality of hospital care. Key areas include improving hospital performance, development of general hospitals with specialty departments, and expansion of diagnostic and treatment technologies.

Another challenge is that linkages between primary and secondary care are poor, and many services are organised in parallel vertical structures, such as tuberculosis services, sanitary-epidemiological services, or the health systems operated by other ministries and government agencies. The resulting poor horizontal integration of services leads to duplication and inefficiencies. In light of this, the standardisation of health services across the country is one of the key objectives pursued by current health reforms. In 2009 the Ministry of Health approved standardised types and volumes of health services at five levels of care.[9]

Main challenges for the future

As this brief overview has highlighted, there are still many elements of Kazakhstan's health system that need to be developed further. Crucially, the ultimate objective of the health system – improving the population's health – has not yet been sufficiently achieved. While information on mortality amenable to health care interventions is not readily available, five-year survival rates for patients with a primary diagnosis of cancer are low, amounting to 50.2% in 2009.[2]

One of the main areas of future efforts will have to be stepping up public health and primary health care. The allocative efficiency of Kazakhstan's health system is undermined by a continued reliance on inpatient care, which consumed 53.4% of total public expenditure on health in 2008, whereas primary health care only received 16%.[2] There is also much scope for improving technical efficiency, in view of a high ratio of hospital beds per population, poor performance indicators for inpatient care, and many narrowly specialist health facilities.

Financial protection of the population is another area that requires more attention, as widespread out-of-pocket payments undermine access to services. There are also pronounced regional inequities in health financing, health care utilisation and health outcomes, although some improvements have been achieved in recent years. Residents of Almaty and Astana cities still have advantages in accessing health services, as these two cities host the most advanced national clinical centres, whereas the geographical accessibility of health services in remote areas is much more challenging, due to the country's vast and sparsely populated territory. In 2010 life expectancy at birth varied between 66.3 in North-Kazakhstan oblast and 73.2 in Astana city. There were also strong regional variations in infant and maternal mortality.[2]

Finally, quality of care has been recognised as another area in need of major improvement and Kazakhstan has embarked on promoting evidence-based medicine and developing and introducing new clinical practice guidelines based on WHO standards, as well as facility-level quality improvement. Preliminary results of the State Health Care Development Programme 2005–2010 indicate progress in quality improvement, in particular with regard to maternal and child health and tuberculosis, but also a strong need for further efforts.

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NEW PUBLICATIONS

New HiTs for the United Kingdom (Northern Ireland, Scotland and Wales)

The new HiTs (Health Systems in Transition) reviews for the United Kingdom (Northern Ireland, Scotland and Wales) have just been released and were officially presented at the King's Fund Annual Conference in London on 28 November 2012.

New HiT for Northern Ireland

By: C O'Neill, P McGregor and S Merkur

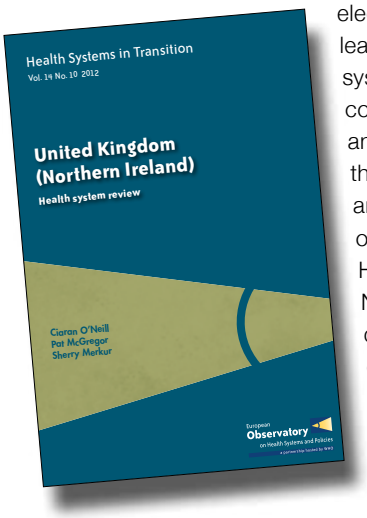
Copenhagen: World Health Organization 2012 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies).

Number of pages: 91

ISSN: 1817-6127 Vol. 14 No. 10

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0007/177136/Northern-Ireland-HiT.pdf

Northern Ireland has an integrated health and social care system and since the establishment of a devolved administration a locally elected Health Minister now leads the publicly financed system. The Minister has considerable power to set policy and, in principle, to determine the operation of other health and social care bodies. The organisation of the National Health Service (NHS) in Northern Ireland is radically different to that in England, despite superficial similarities. A crucial difference is the commissioning of hospital services. Unlike in England, there is no competition between trusts, and this has two implications. Firstly, funds to hospitals are distributed geographically, based on a formula designed to ensure horizontal equity, with no market pressure on individual hospitals. Secondly, control is bureaucratic, with the emphasis being on consultation and cooperation among health and social care bodies. Without competition, effective control over the system requires information and transparency to ensure provider accountability, and a body outside the system to hold it to account. The restoration of the locally elected Assembly in 2007 has created such a body, but it is too early to judge how effectively it exercises accountability.



New HiT for Scotland

By: D Steel and J Cylus

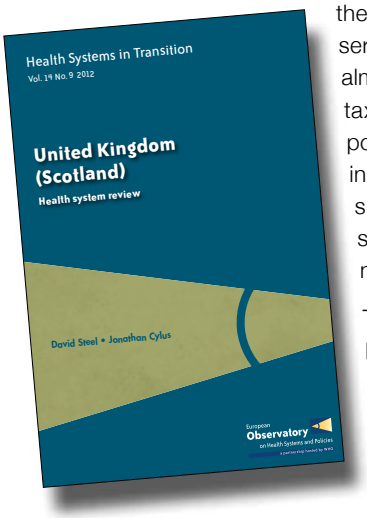
Copenhagen: World Health Organization 2012 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies).

Number of pages: 150

ISSN: 1817-6127 Vol. 14 No. 9

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0008/177137/E96722.pdf

Since devolution in 1999, the Scottish Parliament and Government have been responsible for most areas of domestic policy, including the health system. Health services in Scotland are financed almost entirely out of general taxation, are largely free at the point of need and available to all inhabitants. There is a very small independent health care sector, both private and non-profit-making.



The Scottish health system has increasingly diverged from the health system in England over the past decade. Scotland has pursued an approach stressing integration and partnership among all parts of its national health service (NHS) as opposed to an English approach which, in part, is driven by market forces. Comparatively fewer organisational and structural changes, in addition to consistent policy objectives, have provided a strong launching pad for achieving improvement in health services, as well as in the health status of the population. In addition, substantial increases in funding have led to significant growth in the clinical workforce and numerous performance targets have been set to improve population health, the quality and outcomes of health care, and the efficiency of the health system.

As a result, Scotland has made well-documented progress in terms of population health and the quality and effectiveness of care. However, a number of challenges remain. More progress is needed to close the gap in health status between Scotland and other developed countries, and to address persistent inequalities in health, particularly in the most deprived areas where risk factors such as smoking, alcohol consumption and poor diet are more prevalent. As in many other countries, increased fiscal pressures may make it difficult to maintain both the quantity and quality of health care service provision in future.

New HiT for Wales

By: M Longley, N Riley, P Davies and C Hernández-Quevedo

Copenhagen: World Health Organization 2012 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies).

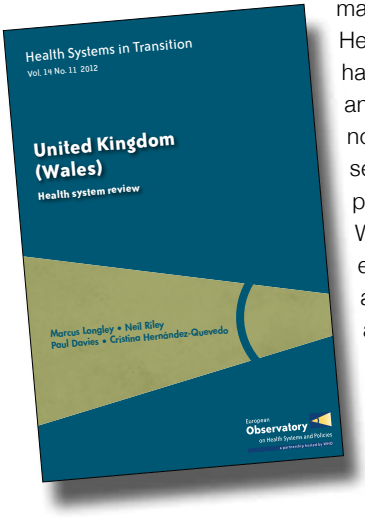
Number of pages: 84

ISSN: 1817-6127 Vol. 14 No. 11

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0006/177135/E96723.pdf

With approximately three million citizens, Wales contains about 5% of the United Kingdom's total population. For several decades, the country had a health system largely administered through the United Kingdom Government's Welsh Office, but responsibility for most aspects of health policy was devolved to Wales in a process beginning in 1999. The overall budget Wales receives from the United Kingdom Government is based on its share of the total United Kingdom population and the National Assembly determines how that 'block grant' is used.

Since 1999, differences between the policy approach and framework in England and Wales have widened. The internal market introduced in the National Health Service (NHS) in England has been abandoned in Wales, and seven local health boards now plan and provide all health services for their resident populations. Health services in Wales are financed almost entirely out of general taxation and are therefore, largely free at point of use. There is relatively limited private financing of health care, and the NHS makes very little use of the private sector.



The health system in Wales continues to face some structural weaknesses that have proved resistant to reform for some time. However, there has been substantial improvement in service quality and outcomes since the end of the 1990s, in large part facilitated by substantial real growth in health care spending. However, with the change in the financial climate, Wales is now facing a severe reduction in expenditure, and there is some concern that the health system is not financially sustainable in the longer term unless additional funds can be found to meet rising demand. Although life expectancy has continued to increase, health inequalities have proved stubbornly resistant to improvement.

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

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

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

Number of pages: xix + 206

ISBN: 978 92 890 0281 3

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

Many of the policies and programmes that affect health originate outside the health sector. Governments therefore need to address population health using a strategy or policy principle that fosters intersectoral action. Health in all policies (HiAP) does just that, encouraging intersectoral approaches to management, coordination and action. This publication captures research on how intersectoral governance structures operate, showing how governments and ministries can initiate action, and how intersectoral governance structures can be successfully established, used and sustained.

Contents:

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

NEWS

International

Conclusions of Employment, Social Policy, Health and Consumer Affairs Council

At a meeting of the Employment, Social Policy, Health and Consumer Affairs Council on 6 and 7 December in Brussels there was a discussion on progress made on a draft decision aimed at strengthening EU capacities and structures for effectively responding to serious cross-border health threats and providing the incoming Irish presidency with guidance for further work.

Serious cross-border health threats can be events caused by communicable diseases, biological agents responsible for non-communicable diseases, as well as threats of chemical, environmental, or unknown origin, including threats of malicious intentional origin. Threats can also derive from the effects of climate change. The objective of the draft decision will be to strengthen epidemiological surveillance in the EU and the early warning and response system; allow the joint procurement of medical countermeasures (e.g. vaccines) by several EU Member States; and give a legal basis to the functioning of the health security committee.

During the Cyprus presidency it was noted that good progress had been achieved and the draft decision amended in line with Member States' comments. Changes proposed by the Cyprus presidency notably ensure Member States' autonomy in preparedness and response planning, the non-mandatory character of preparedness planning at European level and attributes to the Health Security Committee a key role in the consultations among the Member States and the Commission. However, further discussions are needed in order to reach agreement in the Council on the whole proposal. This would enable the incoming Irish presidency to engage in negotiations with the European Parliament with a view to a first reading agreement.

The Council also adopted conclusions on organ donation and transplantation, focusing on the three main challenges addressed by the current action plan: increasing organ availability; enhancing the efficiency and accessibility of transplant systems; and improving quality and safety. Measures to increase organ availability were welcomed and the importance of encouraging people to commit to becoming organ donors after death noted. Mechanisms to increase the availability of organs could include transparent mechanisms for reimbursing living donors for the costs incurred and, if applicable, for compensating the loss of income in direct relation to the living donation procedure. The conclusions also welcomed the establishment of bilateral and multilateral agreements between Member States to exchange organs. It was noted that there is a need to improve knowledge on health outcomes in transplanted patients across countries, including increased knowledge on the transplantation of organs from "expanded criteria donors" such as older donors in order to increase the number of available organs.

The Council also adopted conclusions on healthy ageing across the lifecycle. They build on a conference organised by the presidency in September, and call for efforts to foster health promotion, disease prevention and early diagnosis to be stepped up. More specifically, the conclusions acknowledge that innovative approaches in health promotion and disease prevention could help older people to remain independent longer and improve their quality of life. They underline that good health among working age people contributes to higher productivity and other benefits for citizens and society to meet the goals of the EU2020 strategy for smart, sustainable and inclusive growth. The conclusions call upon Member States to make the issue of healthy ageing across the lifecycle one of their priorities for the coming years and to adopt an approach that shifts the focus towards health promotion, disease prevention and early diagnosis.

The Commission was also invited to contribute to the development of policies towards health promoting activities, and together with the Member States promote strategies for combating risk factors, such as tobacco use, alcohol related harm, illicit drugs, unhealthy diet and a lack of physical activity as well as environmental factors.

Access the Council conclusions at: http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lsa/134090.pdf

Tonio Borg appointed EU Commissioner for Health and Consumer Affairs

On 28 November the Deputy Prime Minister and Foreign Minister of Malta, Tonio Borg, was approved as the new EU Commissioner for Health and Consumer Affairs for the remainder of the Commission's current term of office (31 October 2014). EU ministers approved Tonio Borg's nomination one week after a majority of MEPs backed him in a vote in the European Parliament. A statement from the European Parliament also confirmed that he provided MEPs with written assurances that he will respect the European Charter of Fundamental Rights, as well as the rights of women and gay rights, issues which had been of concern to some MEPs. In his European Parliamentary Hearing Mr Borg promised, without further delay, to release an ambitious Tobacco Products directive by January 2013, stating that the timetable had been "encouraged and endorsed by Commission President Barroso". Subsequently on 2nd December the new Commissioner forwarded the draft Directive to the Commissioner College for approval.

His appointment follows the resignation of previous Commissioner John Dalli on 16 October. A statement released by the European Commission stated that "Mr Dalli informed the President of the European Commission Jose Manuel Barroso of his decision [to resign] following an investigation by OLAF, the EU's antifraud office, into a complaint made in May 2012 by the tobacco producer, Swedish Match. The company alleged that a Maltese entrepreneur had used his contacts with Mr Dalli to try to gain financial

advantages from the company in return for seeking to influence a possible future legislative proposal on tobacco products, in particular on the EU export ban on snus. As soon as the Commission received the complaint it immediately requested OLAF to investigate."

The statement added that "the OLAF final report was sent to the Commission on 15 October. It found that the Maltese entrepreneur had approached the company using his contacts with Mr Dalli and sought to gain financial advantages in exchange for influence over a possible future legislative proposal on snus. No transaction was concluded between the company and the entrepreneur and no payment was made. The OLAF report did not find any conclusive evidence of the direct participation of Mr Dalli but did consider that he was aware of these events. The OLAF report showed clearly that the European Commission's decision making process and the position of the services concerned has not been affected at all by the matters under investigation. The final OLAF report and its recommendations are being sent by OLAF to the Attorney General of Malta. It will now be for the Maltese judiciary to decide how to follow up. After the President informed Mr Dalli about the report received from OLAF, Mr Dalli decided to resign in order to be able to defend his reputation and that of the Commission. Mr Dalli categorically rejects these findings."

New actions against adverse effects of medicines

On 4 October the Employment, Social Policy, Health and Consumer Affairs Council of the European Union adopted new rules aimed at strengthening the post-authorisation monitoring of medicines for human use ("pharmacovigilance"). This followed a first-reading agreement with the European Parliament. The new legislation focuses in particular on obligations on marketing authorisation holders in relation to adverse reactions to medicinal products and further clarifying the procedures when competent authorities follow up such reporting. It entails a further strengthening of the pharmacovigilance rules adopted by the Council on 29 November 2010 (17054/10) and responds to the lessons learnt from the case of an anti-diabetic drug suspected of having caused the deaths of several hundreds of patients in France at a time when it was already withdrawn from the market in other Member States.

An important aim for the Council was to ensure that the new provisions lead to the early discovery of potentially dangerous medicinal products and do not lead to adverse reactions not being noticed due to "information overflow". An example of the strengthened rules is that marketing authorisation holders that withdraw a medicine from the market will have to notify the competent authority and explain the reasons for their decision even if the withdrawal is voluntary. This also applies if the marketing authorisation holder withdraws a medicine from a third country market. This provision aims to avoid that the withdrawal of a medicine for safety reasons goes unnoticed by or is hidden from competent authorities.

In order to better inform patients and medical professionals, additional groups of pharmaceutical products will be included on the publicly available list maintained by the European Medicines Agency (EMA) of medicinal products, subject to additional monitoring (for instance for safety reasons). The amendments to the existing pharmaceutical legislation also contain a further strengthening of the rules concerning wholesale distribution of medicinal products to third countries.

The provisions of the directive have to be applied twelve months after the directive enters into force.

Health spending in Europe in 2010 fell for the first time in decades, says a joint Commission/OECD Report

Health spending per person and as a percentage of Gross Domestic Product fell across the European Union in 2010. This is one of the many findings in the "Health at a Glance: Europe 2012", a new joint report by the OECD and the European Commission. From an annual average growth rate of 4.6% between 2000 and 2009, health spending per person fell to -0.6% in 2010. This is the first time that health spending has fallen in Europe since 1975. Health spending as a share of GDP was highest in the Netherlands (12%) in 2010, followed by France and Germany (11.6%). The share of GDP allocated to health was 9.0% on average across EU countries, down from 9.2% in 2009.

In Ireland, health spending fell 7.9% in 2010, compared with an average annual growth rate of 6.5% between 2000 and 2009. In Estonia, health expenditure per person dropped by 7.3% in 2010, following growth of over 7% per year from 2000 to 2009, with reductions in both public and private spending. In Greece, estimates suggest that health spending per person fell 6.7% in 2010, reversing annual growth of 5.7% between 2000 and 2009. While the report does not show any worsening health outcome due to the crisis, it also underlines that efficient health spending is necessary to ensure the fundamental goal of health systems in EU countries.

Amongst other information in the report it is estimated that spending on disease prevention accounts for only 3% of total health spending, a reduction of 3.2% compared with the previous year. More than half of adults in the European Union are now overweight, and 17% are obese. Obesity rates have doubled since 1990 in many European countries, and now range from 8% in Romania and Switzerland to over 25% in Hungary and the United Kingdom. Obesity and smoking are the major risk factors for heart disease and stroke which accounted for over one-third (36%) of all deaths across EU countries in 2010. In terms of the workforce the report notes that the number of doctors per capita has increased in almost all EU Member States over the past decade from an average 2.9 per 1 000 population in 2000 to 3.4 in 2010. Growth was particularly rapid in Greece and the United Kingdom. There are now many more specialists than general practitioner in nearly all countries due to lack of interest in traditional "family medicine" practice and a growing remuneration gap. The slow growth or reduction in generalists raises concerns about access to primary care for certain population groups.

The report is available at: http://ec.europa.eu/health/reports/european/ and http://www.oecd.org/health/healthataglanceeurope.htm

European Quality of Life Survey 2012 published

The European Foundation for the Improvement of Living and Working Conditions has published its third quality of life survey, covering the 27 EU Member States.

The survey reports declines of over 20% in levels of optimism and happiness in some countries across the EU and over a third of people indicated a deterioration in their financial situation over the past five years. These results largely reflect – with some interesting exceptions – the economic reality, with highest optimism levels reported in Denmark and Sweden and lowest levels in Greece, Italy, and Portugal. The social situation in the European Union today represents a complex and complicated story. Since the last survey in 2007, more people who had good incomes and were in good quality housing are now struggling with unemployment, debts, housing insecurity and access to services.

The survey also highlights that it is harder for many people to make ends meet: 7% report 'great difficulty' making ends meet, with large differences between Member States, ranging from 22% in Greece to 1% in Finland. When asked to whom they would turn to urgently borrow money, most Europeans (70%) would ask a member of their family or a relative for a loan. Another 12% would ask a friend, neighbour or someone else, while 8% would turn to a service provider or institution. One out of ten report they would not be able to ask anybody; this was particularly true among people in the lowest income quartile (15%). Overall, 8% of people in the EU have been unable to pay back informal loans according to schedule.

The overview report examines a range of issues such as employment, income, housing and living conditions, family, health, work-life balance, life satisfaction and perceived quality of society. Further reports on subjective well-being, social inequalities, quality of society and public services, and trends in quality of life over the three survey waves will follow in 2013.

It is also expected that the dataset will be made available to the public through the UK Data Archive in spring 2013.

The report is available at: http://www.eurofound.europa.eu/publications/htmlfiles/ef1264.htm

Country news

Ireland: government looks to clarify law on abortion

The Irish government published the Report of the Expert Group on the judgment in A, B and C v Ireland on November 27. This report provides background information on the termination of pregnancy in Ireland and sets out options for the implementation of the European Court of Human Rights judgment in the A, B and C v Ireland case.

The Court accepted that Article 40.3.3 of the Irish Constitution provides that it is lawful to terminate a pregnancy in Ireland if it is established as a matter of probability that there is a real and substantial risk to the life, as distinct from the health, of the mother, which can only be avoided by a termination of the pregnancy. While the Court dismissed the applications of Ms A and Ms B, for Ms C the Court found that Ireland had failed to respect the applicant's private life contrary to Article 8 of the Convention, as there was no accessible and effective procedure to enable her to establish whether she qualified for a lawful termination of pregnancy in accordance with Irish law. Ms C had been treated for cancer for three years. When she became unintentionally pregnant she was in remission, and being unaware of this fact, went for a series of follow-up tests related to her illness which were contraindicated during early pregnancy. She was unable to obtain clear medical advice as to the effect of the pregnancy on her health/life or as to the effect of the medical treatment on the foetus, and feared the possibility that the pregnancy might lead to a recurrence of the cancer. She decided to have an abortion and travelled to the UK for the procedure.

The Court ruled that "no criteria or procedures have been... laid down in Irish law … by which that risk is to be measured or determined, leading to uncertainty…" and held that further legal clarity was required. In response to the judgement the Government established an expert group to make recommendations on how this matter should be addressed and recommend a series of options on how to implement the judgment, taking into account the constitutional, legal, medical and ethical considerations involved in the formulation of public policy in this area and the over-riding need for speedy action.

The expert report, favours legislation, along with regulation, as the safest way to provide legal clarity. The Government will decide in December 2012 which option put forward by the expert group on abortion to implement.

The publication of the report sadly coincides with public debate in Ireland concerning the death of Savita Halappanavar, who was 17 weeks pregnant when she died at University Hospital Galway following a miscarriage. She had asked for a medical termination before she died on 28 October but was reportedly refused. The Health Information and Quality Authority is to investigate the circumstances surrounding the care and treatment provided to Mrs Halappanavar.

The report of the expert group is available at: http://www.dohc.ie/publications/Judgement_ABC.html

Russia: Parliament takes first step towards ban on smoking in public places

On 14 December, the Russian Parliament (Duma) voted overwhelmingly to approve the first reading of a bill to ban smoking in public spaces and to restrict tobacco sales. Under the draft legislation tobacco advertising will be outlawed and smoking in public places such as restaurants, bars and hotels will be phased out. It will also ban kiosks and outlets in stations from selling cigarettes.

The second reading of the bill is expected in spring 2013. If passed, the restrictions will be fully implemented by 2016. The new move follows plans for an increase in excise duty on tobacco by 40% in 2013 and 2014 and 10% per annum thereafter.

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