

Eurohealth

RESEARCH • DEBATE • POLICY • NEWS

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Periodic health examination: history and critical assessment



Zsuzsanna Jakab: building a healthier, safer, fairer and greener Europe

Comparative clinical effectiveness, drug development and regulatory policy

The EU School Fruit scheme: integrating public health into mainstream policy

Wales: policy development for older people • Child and adolescent mental health in Europe
Poland: hospital privatisation • Community pharmacy regulation • England: evidence for social care

COMMENT

Periodic health checks: handle with care

“Periodic health checks and screening are now very popular procedures. *A priori* they should be effective in reducing the burden of disease and improving wellbeing. Unfortunately the reality seems to be less attractive.” So writes Walter Holland in his brief history and critical assessment of periodic health examinations that features in this issue of *Eurohealth*. Such tests may appear attractive to the public and politicians alike; in recent years there has been an increase in the marketing of what can often be quite expensive diagnostic tests. While some periodic health checks undoubtedly benefit individuals when used appropriately, Holland cautions us not to forget that they are only of use when accepted treatments for the disease in question are available. Moreover, they carry well documented risks of side effects, including increasing anxiety, overtreatment and overdiagnosis. Investment in more upstream measures to tackle the causes of poor health and health inequalities, he suggests, may often be a more prudent course of action.

We are also particularly delighted to feature in *Eurohealth* an article from the new World Health Organization Regional Director for Europe, Zsuzsanna Jakab, who sets out her vision of the way forward for the WHO Regional Office. A number of different measures highlighted include a Strategic Action Review on addressing the social determinants of health and related inequities, in order to inform the European Health Strategy and build on the work of Commission on the Social Determinants of Health. Specific challenges to be met include strengthening the role of the Regional Committee, as well as the need to further develop strong partnerships and joint actions with stakeholders in Europe and beyond who have health mandates or are engaged in actions that have health consequences.

In a packed issue other contributions include our occasional debate series, this time focusing on issues around regulation to help minimise bias in respect of the evaluation of new drugs. We also feature two articles looking at policy implementation: one on mainstreaming public health policy at a European level, the other on the development of policy for older people in Wales.

David McDaid *Editor*
Sherry Merkur *Deputy Editor*
Philipa Mladovsky *Deputy Editor*
Lucia Kossarova *Assistant Editor*
Azusa Sato *Assistant Editor*

Eurohealth

LSE Health, London School of Economics and Political Science, Houghton Street, London WC2A 2AE, UK
fax: +44 (0)20 7955 6090
<http://www.lse.ac.uk/collections/LSEHealth>

Editorial Team

EDITOR:

David McDaid: +44 (0)20 7955 6381
email: d.mcdaid@lse.ac.uk

FOUNDING EDITOR:

Elias Mossialos: +44 (0)20 7955 7564
email: e.a.mossialos@lse.ac.uk

DEPUTY EDITORS:

Sherry Merkur: +44 (0)20 7955 6194
email: s.m.merkur@lse.ac.uk
Philipa Mladovsky: +44 (0)20 7955 7298

ASSISTANT EDITORS:

Azusa Sato +44 (0)20 7955 6476
email: a.Sato@lse.ac.uk
Lucia Kossarova +44 (0)20 7107 5306
email: l.kossarova@lse.ac.uk

EDITORIAL BOARD:

Reinhard Busse, Josep Figueras, Walter Holland, Julian Le Grand, Martin McKee, Elias Mossialos

SENIOR EDITORIAL ADVISER:

Paul Belcher: +44 (0)7970 098 940
email: pbelcher@euhealth.org

DESIGN EDITOR:

Sarah Moncrieff: +44 (0)20 7834 3444
email: westminster.european@btinternet.com

SUBSCRIPTIONS MANAGER

Champa Heidbrink: +44 (0)20 7955 6840
email: eurohealth@lse.ac.uk

Advisory Board

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Vittorio Bertele' is Head, Regulatory Policies Lab, Mario Negri Institute for Pharmacological Research, Milan, Italy.

Frank DeFelice is Director, Health Technology Assessment Policy, Europe and Canada, Merck Sharp and Dohme Europe, Inc, Brussels, Belgium.

Silvio Garattini is Director, Regulatory Policies Lab, Mario Negri Institute for Pharmacological Research, Milan, Italy.

Walter Holland is Emeritus Professor of Public Health Medicine and Visiting Professor, LSE Health, London School of Economics and Political Science, UK.

Zsuzsanna Jakab is World Health Organization Regional Director for Europe, Copenhagen, Denmark.

Martin Knapp is Professor of Social Policy and Director of the NIHR School for Social Care Research, London School of Economics and Political Science, UK.

Maria Lluch is reading for a PhD, LSE Health, London School of Economics and Political Science, UK.

Angela Mehta is Finances and Communications Administrator, NIHR School of Social Care Research, London School of Economics and Political Science, UK.

Felix Mittermayer is Policy Analyst, DG SANCO/02, European Commission.

Gareth Morgan is Project Manager, National Service Framework for Older People, Llanelli, Wales.

Robert Pederson manages the European Agriculture and Health Consortium, Brussels, Belgium.

Lukas Pfister is Executive Director Public Policy, Europe and Canada, Merck Sharp and Dohme Europe, Inc, Brussels, Belgium.

Dainius Puras is Associate Professor, Institute of Institutional Relations and Political Sciences, Vilnius University, Lithuania.

Egle Sumskiene is based at the Social Work Department, Vilnius University, Lithuania.

Peggy Watson is at the Homerton College, Department of Sociology PPSIS, University of Cambridge, UK.



Building a healthier, safer, fairer and greener Europe:

My vision for the WHO Regional Office for Europe

Zsuzsanna Jakab

Europe's public health environment is rapidly changing. The avoidable and remediable but persistent health divide in the European Region, growing and unfair inequities in health both within and between countries in the Region, in conjunction with our changing demographic and social landscape are of greatest concern. These challenges combined with pandemic (H1N1) 2009 influenza, the growing epidemic of non-communicable diseases (NCD), continuing financial crises and the health impact of climate change demand new ways of advocating, managing and responding for public health at all levels in our globalised world.

I believe that the WHO Regional Office for Europe has a key role to play in addressing these challenges, as both a proactive leader and a solid partner when joint actions are needed. Importantly, we need to strengthen our ability to adapt effectively and efficiently to these rapidly changing environments and take full advantage of the collective wisdom, experience and know-how of our vast and diverse Region – not only for the improved health of Europe but also for Europe's contribution to global health.

To this end, shortly after being nominated by the WHO Regional Committee for Europe in September 2009, I launched an informal consultation process with Europe's health community, including a

Zsuzsanna Jakab is World Health Organization Regional Director for Europe, Copenhagen, Denmark.

transition website. The aim of this process has been to stimulate much needed public health discussion, debate and exchange on key challenges and, most importantly, to initiate a broadly inclusive process that provides an opportunity for Europe's public health community to actively engage in and shape plans and efforts to adapt the Regional Office to our changing European environment.

Through this informal consultation process, I elaborated a vision for the Regional Office and posed a series of questions related to leadership, governance, partnership, the Regional Office as a networked organisation and priority actions that could be taken to make this vision a reality. As I now formally assume my role as Regional Director for Europe, I will continue this dialogue as part of WHO's formal consultation process which will inform and shape a 'Way Forward' strategy that will be presented and discussed in the Standing Committee of the Regional Committee and then in the Regional Committee in Moscow in September 2010. I am pleased to now share this vision and some early thoughts on ways to get there with the readers of *Eurohealth*.

Vision statement

I see the WHO Regional Office for Europe as a strong, evidence-based centre of public health excellence that earns the respect and support of Member States and other players for our leadership in health policy and public health. I see the Regional Office as an organisation whose high-calibre, motivated staff take coordinated action with partners to ensure attainment of the highest possible level of health by all

peoples in our Region and beyond, understanding and drawing inspiration from WHO's Constitution and its definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." I see the WHO Regional Office for Europe as an organisation that:

- is an effective champion of public health issues and opportunities;
- seriously addresses inequalities and social determinants of health, appealing to and engaging with a wide range of sectors and stakeholders at all levels;
- continuously strengthens the depth and quality of work in and with Member States through effective policy dialogue and cooperative action programmes;
- ensures its relevance to all Member States and their current and changing health needs;
- unites and integrates the Region, acting as a bridge between the different parts of the Region and promoting the principle of solidarity;
- is there for its Member States whenever and wherever it is needed, especially in times of outbreaks or disaster;
- effectively communicates information and engages its wide and extended networks to advocate for necessary action;
- anticipates and analyses changes, opportunities and developments with a potential impact on health and helps Member States to respond accordingly;
- serves as effective secretariat to the Regional Committee and in collaboration with Member States turns policy

- decisions and recommendations into action;
- innovates and inspires through its technical and policy work and links with research communities;
- works in close partnership with others, including: Member States and their institutions, WHO Head Quarters and other regions, United Nations and other international agencies, European Union institutions, the European public health advocacy and research community, non governmental organisations (NGOs), and the private sector;
- is part of, and actively supports, global developments within WHO, under the leadership of the DG, and also collaborates closely with the other WHO Regions; and
- promotes a healthy, green and supportive working environment for its staff.

Leadership

WHO's constitution provides the moral, inspirational and technical fundamentals for leadership in health policy and public health. However, to ensure relevance and continue to earn and deserve this leadership, there is a need for the Office to actively and meticulously address all the activities listed in the vision above. I see our leadership as facilitative rather than prescriptive. Based upon consultative inputs to date, there appears to be strong support for the Office to catalyse and coordinate the renewal of a common, coherent and comprehensive value-based European Health Policy which specifically addresses current health challenges. Such a policy would be at the core of our 'Way Forward' strategy and would provide a framework and roadmap for Member States and other partners for:

- addressing health inequities and the social determinants of health in the European Region;
- dealing in a systematic and targeted way with present and emerging public health challenges and priorities;
- addressing the impact of major developments that drive societies on health, as well as the contribution of health to these developments: for example, economic and fiscal policies, sustainable energy, environment and climate change, changes in the demographic and social landscape of the European Region, science and technology, etc;

- putting health at the centre of development as a key consideration in all sectoral policies at all levels of Government; and
- engaging a wider (or broad) range of stakeholders.

One of my first decisions after taking Office in the beginning of February has been to commission, under the chairmanship of Professor Sir Michael Marmot, a Strategic Action Review for addressing social determinants of health and related inequities in the WHO European Region. The Review will inform the European Health Strategy and will build on the findings and recommendations of the global Commission on the Social Determinants of Health, the Review of Inequalities in England (the Marmot Review), and gather new evidence which reflects the specific realities of all parts of our European Region. Importantly, this review will translate its findings into policy proposals and practical guidance for capacity building and implementation.

Governance

The WHO Regional Committee (RC) includes Ministers of Health from all 53 countries in the Region, as well as representatives of other UN agencies, the EU and NGOs having official relations with WHO. The RC formulates policies governing matters of an exclusively regional character, and suggests and approves the calling of Ministerial conferences and such additional work or investigation in health matters as in the opinion of the Regional Committee would promote the objective of the Organization within the Region. The RC is a unique and important platform for policy dialogue and decisions that shape the work of WHO and public health more broadly in the Region. I believe there is a need to strengthen the RC and its Executive Board, the Standing Committee of the Regional Committee (SCRC), and I am seeking input on ways to make the RC and SCRC more attractive and effective for our Member States, as well as other partners and relevant sectors.

Governance – international health

As shown in the recent Climate Change negotiations in Copenhagen (COP-15), Europe has an important role to play in global health governance and global health diplomacy to support global developments. At the same time, the impact of globalisation on Europe needs to be explored further.

Partnerships

Over the past decade, Europe has become an increasingly complex health environment, with many new players and challenges. This changing environment has significant implications for the role of the Regional Office. It is critical for public health in Europe and beyond that WHO develop strong partnerships and joint actions with partners who have health mandates or are engaged in actions that have health consequences. These partnerships must find ways to ensure that the added value of each partner is maximally expressed. By clarifying roles and responsibilities, it should be possible to ensure a more coordinated approach and avoid duplication and parallel actions.

The health mandate of the EU has grown and will continue to grow. The membership and geographical basis of the EU has also grown and is likely to continue to grow. This provides a unique opportunity for new strategic partnerships between WHO and the EU. Other important partners include NGOs, the Organisation for Economic Cooperation and Development (OECD), UN Agencies, the Global Fund and others.

The Regional Office as a networked organisation

My vision is of 'One WHO' in Europe, with all its 35 country offices and centres fully integrated as part of one strong network. I see the Regional Office in Copenhagen as providing all strategic core functions related to policy, strategy and programme development and building on the work of the centres that produce evidence and support implementation and country offices which promote these evidence-based approaches and adapt them to their national contexts.

The European Region is diverse, with its 53 countries in different stages of development. This is its beauty, strength and challenge. WHO should build on Europe's strengths and actively engage with the vast wealth of institutional and expert knowledge and experience in Member States. At the same time, the Regional Office can play an important bridging role and act to ensure international collaboration, as well as encourage and promote bi-lateral collaboration and cooperation within the Region.

I believe that evidence-based technical programmes have been and should be the backbone of the Organization. They support development work at European

level, reflecting the priorities, specificity and diversity of the European Region, as well as at country level, adapting interventions to match the specific needs and resources of each Member State.

We will be looking at whether technical programmes should be focused on selected priority topics or ensure coverage of a wide range of health expertise. We will look at how EURO can best catalyse dialogue and cooperation between Member States and link to, engage and utilise the vast health knowledge and experience of Member States.

Our Country offices are crucial in the WHO architecture. While the offices in countries with substantial need for country-specific technical cooperation programmes have a clear cut and straightforward role, the role of the country offices in other Member States (for example, those that joined the EU in 2004 and beyond) may need to be re-examined to find new ways of working. Country offices must be useful in delivering the WHO agenda to the Member States they serve. Their structures and functions should be adapted to context-specific needs, expectations and opportunities. Moreover, WHO has to increase its relevance to the EU countries. This requires better understanding of needs, resources and priorities and identifying issues for which WHO support can add value.

We will review whether EURO should have a country presence in all countries, whether sub-regional arrangements should be considered and if WHO country offices could be joint offices with other partners and/or international agencies.

Topic-focused, policy, settings-based, NGO/civil society, public health and health professional association networks have been critical in advocating public health messages, promoting partnerships, change and innovation. We will be looking at ways to renew, support and strengthen our networks.

Action priorities

While programme prioritisation has always been a balancing act between planning and the need to respond to emergent public health crises and other externalities, I believe that the Regional priorities of the Office, under the guidance of the RC, should reflect the main disease burden of the Region and its determinants, with the aim of improving the health status of the European population.

Action priorities for the Office must include:

Non-communicable diseases (NCDs), which now represent 80 % of the disease burden in the Region. We need an integrated action plan which addresses all relevant social and health determinants, as well as the health promotion and disease prevention issues, and strong political commitment on alcohol, obesity, physical activity, smoking and environment from the Regional Committee.

Communicable diseases (CDs), where detection of and response to new threats, prevention and control of the old ones (such as HIV, Tuberculosis, Vaccine Preventable Diseases (VPDs), malaria); special emphasis on Anti-microbial Resistance (AMR) and Health Care Acquired Infections (HCAIs); and assisting Member States in International Health Regulation (IHR) implementation and capacity building will be crucial.

Environment and health, where we need to ensure implementation of the commitments of past ministerial conferences and identify new strategic priorities for the years to come.

Strengthening health systems, where we bring added value to the Member States and support the prevention aspects of health care systems, as well as the strengthening of public health functions. The further development of primary health care with appropriate emphasis on prevention and health promotion is a must. Continued help to Member States to respond to the financial crisis and supporting ministries of health to argue effectively for the macroeconomic importance of health systems is also important.

Training and capacity building

The Regional Office, supported by collaborating centres and network experts, is involved in a lot of training and capacity development across the Region. We are looking to better define the Regional Office's role in training and capacity building and how it can best take advantage of the vast expertise and experience in this domain available in the Region.

Communications and information system development

EURO should be a strong and clear voice for public health, supporting Member States in their actions, and should be heard consistently in the global arena on major

public health issues. Governments must be supported in their handling of complex public health issues by providing data, evidence, policy options and transfer of good practice. Innovative communication and information tools should be explored and used more systematically to reach WHO's diverse clients such as decision makers, professionals and the public, including vulnerable populations and young people. EURO must make the best use of available information and communication technology.

In this article I have shared with you my vision for the WHO Regional Office for Europe and some of the issues we are grappling with to make it better positioned and capable of supporting the 53 countries of the European Region. These are indeed landmark times for health, but I know that together with Member States, WHO can craft a strategy and take collective action that can affect and improve Europe's health. Together we can help build a healthier, safer, fairer and greener reality across the WHO European Region and beyond.

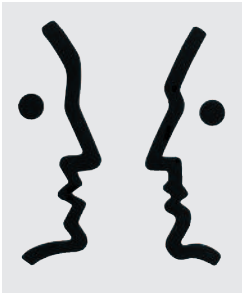
New project on health services research priority setting

The European Observatory on Health Systems and Policies is participating in Health Services Research (HSR) Europe, a Support Action project in the 7th Framework Programme of DG Research.

This project is aimed to identify, evaluate and improve the contribution of HSR to the health policy process both at the national and the EU level.

One of the major activities is the organisation of a working conference, on 8–9 April 2010, where the HSR community and decision-makers are meeting to set an agenda for European HSR and to help strengthen the research-policy infrastructure Europe wide.

For more information see:
www.healthservicesresearch.eu



Debate

Comparative clinical effectiveness

Silvio Garattini and Vittorio Bertele'

Summary: Comparative studies can be done but bias may make them unreliable or even impracticable. This paper discusses three possible areas of bias. The first regards the methodological approach: many methodological options may affect the internal and external validity of a comparison. The second regards the study hypothesis, which sometimes is not relevant for patients and overlooks their needs. The third area is the public domain of drug policy. Often products whose absolute and relative clinical value is uncertain are allowed onto the market on the basis of data produced by the manufacturers themselves. Political and regulatory authorities should stimulate industrial research to comply with patients' and national health services' needs and could contemplate funding independent research addressing important questions that do not attract private investment.

Key words: Drug regulation, independent clinical research, controlled clinical trials, active control, non-inferiority trials.

Clinical effectiveness includes the concept of the benefit-to-risk ratio of a given intervention, considered in its real context where, besides its actual effect, subjective and environmental factors such as tolerability, compliance and cost are all influential.

Clinical effectiveness is always assessed by comparison. Sometimes it may appear self-evident by historical comparisons: the introduction of antibiotics, vaccinations, coronary care units, histamine₂ receptors and proton pump inhibitors clearly reduced mortality or disability, or the need for radical surgery.

Other interventions, more often pharmacological treatments, involve uncertainty and their effectiveness must be carefully assessed – this is usually done in randomised controlled trials. With time these clinical research tools have acquired various means aimed at avoiding bias in planning and conducting the studies and in interpreting the results. These include the adoption of a parallel control group taking placebo or, whenever possible, an active comparator; randomisation, which means that chance distributes subjective characteristics into comparable groups thus

resolving individual heterogeneity into population homogeneity; and statistics, to adequately power the study and interpret its results as to avoid overlooking any effect due to the test treatment (false negative) or unduly attributing it to the effect of chance (false positive).

Even so, there are several biases that may make comparative studies unreliable or even impracticable. These come under at least three headings which will be addressed here in increasing order of importance in terms of responsibility for limiting knowledge about drugs, their optimal use, and their place in therapy in relation to other treatments.

Methodological biases: the choice of comparators

The first area of bias lies in the methodological approach: choice of the population on the basis of inclusion and exclusion criteria, which all too often overlook the needs and interests of children, women and older people; choice and dosage of the comparator; choice of the data analysis strategy – intention-to-treat or drug efficacy criteria. There are many other methodological options that can affect the internal and external validity of comparison. In this article the choice of comparator and its dose are important.

The cardiotoxic effect of a cyclooxygenase-2 inhibitor, rofecoxib, appeared similar to

that of non-steroidal anti-inflammatory drugs when compared with diclofenac, but greater when naproxen was the comparator.¹ The asserted superiority of mycophenolate mofetil over azathioprine² was not confirmed when concomitant treatment with cyclosporin microemulsion achieved better therapeutic levels than the old formulation.³

The claimed superiority of atypical or second-generation antipsychotic drugs over older drugs in this class no longer holds true in the light of a meta-analysis of 150 randomised trials.⁴ This analysis found that as a group the second-generation antipsychotics were no more effective, did not improve specific symptoms, and had no clearly different side-effect profiles from the first-generation drugs. They were also less cost-effective. Therefore the 'atypical' antipsychotics are now regarded as an 'invention only', manipulated by the drug industry for marketing purposes.⁵

The clinical development of atypical antipsychotics is affected by several biases, all favouring second-generation drugs. These include comparing the second-generation antipsychotic with a high-potency first-generation one, likely to involve a high rate of extrapyramidal side effects: of the 150 trials in the meta-analysis, 95 compared the second-generation antipsychotic with haloperidol. Comparison with a medium-potency first-generation anti-

Silvio Garattini is Director and Vittorio Bertele' Head of the Regulatory Policies Lab, Mario Negri Institute for Pharmacological Research, Milan.
Email: sgarattini@marionegri.it

psychotic was avoided, because these are likely to be just as effective as the second-generation drug, and less likely than haloperidol to induce Parkinsonism.

Sometimes industry-sponsored studies select comparators that are not the best available treatments and endpoints that magnify their deficiencies, thus facilitating the better outcome of the experimental drug. The ALLHAT study,⁶ which compared chlorthalidone, doxazosin, lisinopril, and amlodipine for first-line anti-hypertensive therapy, showed that low-dose diuretics were superior in preventing cardiovascular events. Subsequent industry-sponsored trials nevertheless adopted atenolol as the comparator even though beta-blockers are known to provide a mortality benefit in patients with coronary heart disease (atenolol being the least effective⁷) but not to prevent coronary heart disease in patients with high blood pressure.⁸ Moreover, as Psaty and colleagues noted,⁸ since calcium channel blockers are associated with an increased risk of heart failure,⁶ curiously enough, heart failure was excluded from the composite outcome measure in trials where these were the test drugs,^{9,10} but was included when a calcium channel blocker, amlodipine, was the comparator.¹¹

Strategic biases: irrelevant questions for patients

The second area of bias is the study hypothesis, which should address clinical questions relevant for patients, meaning looking for answers to unmet needs. Testing the superiority of a new product over placebo when active comparators are available, or its non-inferiority to active drugs, aims at satisfying marketing purposes, not patients' needs.

The MATCH study randomised patients with a recent transient ischemic attack (TIA) or ischemic stroke to clopidogrel plus aspirin compared with clopidogrel plus placebo. The study showed that any benefit of the combination over clopidogrel alone in reducing the risk of ischemic events after a TIA or stroke was small. Testing aspirin as an add-on to clopidogrel took it for granted that the latter was the first-choice treatment in these patients. This assumption was poorly evidence-based. It relied on the results of the CAPRIE study¹² which had shown marginal statistical superiority of clopidogrel over aspirin: five cardiovascular events avoided yearly every 1,000 patients treated. Besides being small, the benefit

was not evenly distributed among groups at risk: patients with peripheral vascular disease benefited, those with coronary or cerebrovascular disease did not. The alleged advantage also reflected the selected primary outcome measure: statistical significance disappeared in secondary combined endpoints, particularly including major amputation, the most obvious outcome measure for peripheral artery disease. The CURE trial addressed the main question for patients and national health services.¹³ It showed that adding clopidogrel to aspirin had an acceptable safety profile in patients with acute coronary syndromes and was more effective than aspirin alone.

The questions that are important for patients and public health services are those that also consider the feasibility and affordability of experimental interventions and test their comparative cost-effectiveness where possible. The trials with clopidogrel should have taken into consideration the fact that aspirin was the best known, most widely used and least expensive anti-platelet drug.

Sometimes the hypothesis, though inspired by marketing aims, is of public health interest too. However, the methodological approach mostly addresses industrial interests. For instance, non-inferiority trials are only designed to prove that a new drug is no worse than a comparator already on the market. From the industry's point of view these studies are preferable since it is easier to show non-inferiority than superiority and less risky too: failure to prove superiority may damage a product and a company's image whereas proof of non-inferiority ensures a place on the market. However, these studies only produce 'me-too' drugs with no identifiable added value and no real place in therapy.

It is also worth recalling that non-inferiority is defined as a kind of similarity within a limit which includes a degree of inferiority that is believed to be tolerable. A test drug that has been proved non-inferior may actually be less effective or less safe than the comparator, but not so much as to be recognised as such. Non-inferiority trials allow an excess of adverse events associated with the test treatment and do not consider them enough to signal a difference from the comparator.

The non-inferiority approach can produce paradoxical situations like the PROFESS Study.¹⁴ Assuming that clopidogrel

avoided about thirty (at least ten) strokes every 1,000 patients treated, the non-inferiority hypothesis of this study considered it acceptable if aspirin plus extended-release dipyridamole (ASA-ERDP) preserved at least half the effect of clopidogrel. This allows at least five more strokes (actually 94–95 instead of the 88 per 1,000 patients reported with clopidogrel, according to the non-inferiority margin set at the odds ratio of 1.075), meaning 50 more strokes in the 10,000 patients randomised to ASA-ERDP. This confirms that a non-inferiority hypothesis does not address the interests of patients who would hardly have agreed to participate if they had been aware of this prospect.¹⁵ Moreover, though the clinical outcomes in the two treatment groups were super impossible, the trial could not prove the non-inferiority of the test treatment. Failure to prove non-inferiority of a treatment basically as effective as the standard shows that non-inferiority trials may not even meet their obvious commercial aims of reviving an old drug, providing an extended indication and an updated price, while the newer clopidogrel was losing its patent protection.

Another approach that does not fully meet patients' and National Health Service (NHS) interests is known as the 'add-on'. Sometimes a new drug is added to the current treatment in the experimental arm and compared with placebo given on top of the current treatment in the control group. Comparing one treatment with two seems an uneven match, since it may well be easier for the new drug combined with the standard treatment to perform better than the latter alone. Moreover, this approach does not provide adequate information on how the test drug added on top of ongoing therapies fares in comparison with other treatments. This would only be possible if two active treatments were used, as either an alternative or an add-on to current unsatisfactory therapies. In addition studies placebo should only be allowed if no combinations of effective drugs can be proposed for comparison.¹⁶

The alleged reason for selecting the add-on approach is the need to test remedies for poor responders to current treatments. However, if the current treatment is definitely not effective, it should not be continued in either group, as it would be useless and therefore unethical. If it is partially effective, adding placebo in one arm but an active drug in the other would be unethical too.

Regulatory biases: no added value required

The third area is the public domain of drug policy. Pharmaceutical legislation requires companies seeking marketing authorisation for new products only to provide data demonstrating their good manufacturing quality, lack of toxicity, and clinical efficacy.¹⁷ These product features are meant to stand on their own, with no need for comparison with drugs already on the market. These rules allow products onto the market whose absolute and respective clinical value is uncertain.^{18,19} They also foster overuse of trials against placebo.

Even when new drugs are compared with existing treatments, trials often seek to show non-inferiority rather than superiority. This implies that newly approved drugs might be less active or safe than those in current clinical use.¹⁵ In addition, efficacy is often measured on the basis of soft clinical endpoints or surrogate markers of efficacy.¹⁹ Finally, the documentation on which the marketing authorisation application is judged is mainly produced by the manufacturers, which not only select the clinical area of intervention, choosing the least risky and most profitable, but also the kind of trial, aims and approach, the most suitable investigators, and whether and how to analyse and publish the results.

Health authorities need to stimulate industry research to comply with patients' and NHS services, besides their marketing goals, however legitimate these may be. EU legislation should require the documentation accompanying marketing authorisation applications to include clinical trials designed and conducted by independent institutions and cooperative groups. In addition public institutions could fund independent research addressing clinical questions that are not of interest to the pharmaceutical industry which do not attract investment.

In Europe there are no real incentives for independent clinical research, albeit with a few exceptions, as in Italy. In 2004 the Italian Parliament passed a law requiring pharmaceutical companies to pay a fee equivalent to 5% of all their promotional expenses, except salaries. This money is to be utilised by the Italian Agency for Drugs (AIFA) to support independent clinical research in three main areas: orphan drugs for rare diseases, head-to-head comparisons of drugs with similar indications and outcome studies with particular reference

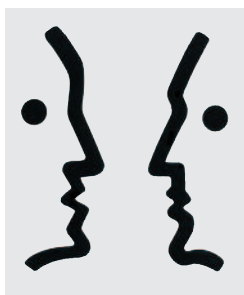
to pharmacovigilance. The results should help improve NHS pharmaceutical policy and reinforce decisions on drug reimbursement.

A call for proposals indicates the topics of interest each year. Letters of intent are screened by AIFA to identify a list of projects then evaluated by international study sections. The third call was concluded in 2008. Thus far 151 projects have been approved with a budget of €78 million. This is a significant amount of money because under this law pharmaceutical products, insurance and fees for the ethical committees are all paid by the NHS. The Italian initiative may offer a model that can be extended to other countries or the European Union as a whole. If this happens the number of independent clinical trials may build up to become a significant counterpart to industrially supported studies.

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REFERENCES

1. Psaty BM, Weiss NS. NSAID trials and the choice of comparators—questions of public health importance. *New England Journal of Medicine* 2007;356:328–30.
2. Fulton B, Markham A. Mycophenolate mofetil. A review of its pharmacodynamic and pharmacokinetic properties and clinical efficacy in renal transplantation. *Drugs* 1996;51:278–98.
3. Remuzzi G et al. Mycophenolate mofetil versus azathioprine for prevention of acute rejection in renal transplantation (MYSS): a randomised trial. *Lancet* 2004;364:503–12.
4. Leucht S et al. Second-generation versus first-generation antipsychotic drugs for schizophrenia: a meta-analysis. *Lancet* 2009;373:31–41.
5. Tyrer P, Kendall T. The spurious advance of antipsychotic drug therapy. *Lancet* 2009;373:4–5.
6. ALLHAT Group. Major outcomes in high-risk hypertensive patients randomised to angiotensin converting enzyme inhibitor or calcium-channel blocker vs. diuretic: the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). *Journal of the American Medical Association* 2002;288:2981–97.
7. Freemantle N et al. Beta-blockade after myocardial infarction: systematic review and meta-regression analysis. *British Medical Journal* 1999;318:1730–37.
8. Psaty BM, Weiss NS, Furberg CD. Recent Trials in Hypertension. Compelling Science or Commercial Speech? *Journal of the American Medical Association* 2006;295:1704–6.
9. Pepine CJ et al. A calcium antagonist vs. a non-calcium antagonist hypertension treatment strategy for patients with coronary artery disease: INVEST: a randomised controlled trial. *Journal of the American Medical Association* 2003;290:2805–16.
10. Dahlof B et al. Prevention of cardiovascular events with an antihypertensive regimen of amlodipine adding perindopril as required vs. atenolol adding bendroflumethiazide as required in the ASCOT-BPLA: a multicentre randomised controlled trial. *Lancet* 2005;366:895–906.
11. Julius S et al. Outcomes in hypertensive patients at high cardiovascular risk treated with regimens based on valsartan or amlodipine: the VALUE randomised trial. *Lancet* 2004;363:2022–31.
12. CAPRIE Steering Committee. A randomised, blinded trial of Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events (CAPRIE). *Lancet* 1996;348:1329–39.
13. Yusuf S et al. Effects of clopidogrel in addition to aspirin in patients with acute coronary syndromes without ST-segment elevation. *New England Journal of Medicine* 2001;345:494–502.
14. Sacco RL et al. 1. Aspirin and extended-release dipyridamole versus clopidogrel for recurrent stroke. *New England Journal of Medicine* 2008;359:1238–51.
15. Garattini S, Bertele V. Non-inferiority trials are unethical because they disregard patients' interests. *Lancet* 2007;370:1875–77.
16. Ottolenghi L, Bertele V, Garattini S. Limits of add-on trials: antirheumatic drugs. *European Journal of Clinical Pharmacology* 2009;65:33–41.
17. Regulation (EC) No. 726/2004, European Parliament and Council of 31 March 2004. Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. *Official Journal of the European Union* 2004;L136/(30 April):1–33).
18. Joppi R, Bertele V, Garattini S. Disappointing biotech. *British Medical Journal* 2005;331:895–97.
19. Apolone G et al. Ten years of marketing approvals of anticancer drugs in Europe: regulatory policy and guidance documents need to find a balance between different pressures. *British Journal of Cancer* 2005;93:504–9.



Debate:

Drug development: a complex and risky but potentially rewarding collaborative process

Lukas Pfister

Summary: Clinical research standards evolve in line with new knowledge and experience. Research and development is focused on current health challenges and is increasingly outcome and health gain oriented. New regulations ensure transparency, elimination of bias and that under-served yet complex populations are included in clinical studies while industry is commensurately rewarded. Clinical studies performed for regulatory approval purposes should remain the responsibility of the pharmaceutical industry and continue to be grounded in collaboration with clinical investigators and the public authorities. There is no basis for introduction of a relative effectiveness barrier at the regulatory approval stage. There is no evidence that a tax on innovator companies will provide an efficient system of funding productive independent studies.

Key Words: Drug regulatory policy; clinical trial standards, approval and monitoring; clinical trials in complex populations; relative effectiveness.

In this issue of *Eurohealth*¹ in their paper on comparative clinical effectiveness, Garattini and Bertele² question the validity and aptness of clinical studies performed or sponsored by pharmaceutical companies. This view is based on generalisations and selective citing of the literature, while failing to appreciate some of the immense challenges facing development of new medicines.

Throughout the twentieth century, scientific advances provided for the development of new medicines both to treat conditions which were previously untreatable and to improve disease management. This progress was accompanied by increasingly rigorous standards of product efficacy, safety and quality. The innovative pharmaceutical industry was actively involved in the development, implementation, and promotion of these standards. Similarly, industry has been a strong supporter of evidence-based medicine (EBM) and has structured promotional activities in the context of treatment outcomes. Numerous protocols

and guidelines for patient management, developed by independent professional consensus teams, provide essential support to physicians in navigating available treatment options for their patients.

More recently, payers have focused on the relative effectiveness of medicines in terms of their comparative value for money. The European High Level Pharmaceutical Forum provided a working definition of relative effectiveness as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results, when provided under the usual circumstances of health care practice.² The last two decades have seen the establishment of national health technology assessment (HTA) agencies, whose task is the appraisal of medical therapies and interventions for public funding (and in some cases pricing) purposes.

Research and development

The process of developing drugs from the first idea through to regulatory approval is long, complex, resource-intensive and is full of risk with return on investment uncertain and often delayed. Uncertainty continues post-approval since pharmacovigilance concerns may result in withdrawal of a new medicine at any stage

of its life cycle. It is only the commercial laboratories with their capacity and resource to undertake such high-risk investment that can take forward the applied research and development from a promising idea to a successful medicine.

The drug development process is generally incremental. The choice of therapeutic area is often driven by a company's prior experience in that area, but industry research activity also focuses on those areas which are of major interest to health authorities, the medical community and patients alike. Neurodegenerative disorders and cancer are clear leaders in the pipeline of the largest pharmaceutical manufacturers.³

The sharing of knowledge within the wider scientific community concerning basic scientific research and new technology means that pharmaceutical research laboratories may be working in parallel on new chemical entities with similar mechanisms of action. In the seventies, the average time between the approval of the first-in-class product and the next was about eight years. This gap decreased to less than two years in the late nineties.⁴ It is not unusual for first market entrants from a new class of drug to undergo regulatory approval concurrently. Such robust development activities are good for patients since identical substances may

Lukas Pfister is Executive Director Public Policy, Europe and Canada, MSD (Merck Sharp and Dohme) Europe, Inc, Brussels, Belgium.

affect patient subgroups differently due to genetics, age, co-morbidities, multiple drug treatment, and even subjective personal preferences. Within one class (defined by the mechanism of action), and depending on the end-points, certain differences in adverse events and efficacy may be expected.

In some cases, later entrants in a class were ultimately preferred to the first-in-class. Indeed, as long as twenty years ago, half of the drugs on the WHO Essential Drugs List were compounds introduced subsequent to the first in a therapeutic class.⁵ While clinical studies in the drug development period are sufficient for regulatory purposes, it is the information arising from their everyday use which provides for the build-up of their reputation and this can be seen in the generic companies' choice of products for manufacture when the drug patent expires. Application of the term 'me-too' to medicines which are the result of simultaneous research often greatly underestimates the enormous challenges and complexity of the underlying research conducted and fails to recognise the intensified competition between innovators. The appearance of more than one product in the same class provides for choice based upon the individual patient's circumstances. Choice between innovative products also ensures competition between research-based companies and has a role in modifying product launch price. Moreover, the fundamental principles of a market-driven economy underscore the inevitability of such simultaneous appearance of multiple products.

Clinical studies

Clinical studies are highly regulated and increasingly so. The provisions of the EU Clinical Trials Directive⁶ ensure that sponsors and others involved in clinical research apply the standards of good clinical practice (GCP) rigorously when designing, conducting, recording and reporting clinical trials. Compliance with these standards provides for credibility of study results. Clinical study protocols which describe the objectives, design, methodology, inclusion and exclusion criteria, statistical considerations and organisation of a trial, must be submitted for approval to independent ethics committees and competent national authorities (usually the Regulatory Agency or Ministry of Health). This also takes into account the relevance of the trial hypothesis, its design, the suitability of the investigative team, the investigators

brochure (a compilation of relevant data on the product under study), and subject recruitment arrangements. Trials may only commence once ethics and regulatory approvals have been secured. Indeed, ethical committees have the power to reject a clinical trial. A clinical trial may only be undertaken if risks and inconveniences have been weighed against the anticipated benefits for the individual trial subjects and future patients. Regulatory agencies understand the complexities and challenges associated with comparative studies, and take these into consideration when approving treatments.

Since many trials have a multi-national scope, applications for approval must be submitted in every Member State concerned. Relevant information about the trial must be entered into the European database accessible to the Commission and to the competent authorities of Member States. Appropriately qualified and trained inspectors are appointed by competent authorities to verify compliance with GCP according to set procedures.

The competent authorities also have the power to require a comparison to be carried out and to suggest a placebo or a specific comparator. In Europe, it is more common to use a standard existing treatment, although the multi-national character of clinical trials means that the comparator may not always be the most commonly used treatment in all participating countries. A review of products authorised in the EU between 1999 and 2005 showed that 71% of studies used active standard treatment as comparator and 81% of new medicinal products had been tested against active standard treatment in at least one trial.⁷

Non-inferiority trials have a role to play as they satisfy the regulatory requirements for safety, efficacy and quality. Moreover, they leverage upon the long term experience and clinical trial data of comparator products. Real life use of the medicine over the longer term and phase IV studies then allow for the evaluation of its place in disease management. Trials to evaluate superiority are sometimes not practical – they may require sample sizes that are impractical – and superiority in one aspect (such as one measure of efficacy) may not be the goal; sometimes the goal is to improve the safety profile while maintaining efficacy, for example.

Different strategies may be adopted ranging from studying the target popu-

lation as a whole, the largest group of potential beneficiaries, or a special sub-population first. Studies in populations with significant co-morbidities and multiple drug treatment are more complex, may take longer, have recruitment challenges and require greater resources. Initial trials in simple populations may allow faster completion of studies and regulatory approval and earlier availability as a treatment option. Later studies may then look at special sub-populations to ensure that the benefits of treatment may be accessible to patients who would otherwise be disadvantaged.

Until recently, medicines used in children lacked adequate information on efficacy and safety. That unfavourable situation has already changed dramatically. The enactment of the Paediatric Regulation in the EU⁸ has meant that since July 2008 all new applications for marketing authorisation have had to include results of studies in a paediatric population conducted according to an approved Paediatric Investigation Plan unless a waiver or deferral has been obtained. Similarly, since January 2009, applications for additional indications, formulations or routes of administration for medicines which are already approved must also conform to this requirement.

Standards for inclusion for older patients are provided by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical for Human Use (ICH) Guidelines.⁹ In 2006 a report for the European Commission on the adequacy of the guidance of the European Medicines Agency¹⁰ found overall reasonable compliance with the ICH guidelines and with disease related efficacy guidelines. The need for some revision of the guidelines resulted in an ICH concept paper in October 2008 which set out those elements which were essential to ensure that clinical trials were relevant to the elderly population. Additional issues for discussion prior to trial approval would include the number and age distribution of expected old, particularly very old participants, appropriate characterisation of safety in this population which could be obtained post-marketing, specific elements for evaluation of risks and benefits, including concomitant co-morbidities and therapies, discussion and justification of specific age related end-points (elderly-relevant outcomes), and defining the usefulness of specific pharmacokinetic studies.¹¹

Public policy and medicines

Extensive regulation of the manufacture and licensing of medicinal products is justified by the harm that could arise from unregulated access of medicines. The legislators of the European Union have adopted the policy position that marketing authorisations based upon safety, efficacy, and quality are sufficient to ensure patient benefit and safety, without the need for the introduction of additional barriers to market entry, which would delay patient access to new medicines significantly.

Since access to medicines in the public health systems in Europe is largely based upon reimbursement from public funds, the payer interest is safeguarded because adequate prescribing occurs only when reimbursement authorities decide upon coverage. Increasingly, the effective value of a new medicine to the payer is determined by HTA. The innovative industry supports the concept of HTA, providing it is performed correctly, used for the right purposes and not limited to drug versus drug comparisons. Furthermore, treatment guidelines and recommendations developed by professional societies play a leading role in disease management. However, there is a significant lag before new medicines appear in the guidelines, during which their usefulness compared with products available earlier is often established from results of phase IV studies.

The generation of efficacy, safety and quality data is a necessary part of the development of a proprietary new medicine and should be performed by the innovator company as the prospective holder of the marketing authorisation. Repetition of such studies by another party would not be justified for economic and ethical reasons. Nonetheless, generation of regulatory data is a collaborative process between research laboratory scientists and the clinical investigators and their institutions. This is a transparent process that is open to ethics committee and competent authority review and subject to "live" inspection throughout the trial. Casting doubt on the credibility of these data is to cast doubt on the credibility of all parties. Additional transparency arises from clinical study registries with online public access (www.clinicaltrials.gov and www.clinicalstudyresults.org) which provide information on ongoing studies as well as on study results.

Hopes in significant drug development ini-

tiatives by the state instead of the private sector have continuously been disappointed, be it in market economies (where the governments created the conditions for private sector innovation to flourish), or in the former state controlled economies of Central and Eastern Europe (where virtually no innovative products were developed). Instead, competitive research within the private sector has been a key driver for innovators to make enormous investments, shouldering the tremendous risk associated therewith and bearing the high development costs, particularly those of phase III clinical studies, the most expensive part of research and development.

Public authorities did not themselves undertake development of drugs in underserved populations such as those with orphan disease, but what they have done is to encourage commercial entities to develop orphan drugs by providing incentives including a two year extension of regulatory data protection (i.e. generic manufacturers may generate their own data but the original innovator company's data cannot be referred to for regulatory purposes).¹² Incentives were also provided to encourage paediatric studies through extension of regulatory data protection and Supplementary Protection Certificate term.

Disincentives against innovative research activities such as putting a levy on innovator companies (e.g. asking a payment of a portion of profits into a research fund) must be strongly cautioned against, as they may force companies to fund research of their competitors. Apart from the risk of not producing the intended effect, the concern of regulating in a discriminatory manner against one particular sector of the economy should not be taken lightly.

Conclusion

Evaluation of current practices is welcome since this can draw attention to the need to amend future practices. With hindsight, it is easy to say that former trials should have been designed differently. However, whenever unrecognised forms of bias are identified, they are successively eliminated from new study designs. The current model of the regulatory approval process is collaborative rather than adversarial with improvement in clinical trial design arrived at by discussion with the authorities. Identification or emergence of new needs is accompanied by the enactment of new regulations in a process that allows

stakeholder involvement. The new provisions are reflected in training programmes for those in the research community.

The suggestion that industry sponsors and investigators manipulate data constitutes a simplistic generalisation and is grossly unfair to the thousands of scientists who devote their lives to the development of new medicines. Indeed, companies and industry associations have developed and implemented strict ethical codes of conduct which are sometimes more stringent than state regulations.

Efficient use of public funds is essential to ensure the maximisation of health gains. Stakeholders have a common goal in ensuring progress so that disease can be eliminated or limited.

REFERENCES

1. Garattini S, Bertele V. Comparative clinical effectiveness. *Eurohealth* 2009;15(4):4–6.
2. Core principles on relative effectiveness. *High Level Pharmaceutical Forum*. Available at www.ec.europa.eu/pharmaforum/docs/rea_principles_en.pdf
3. DiMasi JA. *The Economics of New Drug Development: Costs, Risks, and Returns*. Tufts Center for the Study of Drug Development Tufts University. The New England Drug Metabolism Group Spring Meeting Cambridge, MA, 12 March 2008. Available at www.nedmdg.org/docs/2008/joseph-dimasi-spring-2008.ppt
4. DiMasi JA, Paquette C. The economics of follow-on drug development. Trends in entry rate and the timing of development. *Pharmacoeconomics* 2004;22(suppl 2):1–14.
5. Wastila L, Elcickas M, Lasagna L. The WHO essential drugs list. The significance of me-too and follow-on research. *Journal of Clinical Research and Drug Development* 1989;3:105–15.
6. Directive 2001/20/EC, European Parliament and Council of 4 April 2001. Approximation of laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. *Official Journal of the European Union* 2001; 1 May:L121/34–44.
7. van Luijn JCF, van Loenen AC, Gribnau FWJ, Leufkens HGM. Choice of comparator in active control trials of new drugs. *Annals of Pharmacotherapy* 2008;42(11):1605–12.
8. Regulation (EC) No 1901/2006, Euro-

pean Parliament and Council of 12 December 2006. Medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. *Official Journal of the European Union* 2006; 27 December: L378/1–19.

9. *ICH Tripartite Guideline. Studies in Support of Special Populations: Geriatrics*. Geneva: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1993. Available at www.ich.org/LOB/media/MEDIA483.pdf

10. European Medicines Agency. *Adequacy of Guidance on the Elderly Regarding Medicinal Products for Human Use*. London: EMA, 14 December 2006. Available at www.emea.europa.eu/pdf/human/opiniongen/49892006eu.pdf

11. *Final Concept Paper E7(R1): Studies in Support of Special Populations: Geriatrics (Revision of the ICH E7 Guideline)*. Geneva: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2008. Available at www.ich.org/LOB/media/MEDIA4930.pdf

12. Regulation (EC) No 141/2000, European Parliament and Council of 16 December 1999. Orphan medicinal products. *Official Journal of the European Union* 2000; 22 January: L18/1–5.



Debate reponse to Pfister

Silvio Garattini and Vittorio Bertele'

It is impossible to tackle all the arguments raised in this limited space. We shall only make a few points. There is no need for industry to manipulate data: it is enough to select targets and approaches suited to its legitimate commercial aims according to the current rules. The criteria of intrinsic quality, safety and efficacy on which marketing authorisations are based may ensure patients' benefit and safety, but not necessarily their best possible benefit and safety. This is because it is legitimate to compare a new product with placebo or with the most suitable comparator(s) to highlight its clinical merits, or to look for non-inferiority compared to the appropriate comparator, and so on. The risk-benefit profiles of newer and available products are deliberately not compared since the definition of later entrants' place-in-therapy might limit their place in the market. Evaluation of a drug's clinical value cannot be left to post-marketing everyday use; experience outside a controlled setting cannot replace evidence as a basis for a new drug's reputation. Later

entrants are usually preferred to older products not because of their proven better efficacy or safety but thanks to more intense advertising.¹ Moreover, off-label use of drugs is repeatedly promoted to boost sales.² If not even inappropriate indications are available, bizarre diseases are 'invented' just to find a market for products with no real place-in-therapy.³ All this makes commercial interests prevail over those of public health.

REFERENCES

1. Day RO, Williams KM. Open-label extension studies: do they provide meaningful information on the safety of new drugs? *Drug Safety* 2007;30:93–105.
2. Hopkins Tanne J. Pfizer pays record fine for off-label promotion of four drugs. *British Medical Journal* 2009;339:3657.
3. Moynihan R, Heath I, Henry D. Selling sickness: The pharmaceutical industry and disease-mongering. *British Medical Journal* 2002;324:886–91.



Debate patient health improvement: moving to what is adequate and feasible in assessment of innovative medicines

Lukas Pfister and Frank DeFelice

Pharmaceutical innovation, in the form of either a 'breakthrough medication' or an incremental enhancement, has brought improvements to patient health and quality of life.

The goal of health care delivery should be value for patients, not containing costs.^{1,2} Examined in the context of overall health

system spending, pharmaceutical expenditures are among the most measured for value by public payers. The processes for marketing authorisation approval, the review of clinical and cost-effectiveness, and the consideration of budget impact for public plan reimbursement, are among the most rigorous and evidence-based across public health care expenditures. In addition to thorough pre-authorisation and pre-reimbursement reviews, ongoing patient impact of medication use is measured via indicators, including surrogate markers such as HbA1c for long-term blood glucose control for patients with diabetes.^{1,2}

Surely, on the road to the 'best possible benefit', which Garrattini and Bertele' and all of us in society aspire to, we can make improvements to patient health and quality of life, be it via enhanced clinical impact, improved side-effect profiles, and better tolerance and dosing?

Instead of an ideological simplification of interests as conveyed by the authors, the debate should be focused on how to ensure patients have timely access to needed, appropriate innovative medications. Had HIV/AIDS patients been forced to await treatment at the time of introduction of the promising early AIDS medication pending

Lukas Pfister is Executive Director Public Policy and Frank DeFelice Director, Health Technology Assessment Policy, Europe and Canada, MSD (Merck Sharp and Dohme) Europe, Inc, Brussels, Belgium. Email: frank_defelice@merck.com

real outcome versus surrogate outcome data, morbidity and mortality rates would have been adversely affected. In other words, millions of lives were saved as a result of reimbursement decisions based on a reasonable review of available data, with the understanding that as further data became available that amendments could be made to how products would be reimbursed. This exemplifies a 'patients-first' approach.

Public payers themselves have characterised the debate in this manner and are already posing the reasonable question – what is 'adequate' in terms of data and information requirements to ensure due diligence in the review of medications yet is also 'feasible' to request of manufacturers at the front end of the approval process? Posed in this way, one needs to be mindful of the patient impact of delays or restrictions on novel medicines.

In the past twenty years alone, innovative medications have helped to reduce hospitalisation rates dramatically for ulcers, HIV/AIDS, diabetes, respiratory diseases and liver diseases among others. In that same time frame, death rates have also been reduced dramatically for cardiovascular and HIV/AIDS patients to cite two examples.⁴

Instead of establishing new regulatory and reimbursement hurdles, we should be providing incentives for innovation that expedite access for patients and will allow certain innovative drugs to be fast-tracked by, for example, bypassing customary cost-effectiveness review.⁵

Leading clinical practice is guided by health professionals that are swayed most by persuasive scientific evidence and what is in the best interests of their patients. Marketing has a role and can be effective but if it is not based on strong scientific evidence and on advancing patient health, it will not resonate convincingly with leading clinical practitioners.

We have previously pointed out the complex and high risk nature of discovering new medicines. The research and development costs for one drug have been estimated to be over \$800 million.⁶ Clearly funding by both public institutions and private firms has a critical role to play in advancing pharmaceutical research and development and finding the next cure, treatment, or vaccine. In an era of difficult economic circumstances, providing greater incentive for innovation by the private sector is a particularly productive way to

improve patient health. It is puzzling that one would advocate the reduction of exceptional scientific minds that are applying themselves fully to the discovery of treatments and that are being financed by means other than by taxpayers. The value of pharmaceutical innovation rests ultimately in providing better health care, better quality of life, and the ability to live longer for patients.⁴ Pharmaceutical companies and publicly funded bodies have a role in fully capturing this value.

REFERENCES

1. Porter, Michael. *Value-based Health Care Delivery*. Presentation, University of Toronto, 11 June 2009.
2. Porter M. *Redefining Health Care: Creating Value-based Competition on*

Results. Cambridge, MA: Harvard Business School Press, 2006.

3. *Best Brain Consultation: The Data Divide – Determining the Adequacy and Feasibility of Data for Funding Decisions*. Forum held by the Canadian Institute of Health Services and Policy Research and the Ontario Ministry of Health and Long-Term Care. The University of Toronto, June 2009.

4. Griller D. *Pharmaceutical Research and its Value to Canadians*. Montreal: SECOR, 2007

5. Reuters Health. *UK Plans to Let Some Drugs Bypass Value Watchdog*. 14 July 2009.

6. DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. *Journal of Health Economics* 2003;22(2):151–85.

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Social Care: a new initiative in England to fill evidence gaps

Martin Knapp and Angela Mehta

Many millions of adults in Europe are receiving social care, which can be defined as support for individuals with the activities of their daily lives, which can range across personal needs, domestic tasks, social activities and friendship. Most of this support is unpaid care from family and friends, but there are also large numbers of community organisations, charities, for-profit (private) companies and state bodies delivering 'organised' care services.

With the ageing of populations in European countries, and indeed with the longer survival into old age of increasing numbers of people with disabilities and enduring illnesses (people who, in previous generations, would generally not have lived for as long), the future social care challenge facing Europe is clearly enormous.

The largest groups of users are older people, children and adolescents, people with long-term disabilities or conditions, and those with sensory impairments. Depending on the country, other groups might be using social care services. Indeed, the term 'social care' is not universally applied: other common terms are 'welfare services', 'personal social services', and 'social services'. Unlike health care, there is less international consensus not only about terminology, but about what is included in the sector, and certainly there is less awareness among the general population of the social care needs of

individuals or what services can do to meet them.

Again, in contrast to health and health care, the evidence base upon which practice and policy decisions are taken in social care is rather less well developed. Although hard to substantiate with figures, it would generally be recognised that there has not been the same level of investment in robust research. Consequently, governments, state agencies, community organisations and others do not have much of a platform of evidence about how to meet needs, improve quality of life, or pursue cost-effectiveness.

Challenges

It is an enormous task to ensure that support and care are available for people who need them, and that the arrangements are what those individuals want. So too is the task of generating and organising resources so as to achieve the best outcomes in an efficient, equitable manner. Another challenge is to dovetail responses and activities across different sectors – making sure that central, regional and local government agencies work effectively with the voluntary and community sector, as well as with for-profit entities.

Most importantly, responses must be planned sensitively and appropriately with families and other unpaid carers. There is also an obvious need to make sure that action across different service systems – particularly social care, health, housing, education, social security and transport –

is coordinated with the best interests and the preferences of the individual in mind, while cognisant of resource constraints.

Research needs

Clearly social care touches the lives of many people. It contributes a huge amount to the nation's well being and health. To support the development of social care practice in Europe, there is a need for research evidence on what people want, how it can be provided, what works and what it costs. All of this is needed to provide policy makers with the tools to develop innovative, cost-effective services.

Evidence generated by research has the potential to contribute substantially to meeting these challenges. But that research needs to be carefully planned, competently executed and skilfully communicated to target audiences.

New investment in adult social care research in England

The National Institute of Health Research (NIHR)*, located within the Department of Health, spends considerable amounts on health and social care research in England. Established in April 2006 to carry forward the vision, mission and goals outlined in the Government's health research strategy for England, *Best Research for Best Health*, the NIHR had a £790 million revenue budget with £31 million capital funding in 2008/09.^{1,2} Its vision is to improve the health and wealth of the nation through research.

Martin Knapp is Professor of Social Policy, Director of the Personal Social Services Research Unit and Director of the NIHR School for Social Care Research, London School of Economics and Political Science. Angela Mehta is Finances and Communications Administrator, NIHR School of Social Care Research, London School of Economics and Political Science.
 Email: sscr@lse.ac.uk

* The National Institute for Health Research (www.nihr.ac.uk) provides the framework through which the research staff and research infrastructure of the National Health Service (NHS) in England is positioned, maintained and managed as a national research facility. The NIHR provides the NHS with the support and infrastructure it needs to conduct first-class research funded by the Government and its partners alongside high-quality patient care, education and training. Its aim is to support outstanding individuals (both leaders and collaborators), working in world class facilities (both NHS and university), conducting leading edge research focused on the needs of patients.

The impacts of social care services both to the public purse and to individuals in England are substantial (Box 1). In 2008, the Department of Health in England announced plans to set up a national School for Social Care Research (SSCR), to be established within the NIHR. The new School formally began work in May 2009 with a budget of £15 million over five years, almost all of which was to be spent on new research.

The School is a partnership between six leading centres of social care research in England. It is directed by Martin Knapp (London School of Economics and Political Science) and there are five Associate Directors: David Challis (University of Manchester), Caroline Glendinning (University of York), Jill Manthorpe (King's College London), Jim Mansell (University of Kent) and Ann Netten (University of Kent). Its primary aim is to develop the evidence base for adult social care practice in England and so help to improve the quality of care and support experienced by individuals and families. It will conduct and commission high-quality ('world class') research to produce new knowledge (including, where appropriate, reviews and syntheses of existing evidence) to inform the development of adult social care practice in England.

Consultation and commissioning

The School is consulting with a wide range of people interested in social care – whether as users, unpaid carers, paid practitioners, providers, managers, strategic decision-makers, and researchers. More than a hundred research suggestions have been received thus far. One reason is to identify areas where new research evidence could help to improve practice and so improve people's lives. The School is also working with an Advisory Board of highly experienced, motivated individuals; and with a User, Carer, Practitioner Reference Group to develop research ideas and to ensure wider involvement in the projects that are funded.

The SSCR is now commissioning research projects with a clear element of originality, and which have relevance and potential to improve adult social care practice in England. Research can be commissioned from anywhere – not just from researchers in England – but the findings must be relevant to English adult social care. Further calls for proposals are expected in 2010 and details will be provided on the School's website (www.sscr.nihr.ac.uk), which also

has summaries of commissioned studies.

The School is also currently commissioning expert reviews on research methods in the field, with a number recently agreed (for completion by summer 2010). They focus on:

- Randomised controlled trials
- User-led research
- Modelling
- Research methods and visual impairment
- Observational methods with a focus on learning disabilities
- Sexualities in social care research
- Outcome measurement overview
- Cost-effectiveness
- Large-scale datasets
- End-of-life care research methods
- Social care research and black and minority ethnic groups
- Research in care homes
- Qualitative methods
- Systematic reviewing

It takes longer to commission research projects, but again some progress has been made. Among those projects commissioned are: a scoping study focusing on individualisation of services; an investigation of practice models for social care practice with carers; a scoping study on care and support for people with complex and severe needs, looking at innovations and practice; and a study of the costs and outcomes of skilled support for adults with complex needs in supported accommodation. Another five projects are soon to be commissioned.

Path-breaking initiative

The NIHR School for Social Care Research is the first of its kind. It was the initiative of Professor Dame Sally Davies, Director General of Research and Development at the Department of Health, who announced the establishment of the School with the aspiration that "the new NIHR SSCR ... will give researchers the time and

Social care practice in England

In England, social care services are utilised by many people and much of the population will use such services in their lifetime – the lifetime risk of entering residential or nursing home care is around one in six for a man and one in three for a woman in England. In 2007–08, 1.75 million adults in England used social care services, with a spend of £16.5 billion by local municipalities on social care for adults, while another £3.5 billion was spent by older people on their own care because they were ineligible for public financial support.

Social care provision in England is provided through services and support offered by local authority adult services departments, the independent sector, third sector organisations, unpaid family and other carers. In 2007–08 there were approximately 18,000 care homes with 450,000 places for adults and 42,000 home care agencies in England, with an additional one million people supported in their own homes.³ About 1.5 million people worked in adult social care, and 5.2 million people provided unpaid care (and a third of them did so for twenty or more hours per week).

funding to ask the important questions and improve our understanding of what works, what doesn't work and why. This new School will provide considerable benefit to the health and well-being of the population through the new knowledge gained."

Social care aims to reduce, lessen the consequences of, or compensate for disability or disadvantage by supporting families and communities as well as empowering individuals by lessening their dependence, and to improve quality of life. A key objective is often to support people so that they can enjoy the ordinary, everyday aspects of life experienced by the rest of the population. In this context of a multitude of unanswered questions about social care, £15 million is modest, but it represents a very important step in the development of this research area.

For further information visit the School's website at www.sscr.nihr.ac.uk or contact the SSCR (sscr@lse.ac.uk).

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REFERENCES

1. Department of Health. *Best Research for Best Health: A New National Health Research Strategy*. London: Department of Health, 2006. Available at: http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/Researchanddevelopmentstrategy/DH_4127109
2. Commission for Social Care Inspection. *State of Social Care in England 2007–08*. London: CSCI, 2009. Available at: http://www.cqc.org.uk/_db/_documents/OSC08%20Report%2008_Web.pdf
3. Department of Health, Research & Development Directorate. *Delivering Health Research: National Institute for Health Research Progress Report 2008/09*, London: Department of Health, 2009. Available at: http://www.nihr.ac.uk/files/Publications/296542_DeliveringHealthResearchReport_acc3.pdf

Child and adolescent mental health in Europe

Research on best practice

Dainius Puras and Egle Sumskiene

This snapshot looks at the Child and Adolescent Mental Health in an Enlarged European Union: Development of Effective Policies and Practices (CAMHEE) project. This European Commission (EC) funded project aimed to provide a set of guidelines for effective mental health policies and practices. One element of the work was to map research on best practice with the specific objective of analysing community based child and adolescent mental health (CAMH) activities, specifically focusing on successful examples of deinstitutionalisation. The research uncovered predominant service areas, the most frequently targeted client groups, philosophies and ways in which services are structured, budgets, financing and other aspects of service provision. The most problematic issues identified by the research were political passiveness and a lack of transparency in some settings.

Dainius Puras is Associate Professor, Institute of Institutional Relations and Political Sciences and Egle Sumskiene is based in the Social Work Department, Vilnius University, Lithuania.
 Email: dainius.puras@gmail.com

Further information on the CAMHEE project is available at <http://www.camhee.eu/>

Moving up the European policy agenda

It is stated that European citizens have a right to a good mental health. This especially should be true for our youngest generation, upon whom rest our future hopes for strong social cohesion, productivity and better health. Through the enlargement of the European Union (EU) in 2004, as well as in preparations for a World Health Organization (WHO) European Region Ministerial conference on Mental Health in 2005, the importance of CAMH began to be addressed through the concerted efforts of the EC, WHO and national authorities of EU member states. Recommendations of a pre-conference on Child and Adolescent Mental Health in Luxembourg in September 2004, as well as the final Declaration and Action Plan approved in the Ministerial Conference on Mental Health in Helsinki in January 2005, put a clear emphasis on the urgent need for the development of effective CAMH policies and practices in an enlarged Europe. Most countries that joined EU in 2004 and 2007 have had to contend with major problems in the field of CAMH, revealed by strikingly high rates of poor mental health among children and young people.

There remains a concern that in many countries in central and eastern Europe financial and human resources are still

largely invested in services that contribute to traditional patterns of social exclusion, institutionalisation and stigmatisation of children, youth and parents at risk. This creates and reinforces the vicious circles of a culture of dependence, learned helplessness, exclusion and a lack of tolerance. Many new EU member states acknowledge that they need to undergo a complicated transition to a system based on principles of participation, the involvement of families and communities and strong primary care involvement. Moreover, there needs to be an emphasis placed on mental health promotion and the concept of citizenship as basic prerequisites for the good mental health of children and their parents.

The CAMHEE initiative: mapping best practice

In January 2007 a new EU-wide initiative in CAMH emerged in Lithuania, through the creation of the CAMHEE project supported by the EC's Public Health programme. As noted above, CAMHEE had the objective of providing a set of recommendations and guidelines for effective CAMH policy and practice in EU, with a special emphasis on new EU member states. It was conducted in light of the Declaration and Action Plan endorsed by WHO European Ministerial Conference on Mental Health in 2005.

The general approach was based on the understanding that new EU member states have to make proactive concerted efforts to develop effective approaches to CAMH promotion. They need to evaluate the new situation, and identify opportunities for action, as well as gaps to be plugged, by drawing on the rich experience of EU15 countries. One element of the work was to map research on best practice, with the objective of analysing community based CAMH activities, specifically focusing on successful examples of deinstitutionalisation of children with disabilities and other risk factors.

A bespoke questionnaire was developed and disseminated to health, social care and educational organisations that had some responsibility for CAMH. This research was conducted between May and July, 2008. Sixty-four questionnaires were completed by experts in Lithuania, Bulgaria, Norway, Germany, Belgium, Latvia and Greece. Forty-seven organisations were from new member states. Data were analysed using the Statistical Package for Social Sciences (SPSS) and Microsoft Excel. Descriptive statistics were applied to the data analysis.

Survey results

Approximately two-thirds of participant organisations indicated that their main service domain comprised of primary and secondary prevention (66%), psychosocial care (64%) and the provision of educational services (61%). Families were most frequently targeted, with 92% of organisations providing services to families. Emotional and conduct disorders were the most frequently targeted problems (70% and 69% respectively) reported by respondents. Providing services to victims of abuse and individuals with poor parenting skills was also noted as an important activity (62%).

79% of respondents emphasised that teamwork was the overarching service provision philosophy. Community-based service provision was the second most essential issue, with two-thirds of organisations surveyed mentioning its significance. More than half indicated using client involvement (58%), a risk management approach (53%) or individual engagement-based care (53%). The most popular way (81%) of service structuring was to offer training to non-medical clientele to implement interventions, as well as increasing the competence of professional staff, including psychologists. A

considerable number of organisations (71%) had an agreed procedure for arriving at case-formulation through contributions from their staff members and other sources. Only one third of organisations used data such as the average number of sessions, duration of care episodes or costs to indicate their involvement with specific cases.

The majority of organisations (65%) surveyed offered their services for free; almost one-third (31%) stated that they had a mixed system of charging; less than 5% fully charged for services. When pricing their services, only 16% applied market prices, while one third used their own price lists. The remainder employed a variety of strategies for setting prices.

Projects, rather than maintenance grants, are the main source of financing (58%), which raises questions about the sustainability of some services. The respondents identified two key sources of funding: local government (26%) and central government (20%). 22% supplemented public funds with their own income, largely generated through fees paid by service users, as well as membership subscriptions, donations and the time of volunteers.

The majority of the organisations are autonomous (60%), while one-third are integrated into other services (33%). When integrated, organisations usually noted that they held a special position, having been founded by an institution (for example, a municipality or hospital) but enjoying extensive autonomy. One of the organisations described its functioning as separate and autonomous but dependent on specialist care units for service provision.

Despite the fact that research participants were identified as 'best practice' examples (and respondents also stressed their achievements instead of problems), the questionnaires revealed several challenges. First of all, participants remain inactive in the sphere of policy development; less than one-third (31%) stated they had taken a proactive stance. This fact may signal a discrepancy between services provided and priorities in national mental health policy. Gaps in legislation, coupled with unclear mandates for different actors in the field, have created uncertainty, with overlapping services on the one hand and serious gaps in service provision on the other.

Though human rights violations for individuals in residential mental health institutions represent significant challenges

for new EU member states, approximately one fifth also indicated deinstitutionalisation as an essential element of their future activities. A similar trend was identified when analysing targeted problems: institutional stigma turned out to be the least interesting issue for respondents, with only 23% being active in this area.

Secondly, we encountered a significant lack of evaluation culture, evidence based service evaluation and monitoring. 85% of organisations chose to carry out an internal evaluation of services provided, whereas only 51% were subject to any external evaluation. External evaluation is likely to be more objective, critical and show the real state of the affairs. Organisations in 'old' member States more often acknowledge the importance of such evaluation, unlike the situation in eastern and central Europe where they remain committed to internal evaluation. This situation reflects different democratic traditions, attitudes towards clients, quality of services and a lack of constant verification of compliance with national mental health policy.

Interestingly, several organisations from new member states claim to use informal conversations instead of any official complaints mechanism, implying that unregistered complaints do not appear in the records. This may hide dissatisfaction with services provided. Sharing experience of best practices and moving towards a better culture of evaluation and evidence based decision making process would help to identify strengths, weaknesses and challenges for the development of evidence based and sector wide national CAMH policies in both the current enlarged EU and candidate countries.

It is hoped that the outputs of the CAMHEE project, allowing for the exchange of positive experiences and facilitating cooperation across countries, will provide a new impetus and support for better mental health promotion, mental disorder prevention and treatment for children and adolescents. However, negative factors, like the apparent lack of external evaluation and political passiveness of some research participants in new EU member states, allow us to presume that this is only the tip of the iceberg and that there is much more to do. Child and adolescent mental health requires much more academic, political and social awareness, as well as support and incentives for further development.

Periodic Health Examination – A brief history and critical assessment

Walter Holland

Summary: The development of the periodic health examination (PHE) is outlined with a critical analysis of the evidence for its benefits to health improvement. The policies of governments in supporting the use of PHE are questioned. Evidence is presented that population policies are more effective in health improvement and reducing social-health inequalities. PHE is more an attractive populist measure and supported by commercial interests. The lack of effectiveness in improving health, increasing health inequalities and its unfortunate side-effects are ignored.

Keywords: periodic health examination, multiphasic screening, screening, history, public health policy

The start

D'Souza,¹ stated that the origins of the Periodic Health Examination (PHE) or screening occurred in a brothel in the papal state of Avignon in 1347, “when an abbess and a local surgeon, every Saturday, singly examined women ‘in the home’ and if any of them had contracted any illness by their whoring, they were separated from the rest and not allowed to prostitute themselves for fear the youth who had to do with them should catch their distempers.” This account is an early record of screening applied in the cause of community medicine and antedates by at least five centuries, the use of medical examination for the apparently healthy to prevent the spread of disease.

The precise origin of PHE is difficult to trace but it has been suggested that the intellectual beginnings were due to a British physician, Horace Dobell,² a renowned clinician, author and expert on tuberculosis and diseases of the chest. Dobell proposed the periodic health examination as a way to identify “these earliest invasive periods of defect in the physiological state and to adopt measures for their remedy”.

Walter Holland is Emeritus Professor of Public Health Medicine and Visiting Professor, LSE Health, London School of Economics and Political Science, UK.
Email: w.w.holland@lse.ac.uk

In the United States (US), the public health use of screening probably first became established in the mid 19th century when, in conjunction with quarantine regulations, it was applied to immigrants. Its value in checking the flow of epidemics was taken for granted and at no time was its effectiveness tested. At the beginning of the 20th century, medical examinations were recognised as being of use to insurance companies for the purpose of rejecting or loading the policies of poor risk clients. The terms PHE and screening have similar meanings and are used interchangeably.

PHE in the US

In the US, the first universal PHE proposals began to appear at the turn of the 20th century. Possibly the first to suggest this was George Gould, a national figure in the medical community.³ In 1915, the National Tuberculosis Association designated a week for general physical examinations. This helped popularise these examinations as a tool for the early diagnosis of disease in general, and tuberculosis in particular.⁴

Organised medicine also played a major role in the development of the PHE. In 1922 the American Medical Association (AMA) officially endorsed PHE and began a campaign to spread its practice in 1923.⁵ A manual for physicians was published.⁶ George Rosen⁴ argued that organised

medicine saw the examination as serving the instrumental purpose of enhancing the position of the practitioner in the community, particularly in the wake of its opposition to compulsory health insurance. However, it has to be noted, that in the early 20th century, there was a great deal of neglect of periodic health examinations and apathy from the public.

The benefits of screening were first demonstrated by the use of mass miniature radiography (MMR) for the identification of individuals with tuberculosis. The use of MMR became common in many countries with the introduction of effective treatment for tuberculosis after 1946. With the reduction in the burden of tuberculosis, the application of screening for other chronic conditions began to be considered. This was particularly marked in the US, where a law on the control of chronic disease and the availability of screening was passed in the late 1950s. A Commission on Chronic Illness⁷ was founded in 1957, and a major review published in the *Journal of Chronic Disease*.⁸

There was also the development of what became known as “multi-phasic screening”; the performance of multiple tests aimed at detecting unrecognised disease or defects. The objective was that screening should involve physicians only minimally, and be done by using technology that could be applied economically and efficiently. First conducted in

California and Massachusetts, this spread throughout the US. Prepaid group practice health care was a final important influence on the periodic health examination throughout the mid 20th century.

The most influential experience was that of the Kaiser Permanente Health Plan in the San Francisco area, due to the financial incentive structure of prepayment. An objective was the satisfaction of overwhelming patient demand for health check-ups. This led Kaiser to seek ways to maximise the efficiency of the examinations.⁹ An automated multi-phasic screening procedure that incorporated computerised test equipment and data analysis was developed. Opinion polls indicated a growing popular belief in the value of these examinations. However, it began to be accepted that the effectiveness should be examined.

PHE in the UK

The situation in the UK was somewhat different. In 1926, an experiment was established in London at the Peckham Pioneer Health Centre.¹⁰ This provided not only general practice and medical care, but also family planning advice and routine family health screening. This screening consisted both of formal medical examinations with laboratory tests and informal surveillance. While the purpose of this screening was not simply to act as a disease sieve, it was a natural, though incidental, part of the general aim of promoting health and attending the health centre. Nothing short of a periodic health overhaul on a national scale, the health centre thought could lead to the rational application of medical science and the elimination of sickness! When the National Health Service was established in 1948, the lessons learned from the Peckham experiment were ignored. Unlike the US there was no comparable demand for PHE.

PHE in other countries and WHO guidance

Experiments and practice in PHE were also undertaken in Australia, Canada, France, Germany, Ireland, Israel, Italy, Japan, New Zealand, Norway, Scotland and South Africa. Despite the enthusiasm, or perhaps because of it, in the late 1960s, the value of screening (periodic health examinations) began to be tested and examined more critically. WHO commissioned a comprehensive review of screening worldwide which enunciated ten common sense criteria to be applied before

consideration of screening for a particular disease.¹¹ These were:

1. The condition sought should be an important health problem.
2. There should be an accepted treatment for patients with recognised disease.
3. Facilities for diagnosis and treatment should be available.
4. There should be a recognisable latent and early symptomatic stage.
5. There should be a suitable test or examination.
6. The test should be acceptable to the population.
7. The natural history of the condition including development from latent to declared disease, should be adequately understood.
8. There should be an agreed policy on whom to treat as patients.
9. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
10. Case-finding should be a continuing process and not a 'once and for all' project.

Definitions and objectives

In 1968, the Nuffield Provincial Hospitals Trust produced a book¹² which dealt with the current state of the art of screening for a number of conditions. The general tone of this book was less enthusiastic than the literature of the preceding century. A series of articles in the *Lancet*¹³ was also more critical of screening and it emerged that most of the good evidence in favour of screening centred around pregnancy and early childhood. Following this series of articles, letters to the *Lancet* revealed elements both of confusion and dissent in the debate on whether public health services should increase their involvement with screening. Sackett and Holland,¹⁴ in characterising the opposing teams as 'snails' and 'evangelists', produced a cogent explanation of the main elements in the debate. They observed that the key to much of the argument lay in confusion over the use of terms, particularly what was meant by screening or PHE. There is still no universally accepted definition, and most doctors simply look upon screening (or PHE) as the use of any sort of test to identify possible disease.

Sackett¹⁵ discussed motives for screening, suggesting that there were four reasons. Firstly, to influence the gamble of life insurance; secondly, to protect people other than the patient, as in industrial and public health screening; thirdly, to obtain clinical baselines and fourthly, to do the patient some good, so called, prescriptive screening. Obviously there are also other motives, such as financial reward and biological research, satisfying public and medical demand and gaining information for administrative purposes. Many times these are all combined in one.

Effectiveness of screening and PHE

One of the earliest attempts to demonstrate the effects of screening originated with the use of screening by insurers. Knight¹⁶ produced evidence that such screening might be effective in saving lives. He reported that over a five year period, only 217 deaths occurred, where 303 would have been expected in an uninsured population of 6,000. A similar study¹⁷ on a population of 20,648 men having employer sponsored PHEs reported a favourable ratio of actual to expected deaths, but was more cautious in interpretation and recommended that prospective studies should examine the question.

There are at least three ways in which false conclusions can be reached in this field. Firstly, regression towards the mean, a natural tendency for high or low readings on one occasion subsequently to be nearer their mean level, may easily, and erroneously, be interpreted as clinical improvement in longitudinal screening follow-up studies. Secondly, the increased survival, of say, a cancer patient after detection by screening might be interpreted as a benefit of early diagnosis but in fact, be a reflection of the so-called 'lead' time, that is that the total duration of the disease process has itself remained unchanged, but since the diagnosis was made earlier, the patient appears to survive longer. Finally, there is the danger that the net of any screening process will tend to select out the more chronic and least severe diseases which by definition, will have a more favourable, clinical cause - again, tending to suggest that screening was beneficial.

Rodney Beard in 1959, an influential voice in the US, suggested that periodic medical examinations should be examined more critically. He pointed out that there were two factors in PHE: disease detection and health counselling. The randomised con-

trolled trial undertaken at the Kaiser Permanente was one of the first to examine the problems of periodic medical examinations.¹⁸ About 10,000 people were chosen at random from the 46,000 who were Plan members in 1964, and they were then randomly divided into equal control and treatment groups. The first seven years of the study were evaluated and comparisons made. Overall death rates were not significantly improved in the screening group.¹⁹ However, two specific causes of mortality, in particular age groups, did appear to be significantly improved in the screening group. But as sixty significance tests were performed on these mortality data, this is approximately the same outcome that one would expect purely by chance. The authors failed to make this point clearly in the discussion of their results. Morbidity measures, such as physician consultation rates and hospital admission rates did not significantly differ between the groups. There was little change in these findings at sixteen years.

A further controlled study was undertaken by Olsen, Kane and Procter, on smaller numbers and over only three years.²⁰ This failed to show any measurable morbidity benefit in favour of screening.

A well designed controlled trial of screening was carried out in Malmö, Sweden, in 1970.²¹ Men born in 1914 and residing in the town were randomly allocated to screening and control groups. Following screening, intervention concentrated upon treating blood pressure greater than 165/110 and smoking. After four years the death rate in the two groups was not statistically significantly different, however, there was a significant shift in the causes of death. Twice as many men died of cardiovascular disease in the control group. This was offset by nearly twice as many deaths from cancer and other causes in the screening group. As the authors did not provide any evidence that they had lowered blood pressure and smoking levels in their screening population over the four year period, it might well be that the observed difference in their screening population over the four year period was due to random fluctuation rather than the screening programme.

A further randomised controlled trial was undertaken in England by the Department of Clinical Epidemiology and Social Medicine at St. Thomas' Hospital and group general practices in St Paul's Cray in Kent.²² Within two large group practices, all persons aged 40-64 in 1967 were iden-

tified and then randomly allocated, by family and within a general practitioner list, into two equal groups, designated 'control' and 'screening'. The screening group, numbering 3,297, was invited by personal letter from their general practitioner to be screened.

The overall response rate of those attending for screening was 73.4%. Subsequent to screening, all information was passed to the general practitioner who then did a physical examination on each subject and decided on further tests, diagnosis and treatment. The same group of patients were invited to re-attend the screening clinic in 1969, the response this time was somewhat lower being 65.6%. Both the control and screening groups were examined after seven years and their levels of function were assessed. Overall, the mortality in the screening and control population was not significantly different. No significant difference appeared between the study and control groups for any of the various causes of death. There were no significant differences in certified sickness absence, use of home help or hospitalisation between the control and screening populations. There appeared to be a higher overall consultation rate observed in the screening population compared to the control, but that could perhaps be because of the need to investigate the findings at the initial screen. The economics of screening showed that, if introduced in the total population, it could increase costs to the National Health Service by about 10%, largely because of the examinations which had to be done following screening. Thus, the value of periodic health examinations (or screening), in this population in the UK was doubtful.

In Japan, comprehensive periodic health examinations have been undertaken for many years. There is little evidence of any, other than belief, that it is of any value. Analysis of the procedure showed that it increased health care utilisation and costs. The only possible benefit was that there was an increase in health care utilisation.²³

A more recent systematic review of the value of periodic health evaluation in 2007,²⁴ was unable to show any improvement in outcomes in any of the studies examined. The authors concluded that PHE improves delivery of some recommended preventive services and may lessen patient worry, although additional research is needed to clarify the long term benefits, harms and costs of receiving the PHE. This was not a very comprehensive

review as two controlled trials were omitted^{20, 21} and the assessment of the methods and results of others, was not very critical (for example,^{18, 22}).

Changes in attitude in recent years

Opinion has changed in the United Kingdom over the past twenty years. Whereas in the 1960s, PHE's were promoted by the medical profession and disregarded by the population, now the medical profession considers them to be of dubious value and view them with scepticism.

A recent article in the consumer magazine *Which*,²⁵ cautions the population on the use of these check-ups which cost, on average, £423, particularly the use of scans on people without symptoms. It emphasises the need to link the check-up with appropriate interventions through the NHS. A commentary in the *BMJ* by a general practitioner²⁶ also notes a sound of caution – "in the public psyche there is an unshakeable belief that screening is a good thing. But many doctors, myself included, are sceptical of the absolute benefit of screening; the simplicity of the claim that 'early diagnosis' saves lives is too seductive and open to confounding to be wholly true" and continues "tear stained reasoning should not blind us to the fact that screening for skin, breast, cervical and prostate cancer (not to mention screening for high cholesterol, hypertension or osteoporosis) generates overdiagnosis, overtreatment and health anxiety. Doctors are complicit in the theft of society's most precious possession of all; a sense of well-being. So let's repeat: screening, whatever its benefits, also causes widespread, real, and lasting harm."

The aims of health policy – improvements in health – recent development

Health measures are intended to improve health. The aim of screening and PHE is intended to identify symptoms and signs in individuals at a stage when the condition is treatable and reversible. An alternative for health improvement and reduction in the burden of common diseases which have their roots in life-style, social factors and the environment depends upon a population-based strategy of prevention rather than an approach to identifying and treating 'high-risk' individuals. These alternatives have been analysed by Rose²⁷ who concludes that a population-based approach is better and more cost-effective for common diseases. For relatively

uncommon conditions screening may be better if an effective form of treatment is available. There have been many publications reviewing individual screening tests (for example Holland and Stewart²⁸). Some health administrations have established national bodies responsible for reviewing individual tests and procedures (for example, UK National Screening Committee, US Preventative Services Task Force).

In spite of all these reservations identified by research, the UK government is planning to implement 'Health Checks' in England for all individuals aged forty and over. These proposals have not been included in the procedures approved by the UK National Screening Committee since they do not meet its stringent criteria. The term 'health check' is also a misnomer, what is intended is a structured risk assessment in general practice for coronary heart disease, cerebrovascular disease and type II diabetes. Economic assessment has been done on the basis of a number of complex models. The modelling shows that the impact of the programme would be significantly beneficial. The total cost per 'Quality Adjusted Life Year' is estimated at about £3,500, which is considered to be a very good use of NHS funds by the government.

Periodic health checks and screening are now very popular procedures. A priori they should be effective in reducing the burden of disease and improving well-being. Unfortunately the reality seems to be less attractive. Most of the proponents neglect the unfortunate side-effects of increasing anxiety, overtreatment and overdiagnosis which have been well-documented.^{26,28} The results of randomised controlled trials which assessed outcomes such as mortality, morbidity and disability have not confirmed the hopes of the well-intentioned proponents, in spite of changes in some of the risk behaviours and increase of health service utilisation, particularly in countries with a competent primary care system. It is unfortunate that health authorities, worldwide, have neglected the need to conduct rigorous, long-term, pragmatic controlled trials with appropriate outcome measures and rely on superficially attractive policies based on modelling and 'expert opinions' or process measures. This short-termism is an unfortunate manifestation of all current policies – whether it be economic or health. The divide between snails and evangelists persists. It is unfortunate that the lesson

propounded by Rose²⁷ is neglected in the UK. Cardiovascular disease (CVD) (and risk factors) is extremely common in the UK population and part of health policy is to reduce inequalities. Common diseases have their roots in life style, social factors and the environment. Successful improvements in health must be based on population strategies. It is far more effective to change the population mean levels of risk (such as smoking habits or cholesterol level) rather than to tackle individuals with high risk levels, as is envisaged in the concept of 'vascular checks'. Population strategies are a far less attractive public relations option and are more difficult politically, but would have a more profound effect in improving the levels of health of the UK population.

In the most recent document for the prevention of CVD at population level issued by the National Institute for Health and Clinical Excellence (NICE) the draft guidance states "interventions focused on individuals have tended to dominate CVD prevention activities. However, the largest overall benefit could be achieved by making changes (albeit small ones) within the population as whole. As indicated by the Rose hypothesis,²⁷ a small reduction in risk among a large number of people may prevent many more cases, rather than treating a small number at higher risk. A whole-population approach explicitly focuses on changing everyone's exposure to risk. This may be best achieved through 'upstream' interventions: fiscal measures (including taxation), national or regional policy and legislation (including, for example, legislation on smokefree public places or the way food is produced).

Social and economic action can also result in a change in CVD risk (in such cases, the health outcomes are side effects – albeit desirable). Voluntary action may be effective. Sometimes, however, it may need to be supported by mandatory measures, for instance, when the pace of change is insufficient. Data from 'natural experiments' in a whole population (where there were no randomised controlled trials to assess the results) provide compelling evidence. One example is the reduction in the consumption of animal fats in Eastern Europe, following the break-up of the Soviet Union (29). Another example is the introduction of legislation in Mauritius to make it mandatory to use polyunsaturated oils as a substitute for highly saturated cooking oils. In such cases, there has been a remarkably rapid reduction in CVD

mortality among the populations.³⁰ Conversely, rapid rises in CVD mortality have been seen in China and elsewhere, principally due to the adoption of a Western diet rich in saturated fats.³¹

Interventions which rely on people deciding to change their behaviour are likely to vary in effectiveness. For example, people who are disadvantaged might find it more difficult to change than affluent people. As a result, some interventions that focus on changing behaviour may inadvertently increase health inequalities. To overcome this, the recommendations do not, in the main, rely on individual choice but, rather, aim to make the healthy choice the easy choice. Hence, the emphasis is on changing policies, systems, regulations and other similar 'upstream' factors. This approach is likely to reduce, rather than increase, health inequalities and is congruent with NICE's guidance on behaviour change.

The use of preventive health examinations or multi-phasic screening may be justified for populations that have few medical facilities, or organised health systems, to identify those individuals who require care or treatment. In most developed countries individuals have easy access to health facilities so that benefits to improve the population's health through these measures are difficult to identify. The occasional individual may benefit – but at the cost of harm to others. It is for this reason that WHO, US, Canada, the UK and other health authorities have introduced clear principles by which screening measures should be assessed before introduction to medical practice. PHE is an attractive commercial undertaking leading to the consumption of drugs and the use of diagnostic equipment. The stake that industry and advertising have is exemplified by the unscrupulous behaviour toward those who are more questioning.²⁸ It is also, superficially, very attractive to the layman, after all our cars have to be tested and examined regularly to ensure that the engine and brakes work. Thus health policy and politicians reacts favourably to such populist procedures – but completely neglects that all such examinations are fallible, leading to unnecessary further tests, the induction of anxiety and to being 'labelled' ill.

REFERENCES

1. D'Souza MF. Early diagnosis and multi-phasic screening. In: Bennett, AE (ed). *Recent Advances in Community Medicine*.

London: Churchill, 1978.

2. Dobell H. *Lectures on the Germs and Vestiges of Disease, and on the Prevention of the Invasion and Fatality of Disease by Periodical Examinations*. London: Churchill, 1861.

3. Gould GM. A system of personal biologic examinations; the condition of adequate medical and scientific conduct of life. *Journal of the American Medical Association* 1900;35:134–38.

4. Rosen G. Preventive medicine in the United States, 1900-1975. *Trends and Interpretations*. New York: Science History Publications, 1975.

5. Emerson H. Periodic medical examinations of apparently healthy persons. *Journal of the American Medical Association* 1923;80:1376–81.

6. Council on Scientific Affairs. Medical evaluation of healthy persons. *Journal of the American Medical Association* 1983;249:626–1632.

7. Commission on Chronic Illness. *Chronic Illness in the USA. Vol.1. Prevention of Chronic illness*. Cambridge, MA: Harvard University Press, 1957

8. Breslow L, Roberts DW (eds). Screening for asymptomatic disease. *Journal of Chronic Disease* 1955;2:363–490.

9. Collen MF. The multi-test laboratory in health care of the future. *Hospitals* 1967;41:119–25.

10. Pearse I, Crocker L. *The Peckham Experiment*. London: George Allen and Unwin, 1943.

11. Wilson JMG, Jungner G. *Principles and Practice of Screening for Disease*. Geneva: World Health Organization, 1968.

12. McKeown T (ed). *Screening in Medical Care: Reviewing the Evidence*. Oxford: Oxford University Press for the Nuffield Provincial Hospitals Trust, 1968.

13. Various papers in a series on 'Screening for disease'. *The Lancet* 1974;2.

14. Sackett D, Holland WW. Controversies in the detection of disease. *The Lancet* 1975;2:357–59.

15. Sackett DL. Screening for early detection of disease. To what purpose? *Bulletin of the New York Academy of Medicine* 1975;51:39–52.

16. Knight AS. Value of periodic medical examination. *Statistical Bulletin of Metropolitan Life Insurance Company* 1921;2:1.

17. Roberts NJ, Ipsen J, Elsom KO, Clark TW, Yanagawa H. Mortality among males in a periodic health examination program. *New England Journal of Medicine* 1969;281:20.

18. Cutler J, Ramcharan S, Feldman R, et al. Multiphasic checkup evaluation study. I – Methods and population. *Preventive Medicine* 1973;2:197–206.

19. Ramcharan S, Cutler JL, Feldman R, et al. Multiphasic evaluation study. 2. Disability and chronic disease after seven years of multiphasic health check-ups. *Preventive Medicine* 1973;2:207–20.

20. Olsen DM, Kane RL, Procter PH. A controlled trial of multiphasic screening. *New England Journal of Medicine* 1976;294:925–30.

21. Lannerstad O, Sternby NH, Isacson SO, Lindgren G, Lindell SE. Effect of a health screening mortality and causes of death in middle-aged men. *Scandinavian Journal of Social Medicine* 1977; 5:137–40.

22. South East London Screening Study Group. A controlled trial of multiphasic screening in middle-age: results of the South-East London Screening Study. *International Journal of Epidemiology* 1977;6:357–63.

23. Ren A, Okubo T, Takahashi K. Comprehensive periodic health examination: impact on health care utilisation and costs in a working population in Japan. *Journal of Epidemiology and Community Health* 1994;48:476–81.

24. Boulware EL, Marinopoulos S, Phillips KA et al. Systematic review: the value of the periodic health evaluation. *Annals of Internal Medicine* 2007;146:289–300.

25. Which? check-ups on private health MOTs. *Which* 2009; August:20–23.

26. Spence D. When it's worth repeating. *British Medical Journal* 2009;339:244.

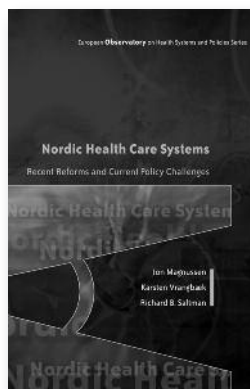
27. Rose G. *The Strategy of Preventive Medicine*. Oxford: Oxford Medical Publications, 1992.

28. Holland WW, Stewart S. *Screening in Disease Prevention, What Works?* Abingdon: Radcliffe Publishing, 2005.

29. Zatonski WA, Willett W. Changes in dietary fat and declining coronary heart disease in Poland: population based study. *British Medical Journal* 2005;331:187–89.

30. Dowse GK, Gareeboo H, Alberti KG et al. Changes in population cholesterol concentrations and other cardiovascular risk factor levels after five years of the non-communicable disease intervention programme in Mauritius. *British Medical Journal* 1995;311:1255–59.

31. Critchley J, Liu J, Zhao D, Wei W, Capewell S. Explaining the increase in coronary heart disease mortality in Beijing between 1984 and 1999. *Circulation* 2004;110:1236–44.



Nordic Health Care Systems Recent reforms and current policy challenges

Jon Magnussen, Karsten Vrangbaek and
Richard B. Saltman

Published by Open University Press

339 pages

The Nordic model of health care systems is assumed to contain consistent features across all five Nordic countries: tax-based funding, publicly owned and operated hospitals, universal access based on residency and comprehensive coverage. The reality is considerably more complex, with great variation at the structural level in the way that institutions are designed and at the policy level in the way strategies are conceived and implemented.

This book examines recent patterns of health reform in Nordic health care systems, including the balance between stability and change in how these systems have developed. Detailed comparisons are undertaken along a variety of policy-driven parameters.

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The EU School Fruit Scheme: Integrating public health into mainstream policy

Felix Mittermayer and Robert Pederson

Summary: Public Health is often considered as a European Union (EU) policy, which lacks immediate tools and funds to deliver concrete results to Europe citizens. One way forward to broaden the approach of public health within the framework of EU policies is to integrate its objectives into mainstream policies. A prime example of placing public health interests into other policy areas is the recently launched 'School Fruit Scheme' which, although small as a programme, offers the opportunity to establish public health objectives within one of the longest running and best funded EU policies – the Common Agriculture Policy.

Key Words: Common Agriculture Policy, Europe, European Commission, diet, public health

On 22 July 2009, the European Commission announced the allocation of EU funds to the twenty-two Member States participating in the 'School Fruit Scheme' (SFS).¹ This is a landmark decision for public health because for the first time, a key EU policy has integrated public health interests as an implicit policy objective.

The SFS aims to improve children's diets by sustainably increasing the consumption of fruit and vegetables through the creation of healthy eating habits. Increasing fruit and vegetable consumption is a public health priority as defined by the World Health Organization (WHO)² and by the EU.^{3,4} Specifically, the EU SFS targets children early in life by increasing accessibility to fruit and vegetables in school environments.

As of September 2009, there will be an annual budget of €157M (of which €90M (57%) are Community funds) available to Member States to provide fruit and vegetables as part of a newly established or expanded SFS. The EU funds will come from within the Common Agriculture

Policy (CAP), one of the core competence areas of the EU with a long history and substantial funds.⁵

Public health objectives

For the first time, the rather general Article 152(1) of the Treaty requiring "a high level of human health protection in all Community policies" is implicitly used to establish a concrete and well-funded policy measure within an EU mainstream policy, the CAP. The sustainable increase of demand for fruit and vegetables by creating healthy eating habits in children does not merely aim at increasing quantity (i.e., calories from agricultural produce) but also at improving the quality of children's diet with the long term goal of improving public health. In contrast, other EU agriculture policy measures, such as School Milk and Food Aid to Most Deprived Persons (MDP), were originally created to dispose of surplus products in order to relieve the respective markets, and have failed to address public health goals.

The SFS, on the contrary, is driven by

demand: Member States' competent authorities are given funding to purchase products of their choice on the market. Eligible products are defined as all fresh and processed fruit and vegetables, including tropical fruit and bananas from third countries. Products that contain added sugar, salt or fat are not eligible, and products incorporated in national schemes must be approved by a competent Member State health authority. This clearly gives priority to health objectives, compared to other schemes that give priority to market impact objectives.

Furthermore, accompanying measures must be defined by Member States in order to receive funding. Accompanying measures aim to proactively integrate parents and teachers and link the scheme to public health, education and agriculture in a comprehensive effort to create environments that support healthy eating habits in children. Although these measures receive no direct EU support, they are to be defined in the strategy clearly demonstrating their contribution to the scheme's overall objectives.

A key element of the policy management is the 'Strategy', which must be developed for each geographical level, i.e. national, regional or municipal, for which the respective Member State chooses to create a SFS. Only a limited number of criteria are obligatory, such as the budget,

Felix Mittermayer is Policy Analyst at DG SANCO/02, European Commission and previously worked in DG AGRI on the EU School Fruit Scheme from its inception.

Robert Pederson manages the European Agriculture and Health Consortium (EAHC), a Brussels-based alliance of health organisations whose main aim is to advocate for health promoting agriculture policy.

Email: robert.pederson@healthyagriculture.eu

duration, and target group, a list of eligible produce, stakeholders and accompanying measures of a SFS.

Strategies have a dual purpose: to ensure that programmes meet the objectives set forth by the Commission and to provide a framework for evaluation and comparing Member State schemes. Strategies are multi-annual, providing a sustainable framework and avoiding short term political and budget constraints to adequately combat the long term problems associated with poor nutrition and obesity.

The 'Strategy' itself is not formally approved by the Commission but submitted for information and publication. The main objective of this document is therefore not to fulfil a legal obligation but rather to initiate an internal discussion process in the respective Member States, bringing together the relevant stakeholders and sectors to agree on a sustainable framework for a long term approach.

Public health in implementation

Public health experts and stakeholders have played an important role in the design of the SFS. They will continue to do so as the programme is implemented. First, the design process offered the opportunity to open up existing Commission platforms for interaction with the agriculture sector (producers, trade and industry) to include public health stakeholders and experts. This increased cooperation was highlighted during a major conference, driven largely by public health expertise, in December 2008 in Brussels, entitled: *School Fruit: a healthy start for our children – Promoting School Fruit Schemes in the European Union*.

Currently, this cooperation is being institutionalised with the creation of a permanent expert group to shadow the management and implementation of the EU-wide SFS. This tool will provide technical expertise, i.e., methodology for evaluation and monitoring of the SFS. At the same time, it will ensure that the effectiveness of Member States' schemes with respect to the overall objective of improving public health is maintained.

Compared to other voluntary schemes, the SFS has a high uptake, twenty-two of twenty-seven Member States are implementing the scheme. Throughout the policy development process transparent communication was used, both as an end and as a means. On the one hand, to raise awareness for the proposal and the under-

lying problem, as well as on-going initiatives in the Member States, and consequently to create public support for the proposal. On the other hand, it aims to create positive peer pressure on Member States by publishing all relevant documents, notably the Strategies as well as monitoring and evaluation reports. The interested public will thus be able to judge for themselves about the effectiveness of the scheme in their respective Member States. In addition, this transparency will facilitate the comparison of schemes between Member States and foster the development of best-practice examples.

Unfortunately, recently published strategies illustrate several problems at EU and Member State levels. The strategies are difficult to understand and compare because a standardised format is not used and strategies are only published in the Member State's language. Published strategies also indicate problems with eligible products, and may require a stronger definition of eligible or non-eligible products by the Commission. Ironically, Greece has only included processed fruit and juice in its programme, which contradicts the original goal of the programme, to increase the consumption of fruit and vegetables.

Establishing both expert and stakeholder groups to address these issues should be a priority to ensure the programme is successful and effective in meeting its goals. Even more so, transparency and accountability of the SFS should remain as an underlying principle and be ensured by an overall evaluation to be undertaken by independent contractors. The results of this exercise will be reflected in the assessment report from the Commission to the European Parliament and the Council, which is due in August 2012.

Perspectives

The discussion on the future allocation of European funds will take place within budget negotiations for the next seven-year financial framework 2013–2021. These are expected to start in earnest in 2011, corresponding to when the SFS assessment report is to be published.

Within the EU budget negotiations, the CAP funds will play an important role: similar to the process in the 1980s, when the CAP started to reflect the environmental impact of agriculture production, the focus today is increasingly on the impact of agriculture production on human health. However, quality is still

mainly defined in terms of quality of production. Human health is not a criterion in establishing EU funding in investment support or direct payments.

However, public health could be a crucial partner in delivering legitimacy to continued CAP funding for European farmers through the creation of a full-fledged EU food quality policy⁶ with the objective of reconciling *quality of production* with *quality of consumption* for food. This would require creating a horizontal approach within the EU's agriculture policy to enhance quality and diversity throughout the whole food chain, ensuring a positive health impact and the highest possible food safety standards for all agriculture products deemed fit for human consumption.

Consequently, the EU SFS, although small in budgetary terms and limited in objectives, is a first attempt at integrating public health objectives within a programme directly linked to the market management measures within CAP. The programme should not be seen as a small, one off programme, but rather as a catalyst that has set in motion long term changes within the CAP, introducing public health, with its stakeholders, their perspectives and new approaches, as an integral part of the mainstream (agriculture) policy.

REFERENCES

1. European Commission decision 5514 final of 22 July 2009.
2. World Health Organization. *Diet, Nutrition and the Prevention of Chronic Diseases. Report of a Joint WHO/FAO Expert Consultation*. Geneva: World Health Organization, 2003.
3. Commission of the European Communities. *EURODIET Core Report*. Brussels: EC Directorate General Health and Consumer Protection, 1998.
4. Commission of the European Communities. *White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues*. COM(2007) 279 final. Brussels: European Commission, 2007.
5. Mittermayer F. Increasing the consumption of fruit & vegetables by school children: which role for the European Union? *ISHS Scripta Horticulturae* 2008; 8:79–94
6. Commission of the European Communities. *Communication on Agricultural Product Quality Policy*. COM(2009) 234 final. Brussels: European Commission, 2009.

Policy development and implementation:

The National Service Framework for Older People in Wales

Gareth Morgan

Summary: In Wales, the National Service Framework (NSF) for Older People sets out evidence-based standards for the health and social care of individuals age over fifty years. Launched in 2006, this ten year programme has made progress in the first three years but further work is needed. This paper offers an overview of the NSF to date using a framework of six policy factors. This overview is discussed within a context of the challenges of policy development and the situation in Wales, including devolvement.

Key words: implementation, National Service Framework, older people, evidence-based health policy, Wales

In Wales, the National Service Framework (NSF) for Older People (Box 1) sets out evidence-based standards for the health and social care of individuals aged over fifty years. This article provides an overview of progress made on the NSF as an exemplar of the challenges of policy development and implementation within a Welsh context, including the devolution of health system responsibilities. As a framework for analysis it considers factors, which if not addressed, may lead to resistance to policy implementation.

Policy development and implementation

The development of evidence-based health policy is challenging¹ and balances a number of factors which have the potential to be in tension with each other. One of these factors is the hierarchy of evidence,² ranging in strength from meta-analysis of randomised controlled trials (RCTs) through to the opinion of respected authorities. Balanced against this hierarchy, however, is the practical consideration that

some situations do not readily lend themselves to RCTs being conducted.³ In addition, a strong case for policy development may sometimes be made using evidence from sources other than RCTs,⁴ such as observational studies. The ethics of delaying policy implementation in these situations has been questioned with the statement that “waiting for the results of randomised trials of public health interventions can cost hundreds of lives....if the science is good, we should act before trials are done”.⁴

A further issue to be considered in the development and implementation of policy is the need to take account of local realities⁵ and resistance factors to policy change.⁶ Specific resistance factors have been described in a case study from the Ukraine about the control of tuberculosis. Health service financing and payment systems, coupled to opposition from policy makers and clinicians, appear to have combined to create a set of circumstances which has undermined tuberculosis control programmes being properly implemented in this country.⁶

More generally, it has been suggested that the failure to fulfil six factors may lead to resistance to policy change.⁷ These are: (i) the importance and value of having multi-disciplinary teams; (ii) the need to have a broad evidence base to draw upon; (iii) the

circular relationship between research and policy; (iv) the need for policy implementation to be locally sensitive; (v) the benefit of stakeholder involvement; and (vi) support by the national government.

Taking the last of these factors, government administrations differ in the way they are constituted and their powers. In Wales, which is one of the constituent countries of the United Kingdom with a population of nearly three million residents, devolution in 1999 transferred a range of policy responsibilities, such as the National Health Service (NHS), to an Assembly of democratically elected members.⁸ Greater political powers to all of the nations of the United Kingdom in the last ten years have led to divergence in health policies.⁹ In Wales, there has been a drive to improve the cohesion between health and social care organisations.¹⁰ In particular Wales has been particularly active in the provision of services to older people. In addition to implementing the ten year NSF for Older People, other examples include introducing a Commission for Older People.

The importance and value of multi-disciplinary teams

The NSF for Older People in Wales is delivered by twenty-three partnerships, constituted on twenty-two local authority

Gareth Morgan is Project Manager, National Service Framework for Older People. The post is supported by Welsh Assembly Government and hosted by Hywel Dda Health Board, Llanelli, Wales.

Email: Gareth.Morgan5@wales.nhs.uk

Box 1 : Summary of the NSF for Older People

The NSF for Older People was launched in March 2006. It sets out evidence-based standards for the delivery of high quality health and social care services in Wales. It was developed with the advice and support of a wide range of stakeholders, including older people. Phase one of the NSF covered the first three years to April 2009 and has primarily set down the structures and foundations underpinning the long term implementation of this programme until 2016.

The NSF is based on eleven standards which address specific service areas, such as stroke, as well as challenging cross cutting themes, such as rooting out age discrimination:

Standard 1 Rooting out age discrimination

Standard 2 Person centred care

Standard 3 Promotion of health and wellbeing

Standard 4 Challenging dependency

Standard 5 Intermediate care

Standard 6 Hospital care

Standard 7 Stroke

Standard 8 Falls and fractures

Standard 9 Mental health

Standard 10 Medicines in older people

Standard 11 Workforce development

The Self Assessment Audit Tool (SAAT) is an internet based reporting system which is used as one of the systems to monitor the NSF implementation. The SAAT, which has strengths and weaknesses, offers evidence that implementation against the phase one targets and milestones for the standards have been largely achieved across Wales. There is, however, variation across Wales within this overall picture and there is further work to do in a number of areas.

For example, the implementation of the mental health standard appears wide ranging across Wales. The developing Dementia Action Plan in Wales will be helpful to progress this standard further forward. There are also issues of information sharing that have challenged the NSF implementation. Different organisational boundaries and information technology systems between health and social care services have resulted in difficulties in capturing all pertinent evidence. This experience perhaps illustrates a wider issue of collaborative working in the provision of integrated services; although in Wales this is mitigated to some extent by an increasing drive toward joint commissioning of services.

areas and one all-Wales service which delivers national programmes, such as cancer screening. The twenty-two local partnerships include health and social care services, both statutory and non-statutory.

The partnerships vary in their size, constitution, frequency of meetings, reporting arrangements and internal cohesion. All of these factors may influence the NSF implementation and a small number of partnerships have been compromised by inter-organisational and inter-personal tensions.

Establishing multi-disciplinary teams *per se* therefore appears insufficient for proper policy implementation and robust professional relationships are also required. Such relationships take time to develop and appear to be compromised by factors such as staff turnover and organisational

re-structuring. In Wales, the NHS is currently undergoing a major reform leading to greater regional working and an abolishing of the internal market.

The need to have a broad evidence base to draw upon

The evidence underpinning each of the diverse NSF standards is broad and was initially compiled through systematic searches of the literature. The importance of this broad evidence base is that it offers a robust approach to policy development. Furthermore, the implementing partnerships across Wales can also have confidence in the NSF as a quality and contemporary framework for service delivery.

Of course, the underpinning evidence base continues to progress and evidence-based

digests are disseminated across Wales, through a monthly Current Awareness Bulletin and a quarterly Newsletter. The interest shown in these digests by the partnerships varies and a more systematic approach to converting new evidence into practice across Wales could be considered. Such evidence is derived from a range of sources including the literature and also professional experience. On the latter point, the SAAT is an open reporting system allowing partnerships across Wales to review the NSF implementation in other areas.

The circular relationship between research and policy

Research can take many forms and from the outset of the NSF there has always been an intention for an independent review to be conducted on progress being made. This review is currently underway by Health Inspectorate Wales (HIW) and Care & Social Services Inspectorate Wales (CSSIW). The review, the first one undertaken jointly by the inspectorate agencies, will report later in 2010 and will inform the policy direction of the NSF between 2011 and 2016.

The review is being driven by the question: What impact has the NSF for Older People had in Wales? Three cross cutting themes will be evaluated, namely dignity in care, nutrition and integrated services. The inspection agencies have consulted with key groups, such as Age Alliance Wales (which consists of voluntary organisations) and Care Forum Wales (who represent the independent care home sector), about how best to engage with key stakeholders, such as service users and their carers, as part of this review.

The need for policy implementation to be locally sensitive

In Wales, there is variation in the population sizes of local authority areas, from about 50,000 to 250,000. Variation also exists in terms of population demography, health profiles and service availability. For example, the valley communities in South Wales, former sites of heavy industry such as coal mining, are characterised by a high prevalence of long term chronic conditions and a life expectancy less than the Welsh average. The implementation of the NSF in these areas will differ from a large local authority in mid Wales, which borders the English midlands, in which there are challenges of a mainly rural population. Language issues are also a factor, for

example areas in the mainland and the two islands of North West Wales have a high number of speakers for whom Welsh is the first language of choice.

The benefit of stakeholder involvement

As well as the independent review, there is a close working relationship between the Welsh Assembly Government and the twenty-three partnerships across Wales. This includes quarterly meetings held on a regional basis, namely Mid and South West, South East and North Wales. These meetings provide a forum for all aspects of the NSF to be discussed and debated by a group of professional stakeholders who are implementing the standards.

In addition, an Implementation Advisory Board convened by the Welsh Assembly Government oversees the implementation of the NSF. This Board consists of Government civil servants, representatives of older people from groups such as the National Partnership Forum for Older People in Wales, academic institutions, local authority umbrella groups, health organisations and other partners such as voluntary sector providers. Whilst acknowledging the debates and differences of opinion that occur, the engagement with all pertinent stakeholders offers a platform for the progression of the NSF.

Support by the national government

In Wales, the Deputy Minister for Health and Social Service, Mrs Gwenda Thomas, AM (Assembly Member), takes the lead for issues relating to older people. Mrs Thomas receives briefings on all aspects of the NSF and regularly answers correspondence. In addition, the National Dignity in Care programme in Wales, which is managed as part of the NSF, was initiated by Mrs Thomas in October 2007. Most recently, £100,000 has been set aside by the Welsh Assembly Government to implement a programme of dignity in care training across Wales. This training may be considered to be an integral part of workforce development in Wales. The support by the Welsh Assembly Government is therefore crucial in allowing the NSF to progress in Wales.

Conclusions

In the first three years of the NSF for Older People in Wales, progress has been made but challenges remain. These include specific service areas and also the need to improve data collection across organisational boundaries. Interestingly, no specific additional money was introduced with the

NSF, contrasting with the situation on the NSF for children, yet this *per se* has not been a barrier to implementation since the NSF is about an integrated and holistic approach to health and social care provision. Given that the population is ageing and the financial challenges facing society, a holistic approach offers advantages of efficient and effective services.

References

1. Kemm J. The limitations of 'evidence-based' public health. *Journal of Evaluation in Clinical Practice* 2006;12(3):319–24.
2. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *New England Journal of Medicine* 2000;22(25):1887–92.
3. Smith G, Pell JP. Parachute use to prevent death and major trauma related to gravitational challenge. *British Medical Journal* 2003;327:1459–61.
4. Potts M, Prata N, Walsh J, Grossman A. Parachute approach to evidenced based medicine. *British Medical Journal* 2006;333:701–3.
5. Potter C, Harries J. The determinants of policy effectiveness. *Bulletin of the World Health Organization* 2006;84(11):843.
6. Morgan G. Evidence based health policy: A preliminary systematic review. *Health Education Journal* (in press).
7. Atun R, Olynik I. Resistance to implementing policy change: the case of the Ukraine. *Bulletin of the World Health Organization* 2008;86(2):147–54.
8. Drakeford M. Health policy in Wales: Making a difference in conditions of difficulty. *Critical Social Policy* 2006;26(543):543–61.
9. Greer S. Devolution and divergence in UK health policies. *British Medical Journal* 2009;338:78–80.
10. Jewell T, Wilkinson J. Health and social care regulation in Wales; an integrated system of political, corporate and professional governance for improving public health. *Journal of the Royal Society for the Promotion of Health* 2008;128(6):306–12.



Health in the European Union: Trends and analysis

Philipa Mladovsky, Sara Allin, Cristina Masseria, Cristina Hernández-Quevedo, David McDaid and Elias Mossialos

Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2009. 164 pages.

This new report investigates differences in health status within and between European countries. The relationship between living conditions, socio-economic factors and health is discussed and analysed with the objective of stimulating a debate and policy action for creating a healthier and more equitable society.

The range of living conditions in the European Union has widened tremendously in recent years and will continue to do so. This diversity has translated into varied patterns of health across the region. Public health has been affected by inequalities in income, education, housing and employment.

The picture that emerges from this review is one of significant improvements in most countries; however considerable challenges remain in the context of an increasingly diverse and ageing population in Europe.

Freely available at: www.euro.who.int/observatory/Studies/20100201_1

Are regulations of community pharmacies in Europe questioning our pro-competitive policies?

Maria Lluch

Summary: Drawing on a recent European Court of Justice ruling against the freedom of establishment of community pharmacies in Germany, this article addresses the tensions in European health care systems that arise between regulating community pharmacies and striving for competition in order to stimulate better quality services. It spans the different types of policies that are currently applied to community pharmacies – restrictions on ownership; restrictions on establishment; registration and licensing; restricting distribution to pharmacy outlets; limiting opening hours; and incentives (pricing and reimbursement) – and provides experiences on the impact of (de)regulation in different Member States. The author concludes by raising some of the trade-offs when (de)regulating community pharmacies in general and advocates for liberalising ownership, in particular.

Keywords: pharmacies, Europe, regulation, competition

On 19 May 2009, the European Court of Justice (ECJ) ruled against the freedom of establishment of community pharmacies in Germany.¹ The court case, which lasted for three long years, was questioning the 800-year old German Pharmacies Act² under which only registered pharmacists may operate a pharmacy – with a maximum of three branches; hence, pharmacy chains continue to be banned while pharmacists continue to enjoy their monopoly. Germany is not the only country in Europe with regulations limiting pharmacy ownership: Austria, Spain or Hungary³ have been cited by the German government and professional associations alike. At the other end of the spectrum, countries including the Netherlands, Ireland and the UK³ hardly restrict ownership although it is mandatory that a pharmacist, as an employee, is always present and supervises the dispensing of prescriptions.

Why regulate community pharmacies?

Pharmacists play a key role in the delivery of health care. They are responsible for

checking and filling prescriptions and traditionally have been involved in the production of patient-specific preparations. With the growing importance of the over-the-counter (OTC) segment of the market and of self-medication, they are increasingly acting as health advisers providing counselling to patients. Thus, their range of services covers not only pharmaceutical specialities but also a number of pharmaceutical services to patients including, for example, health promotion activities. As a result of the relevant role that pharmacists play in the delivery of health care, community pharmacies in the majority of the cases are highly regulated in most Member States of the European Union (EU). Key areas of regulation relate not only to ownership issues (for example, limitation of ownership to pharmacists, and limits to the ownership of multiple pharmacies prohibiting pharmacy chains) but also to the establishment of pharmacies (for example, a needs assessment, or demographic/geographic regulations); registration and licensing issues; distribution of pharmaceutical products outside a pharmacy; opening hours; and pricing, remuneration and incentives issues, given that government backed health insurance or general taxation is the key payer of these services.

Member States and stakeholders justify these restrictions claiming that they ensure the independence of the service provider and facilitate access to pharmaceuticals, whilst guaranteeing equity, quality and safe provision of pharmacy services. These restrictions can result in a monopoly for pharmacists. Governments claim to use reimbursement and incentive mechanisms as a mechanism to counter the inefficiencies of such monopolies.

The OECD in its 2001 report on *Regulatory Reform in Ireland* contested the logic of these regulations.⁴ It argued that the creation of a protected monopoly to cross-subsidise unprofitable activities was not the right solution. In fact, keeping up with competitors is what usually stimulates quality-improving services. This came about at a time when the debate on the deregulation of public services was taking place in several EU Member States.³ One of the sectors receiving attention was health care, including community pharmacies. The rationale behind deregulation in the pharmacy sector is the expectation that liberalisation will increase competition and thus succeed in lowering, or at least containing (public) expenditure, while access to quality pharmacy services will

Maria Lluch is reading for a PhD, LSE Health, London School of Economics and Political Science. Email: m.lluch@lse.ac.uk

remain stable, if not improved, by the opening of new outlets. In sum, deregulation claims to make the market more efficient whilst key areas like equity and access are not compromised.

Together with deregulation in a number of areas of the public sector, the regulation of community pharmacies in Europe was questioned at European Commission³ and Member State levels.⁵ Advocates of deregulation, such as the Office of Fair Trading in the UK or the Internal Market and Services Directorate General at EU level, argued that it would stimulate competition and improve efficiency. Opponents of deregulation, such as the Consejo General de Colegios Oficiales de Farmaceuticos (CGCOF)^{6,7} in Spain, or Pharmaceutical Group of the European Union⁸ at EU level, claimed that liberalising community pharmacies would potentially be detrimental to the delivery of quality services.

The recent ECJ ruling¹ recognising that the rules on ownership and operation of pharmacies can be restricted to pharmacists has only spiced up the debate.

Implications of ownership restrictions

A common set of values for European health care systems – universality, access to good quality care, equity and solidarity⁹ – are the pillars resulting from the health *acquis communautaire*, hence, Member States and any institution within the EU would strive to ensure that those are preserved before implementing any policy, act, ruling or recommendation.

Some of the restrictions imposed on community pharmacies may be justified to a certain extent. For example, Spain regulates the location for the establishment of pharmacies, guaranteeing access and geographical equity, to 99% of the population,¹⁰ whilst in England more relaxed regulations it is claimed offer access to (an arguably inflated) 96% of the population.¹¹ One may therefore contend that regulation in Spain does more good than harm by ensuring a very high level of coverage.

In contrast, some restrictions are not necessary for guaranteeing the right to health care. Restrictions on pharmacy ownership may be one example. Advocates for restricting ownership claim that it has an positive impact on the quality of health care delivery. Clearly, the presence of a pharmacist is required to ensure quality of care¹² but this is a completely different issue from ownership. There is no evidence proving the association between own-

ership and quality of care; in a community pharmacy, quality of care is guaranteed simply by the presence of a pharmacist.

Liberalising the system by divorcing ownership from pharmaceutical activity, thus eliminating restrictions on ownership, therefore may have different implications. The immediate implication is the greater numbers of pharmacy chains, not necessarily being owned by pharmacists. These are often associated with operational efficiencies. Moreover, evidence from the UK⁵ and Iceland¹³ indicates that liberalising the market can stimulate competition, including price competition on OTC drugs with consequent benefits for society. At a later stage, market consolidation and vertical integration may take place, as has occurred in Norway¹³ or in the UK in the case of the takeover of Boots by Alliance Unichem. In the long-run this may run the risk of oligopoly, given that a small number of chains would be the principal players in the field. This would mean that pharmacists as professionals would lose their monopoly but another type of monopoly would appear. Although it seems reasonable to eliminate restrictions in ownership, other types of mechanism should be designed to counter too high a degree of market dominance by pharmacy chains.

Liberalisation also has implications for other stakeholders, such as pharmacist professional associations. In countries where ownership is regulated, these associations play a key role. Governments may delegate them the power to ensure that the rules are implemented appropriately. Spain offers a marvellous example in this case. The CGCOF represents the interests of all pharmacists holding a license, as well as the interests of community pharmacy owners and ensures that regulations are respected. Thus professional, commercial and trade interests, health care priorities and legal issues all fall within the ambit of one institution. In liberalised markets, as in the UK, there are two institutions in the field each with a different role. The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales; the primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The National Pharmacy Association is the trade association for community pharmacy owners and has virtually all community pharmacies enrolled within its membership. The Association provides its members with professional and

commercial support, as well as representing the interests of community pharmacy in dialogue with Government, both at a national and European level. In the light of these two realities, it is not difficult to understand why entities such as CGCOF do not support liberalising ownership.

The impact of liberalising the ownership of community pharmacies on other stakeholders beyond pharmacy owners or chains and professional pharmacy associations is unlikely to be negative. Pharmacists would still be required behind the counter, and as far as this happens, the quality of care is unlikely to suffer: patients will receive at least the same quality of care. If price competition on OTCs is also evident then there may be additional benefits for society.

Conclusions

European health care systems need to find a balance between the values they are committed to – solidarity, equity, availability and access to health care – while striving for efficiency and competition, providing options that benefit the society and help contain health care expenditure, in particular to meet the challenge of an increasingly ageing population. Restricting ownership has not proven to be a threat those European values, whilst they seem to improve efficiency and competitiveness.

This piece of research, although aimed at the European level, has provided an overview of experiences from several Member States. More research including analysis of in-depth experiences of the different models in operation in all Member States, looking at each type of restriction and reform in the field of community pharmacies, is needed to take the case further.

The ECJ ruling¹ stated that “Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies”. It should not be concluded that the ECJ wants to preserve a regulation that makes our health care systems less competitive or that the ECJ is against pro-competitive policies as far as the health *acquis communautaire* is not threatened; it only means that often the ECJ tends to avoid ruling against Member State legislation, in particular when there are further implications to be addressed before liberalisation is achieved. Despite this, steps in the form of recommendations and later on European directives should be encouraged to ensure the efficiency

and competitiveness of our health care systems. However, when formulating pro-competitive policies, risks associated with over-monopoly should also be addressed, preferably avoiding ad-hoc interventions, as has been learnt from experiences in Norway and Iceland.

REFERENCES

1. Joined Cases C-171/07 and C-172/07. Reference OJ C 140 of 23.06.2007, p.11: ECJ, 19/09/2009.
2. Förster A. *Germany's Pharmacy Scene Remains a Patchwork*. Munich: Goethe Institut, 2009.
3. Volkerink B, de Bas P, van Gorp N, Philipsen N. Study of regulatory restrictions in the field of pharmacies. *ECORYS Nederland BV in cooperation with METRO – University of Maastricht*. Rotterdam: ECORYS, 2007.
4. OECD. *Regulatory Reform in Ireland: The Role of Competition Policy in Regulatory Reform*. Paris: OECD, 2001.
5. OFT. *The Control of Entry Regulations and Retail Pharmacy Services in the UK*. London: Office of Fair Trading, 2003.
6. CGCOF. *Argumentario modelo español de farmacia*. [The case for the Spanish pharmacy model] Madrid: Consejo General de Colegios Oficiales de Farmacéuticos, 2006.
7. CGCOF. *Los Modelos de Farmacia en la Unión Europea* [Models for pharmacy in the European Union]. Madrid: Consejo General de Colegios Oficiales de Farmacéuticos, 2007.
8. PGEU-Secretariat. PGEU contribution to the internal market consultation. Brussels: Pharmaceutical Group of the European Union, 2006.
9. Rys A. The contribution of ICT to the modernisation of European health systems. *The European files: eHealth in Europe*. Brussels: European Commission, 2009.
10. Portalfarma. *La farmacia en España*. [Pharmacy in Spain] Madrid: Consejo General de Colegios Oficiales de Farmacéuticos, 2008.
11. Galbraith A. *Review of NHS Pharmaceutical Contractual Arrangements*. London: Department of Health, 2007.
12. PGEU-Secretariat. *Why Pharmacies Need Fully Qualified Pharmacists?* Brussels: Pharmaceutical Group of the European Union, 2009.
13. Anell A. Deregulating the pharmacy market: the case of Iceland and Norway. *Health Policy* 2005;75:9–17.

Hospital privatisation in Poland

Peggy Watson

Summary: Hospital privatisation has been highly contentious and has progressed slowly in Poland. Shortly after winning the 2007 elections, the Civic Platform Party proposed legislation for compulsory, universal and total hospital privatisation. The law was passed by Parliament but later annulled by presidential veto and a fall-back plan for optional hospital privatisation put in its place. This came into force in April 2009. However, the economic crisis has placed a question mark against the new programme. This article outlines the social processes involved in the privatisation of hospitals since the introduction in 1999 of major health care reform.

Keywords: debt, social dialogue, economic crisis, protest, Poland

The 1999 health care reforms

In 1999 Poland went through a series of social sector changes, which constituted a 'second wave' of reforms in the transition to capitalism. These changes included health, pensions, education and territorial administration.

The health care reforms introduced changes in the mechanism of financing laid down in the 1997 Law on Universal Health Insurance which came into force in January 1999. This introduced a system of financing based on the Bismarckian social insurance model, whereby insurance funds are raised from a compulsory deduction from taxable income, originally set at 7.5%. The rate was raised following debates, increasing by 0.25% annually between 2003 and 2007 until it reached its current level of 9%.

The insurance funds were designed to finance the direct costs of health services to patients through contracts between service providers and purchasers. The latter originally took the form of sixteen Regional Sickness Funds (*kasy choroby*), one in each of the new voivodeships (regions), together with one Sickness Fund

for uniformed services. Following criticisms, the sickness funds were replaced in 2003 by a recentralised National Health Fund (NFZ – *Narodowy Fundusz Zdrowotny*). This performed largely the same functions and had a branch in each voivodeship.

The original decision to set the premium at 7.5% of taxable income had a critical effect on the subsequent provision of health care. The figure represented a substantial reduction on the level of 10% advocated by health care professionals and the 10%–11% that had also been mentioned in earlier bills.¹ The issue had been vigorously contested during the first half of 1998, with the action committee KOROSZ (The Committee for the Defence of Health Care Reform – *Komitet Obrony Reformy Ochrony Zdrowia*) being formed at this time.

Given that the income base from which premiums were deducted was low, with many of those in employment on modest levels of pay and about one-fifth of the working population officially unemployed at the time, the decision resulted in a sharp drop in the public funding available for clinical care.² Health care funding was pushed below 4% of Gross Domestic Product (GDP). Coupled to the fact that Poland had one of the lowest GDP per capita rates in Europe, this represented a very modest level of funding indeed.³ The

*Peggy Watson is at the Homerton College, Department of Sociology PPSIS, University of Cambridge.
Email: pw125@cam.ac.uk*

Table 1: Perception of change in extent to which health needs have been met 2000–09.

In the last two years the extent to which health needs are met has (%):	2000	2003	2005	2007	2009
Deteriorated	41	39	38	27	25
Improved	3	4	3	4	3
No change	56	58	59	69	72

Source: Polish Social Diagnosis 2009.⁷

Table 2: Public Hospitals in Poland by Type (December 31st 2007)

Local Government	517
Ministry or central government (except Ministry of Defence and Ministry of Internal Affairs)	19
University/Research Institute	42
Total non-psychiatric public hospitals	578
Psychiatric hospitals	52

Source: Polish Ministry of Health Statistical Bulletin 2008⁹

situation was exacerbated by the rising costs of pharmaceuticals. In 2007, the proportion of total health care spending accounted for by pharmaceuticals was about 32%, more than the proportion of spending accounted for by either ambulatory or hospital care. The proportion spent on hospital care meanwhile was relatively low and roughly the same as the proportion of spending accounted for by ambulatory care – about 28%.⁴

Perhaps unsurprisingly, the reforms were not popular with the general public.^{2,5} An opinion poll carried out in 2001 found that 74% of respondents thought that health care provision had been better before the reform.⁶ Data from the biennial Polish Diagnosis Survey suggest this negative opinion has not improved over time (see Table 1).

Restructuring the hospital system

Starting with the 1991 Health Care Institutions Act, the Polish hospital system became increasingly decentralised during the 1990s. The law allowed for the existence of diverse health care unit owners beyond the Ministry of Health, including regional and local government, other ministries, non-governmental organisations and private bodies. It provided the legal

basis for publicly owned hospitals in Poland to become substantially autonomous and responsible for managing their own budgets. After 1993, ownership of most public sector health facilities passed to the regions and to local government (*gminas*);⁸ when a three-tier territorial division was introduced in 1999, many hospitals passed from *gminas* to larger administrative areas known as *powiats*. Table 2 shows the number of public hospitals in Poland according to ownership in 2007.

According to central statistical agency figures from 2002, the most recent available, among public hospitals, 38.37% of beds were in hospitals owned by the voivodeships and 45.71% in hospitals owned by the *powiats*.⁴ Although privatisation has been legally possible since 1999, for political and economic reasons, this process has been slow. By 2007, there were 170 private hospitals representing approximately 23% of non-psychiatric hospitals in Poland. Most were relatively small and in 2007 accounted for only 5.8% of hospital beds.⁹

Health workers' protests

In the two years following the health reforms (1999–2000), the country was

swept by unrest among health care personnel, including doctors, radiographers, medical technicians and ambulance staff. However, it was the industrial action of nurses which seized the headlines. Nurses represented the largest occupational grouping in Poland, one of the lowest paid, and one most consistently opposed to hospital privatisation. The All-Polish Union of Nurses and Midwives (*Ogólnopolski Związek Zawodowy Pielęgniarek i Położnych – OZZPiP*) became a visible political actor at this time. The national union grew out of a local union originally formed in the town of Włocławek in 1991. By 1995, when it gained its national statute, 86,000 nurses, about one out of every two employed in hospitals, had joined.

Not only had nurses seen no pay improvements with the 1999 reform, benefits such as the inflation-link to their salaries had disappeared. Unrealistic budgets and the increasing proportion of budget expenditure being accounted for by drugs meant extreme downward pressure on staffing costs. While spending on personnel was slightly higher than pharmaceutical costs in 1999, by 2003 total spending on drugs was 29% higher than the combined wage bill for all categories of health care personnel.⁴

The Union's high profile protest action included hunger strikes, the occupation of state buildings and the blockade of national borders and roads. The government eventually conceded to the nurses' demands and signed an agreement awarding all health workers a 203 zloty (PLN) salary increase. The resulting 'Law 203' came into force on 1 January, 2001. However, since no extra funds were made available for this purpose and responsibility for payment remained with the directors of health care institutions, the law served to exacerbate the financial difficulties experienced within the system.

Hospital debt

Debts, in accordance with the Polish Ministry of Health definition refer to accrued liabilities due, that is, all liabilities whose payment date has passed and which have not been cancelled or become time-barred, where the creditor is entitled to impose a surcharge on the amount due – but excludes the value of loans, share issues, and similar.⁴ During the 1990s, many hospitals had accumulated such debts and these were successively cleared in 1994, 1996 and 1997. Hospital debts were also

cleared with the introduction of the 1999 reforms. At the same time, hospital restructuring, at a cost of PLN295 million to the state budget, resulted in a decrease between 1999 and 2002 of more than 92,000 health care staff and 35,900 hospital beds. Unions expressed concerns that personnel reductions had at times taken place in contravention of official staffing norms.¹⁰

However, contractual rates of payment to hospitals after 1999 were significantly less than the cost of services in practice, and this was largely responsible for the fact that levels of hospital indebtedness rose again after the reforms.¹¹ Interest rates on earlier debts, as well as court costs, also contributed to debts spiraling out of control. Between 2002 and June 2004, the accumulation of debts doubled.¹

The most recent legislation to relieve hospital indebtedness was introduced in 2005 (*Ustawa z dn. 15 kwietnia o Pomocy Publicznej i Restrukturyzacji Publicznych Zakładów Opieki Zdrowotnej*). After this intervention, the level of hospital debt decreased. This was due to the roll-over of many outstanding liabilities, the cancellation of others, as well as the fact that hospital revenue increased.

Social health insurance contribution rates went up year on year between 2003 and 2007, while at the same time the base to which the rates applied improved with rising incomes and falling rates of unemployment. The combination of these factors meant that health sector income from social insurance contributions went up from PLN31.5 to 42.2 billion between 2004 and 2007.⁴

Nevertheless, the question of hospital underfunding was far from resolved. For example, a 2008 monitoring survey of psychiatric in-patient care found that contracts with the NFZ in general covered between 60% and 80% of costs. For example, in 2006–2007 the daily rate paid by the NFZ for a person/day in a psychiatric ward stood at PLN78 and 84, respectively, while in the Lubiąż hospital the average cost of a person/day was PLN125.11 and 145.5. This resulted in losses of PLN1.55 million in 2005, PLN2.41 million in 2006, and PLN973,700 in the first half of 2007.¹²

After 2005, the structure of hospital indebtedness significantly changed. Unpaid wages to employees which represented about 16% of debt at the end of 2005, were reduced to a residual 3% by the

end of 2007. Between the end of 2005 and the end of 2007, the percentage of debt accounted for by unpaid local taxes, land taxes, and social insurance contributions on behalf of employees fell from just over 43% to about 28% of all debt, largely because much of this debt was cleared. On the other hand, the proportion of all debt accounted for by amounts owed to the suppliers of pharmaceuticals and medical supplies/equipment rose from 20% to 30%.⁴

The politics of privatisation

Health care has become a highly politicised issue in Poland, and health care issues played a prominent role in the election which took place at the end of 2007. The year had seen strikes and other high profile industrial action by health workers, culminating in mass protests, most visibly by the OZZPiP nurses' union. The hub of the 'white protest' as it came to be known, was an encampment (*the białe miasteczko* or 'white village') along the grass verges opposite the Prime Minister's Chancellery, where a request for pay negotiations had been handed in.

The *białe miasteczko* dominated the Warsaw horizon for a short but significant time. During the twenty-seven days of its existence (from 19 June to 15 July) hundreds of nurses arrived from all over Poland to take part in the protests. The protests received overwhelming public support. In a poll carried out by the public opinion research centre CBOS in 2007, 88% of respondents were in support of the nurses, including their hunger strikes. The encampment was visited by Warsaw residents, politicians, as well as figures from academia and the arts who also voiced their support. The protest ended without negotiations when Parliament dissolved.

During the election campaign, the Central Anti-Corruption Agency (*Centralne Biuro Anti-Korupcyjne* – CBA) released tapes of a conversation it had secretly recorded earlier in the year, between a Civic Platform parliamentarian, Beata Sawicka, and a CBA official posing as a businessman. The tapes, apparently indicating corruption at the heart of hospital privatisation, caused a furore. Prime Minister Jarosław Kaczyński described the affair as 'a gigantic plan to rob Poland, and to rob Polish patients', the former President Aleksander Kwaśniewski criticised the use of the CBA during the election campaign, and Sawicka was expelled from her Party on the spot. Nevertheless, the

tapes did not prevent the Civic Platform from coming to power.

Among its early actions were high profile consultations – the 'White Summit' (*biały szczyt*), with stakeholders in health care change. The health care workers' unions, professional bodies and other social organisations were all present at meetings held between January and March 2008. A number of points were eventually agreed. These included the right to buy treatment to avoid queues, the introduction of modest fees for clinic visits and hospital meals, and the right to buy private health insurance in addition to, or instead of, social insurance. The introduction of a basket of guaranteed services was deferred, while agreement to hospital privatisation that was optional and partial was secured.

Several weeks later proposed legislation was revealed which departed radically from the White Summit agreement. The new law was to make it compulsory for all hospitals – most of which were still independently functioning units under local authority management – to become businesses, thus opening the way for their sale. A simultaneous newspaper poll indicated that over half of respondents were against privatisation, as compared with about one third in favour (*Rzeczpospolita*, 8 May 2008).

It is unclear what took place between the March and May policy announcements, however, a former Health Minister, Mariusz Łapiński, gave his view in a recent interview stating that 'there are firms in Poland which are ready to take over indebted hospitals, firms which bought hospital debts earlier on. The lobby acting on behalf of these firms has been forcing through changes in the law which to allow this kind of operation'.³

The new proposals were eventually put to Parliament in the form of a members' bill. This meant that the statutory requirement for consultation with social organisations in the field of health care did not apply. Most of these organisations were against the compulsory commercialisation – and hence privatisation – of hospitals, and had indicated this at a meeting with the President.¹³ A presidential bid to hold a referendum on hospital privatisation was overruled. This idea had had widespread support – a survey commissioned by *Rzeczpospolita* had found 71% of respondents to be in favour of one.¹⁴

In October 2008, the bill was accepted by the Polish Senate. The health workers'

unions continued to argue that commercialisation meant an open door to privatisation, saying that it would bring a deterioration of living conditions both for workers and for patients, leading to further social divisions and worse access to health care for the poor.¹⁵ Approximately one month later, President Lech Kaczyński of the opposing PiS Party used his powers to veto the bill. The consequence was the introduction by the government of what has come to be known as 'Plan B' for hospital privatisation, which took an extra-legislative route.

The economic crisis

Health policy in Poland entered a new phase with the financial crisis of 2008. Increasing unemployment and falling levels of pay has meant that in 2009, NFZ revenue fell below the level assumed in its budget for the first time in five years.¹⁶ At the same time, a fall in the value of the currency has translated into higher costs to the NFZ for the health care of Polish patients elsewhere in Europe.

Hospitals will receive less from the NFZ than in 2008, since there are no excess funds from which payment can be made for patients treated over and above the limit defined in contracts – and in some cases the limits for 2009 have already been reached.¹⁷ Banks are even less willing to lend to hospitals than before the crisis, opening the way for debt purchasing firms to extend their services to the provision of loans, often at high rates of interest (figures of 15%–20% have been quoted in the press).

Plan B for hospital privatisation was introduced in April 2009, and is scheduled to run until 2011. It offers to cover from government funds part of the outstanding debts of hospitals where local authorities have agreed to privatise hospitals and have put forward an acceptable business plan. However, the sum earmarked for the purpose has changed from an initial sum of PLN2.7 billion (the total debt of Polish health care institutions), to PLN1.38 billion. As of writing no agreement has been signed between a local authority and the Ministry of Health within the framework of this programme, and where local authority preparations are underway, they have provoked health workers' protests.¹⁸

Although the government has not withdrawn Plan B, some hold the view that it would now suit the government to defer the implementation of the programme

until 2011, when the state budget may be in better health.¹⁹ What will happen between now and then is, however, uncertain to say the least.

REFERENCES

1. Kuszewski K, Gericke C. *Poland. Health Systems in Transition*. Copenhagen: World Health Organization Regional Office for Europe, 2005.
2. Watson P. Unequalizing citizenship: The politics of health care change in Poland. *Sociology* 2006;40(6):1079–96.
3. Piński J. Skok na Szpital: Rozmowa z Mariuszem Lapińskim, Byłym Ministrem Zdrowia [Hospital raid: interview with Mariusz Lapiński, former Minister of Health]. *Wprost* 30 November 2008:38–39.
4. Ministerstwo Zdrowia. *Raport: Finansowanie Ochrony Zdrowia w Polsce – Zielona Księga II* [Report: Financing Health Care in Poland – The Green Book II]. Warszawa: Ministerstwo Zdrowia, 2008.
5. Watson P. Stress and social change in Poland. *Health and Place* 2006;12:372–82.
6. CBOS. *Opinie o Opiece Zdrowotnej Pod Koniec Drugiego Roku Reformy* [Opinions Regarding Health Care at the end of the Second Year of the Reform]. Warszawa: CBOS, 2001.
7. Polish Social Diagnosis 2009, Table 4.7.4, p.114. Available at: http://www.diagnoza.com/pliki/raporty/Diagnoza_raport_2009.pdf
8. Karski J, Koronkiewicz A, Healy J. *Health care systems in transition – Poland*. Copenhagen: World Health Organization Regional Office for Europe, 1999.
9. Polish Ministry of Health Statistical Bulletin 2008, Table 4.3, p.45. Available at: <http://www.csioz.gov.pl/pliki/file.php?s=cD80>
10. Banachowicz B. Chair of OZZPiP, Statement to the Tripartite Commission for Social and Economic Affairs, 2004.
11. Chmielewski D. Sekurytyzacja – Lekarstwo na Szpitalne Długi? [Securitisation: medicine for hospital debt?]. *Służba Zdrowia* March 7–18 2002:19–22.
12. Najwyższa Izba Kontroli Informacja o Wynikach Kontroli Funkcjonowania Opieki Psychiatrycznej, Ze Szczególnym Uwzględnieniem Opieki Stacjonarnej [Findings from the Monitoring of Psychiatric Care, with an Emphasis on In-patient Care]. Wrocław: NIK, Delegatura We Wrocławiu, 2008.
13. Cichocka E. Bez Referendum w Sprawie Prywatyzacji Szpitali [Without a referendum on hospital privatisation]. *Gazeta Wyborcza* 29 October 2008.
14. Dziennik Polski. O Prywatyzację Szpitali Zapytajmy Lud [Let's ask the people about hospital privatisation]. *Dziennik Polski* 10 October 2008. Available at: http://www.dziennik.pl/wydarzenia/article249642/O_prywatyzacje_szpitali_zapytajmy_lud.html
15. Polskie Radio. Związkowscy Apelują do Prezydenta o Zawetowanie Ustaw Zdrowotnych [Unions call on President to veto health laws]. *Polskie Radio* 24 November 2008. Available at: <http://www.polskieradio.pl/iar/wiadomosci/artykul76723.html>
16. Szparkowska S. Kryzys Dotarł do NFZ [The crisis has reached the NFZ]. *Rzeczpospolita* 4 September 2009. Available at: <http://www.rp.pl/artykul/288705.html?>
17. Sroka, J. Doctors protest against reduced financing of hospital services, *European Industrial Relations Observatory Online* 13 February 2009. Available at: <http://www.eurofound.europa.eu/eiro/2009/01/articles/pl0901049i.htm>
18. Kasperska M. Szpitalni Związkowscy Protestują, Nie Strajkują. [Hospital unions are protesting, not striking] *Gazeta Wyborcza* 14 September 2009. Available at: http://miasta.gazeta.pl/wroclaw/1,79448,7037993,Szpitalni_zwiazkowscy_protestuja_nie_strajkuja.html
19. Sikora D. Przekształcenie Szpitali w Spółki Wciąż Niepewne [The transformation of hospitals into firms still uncertain]. *Gazeta Prawna* 15 September 2009. Available at http://praca.gazetaprawna.pl/artykuly/351902,przekształcenia_szpitali_w_spolki_wciaz_niepewne.html

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Investigating over-the-counter oral analgesics

There is good evidence supporting the efficacy of standard doses of aspirin, paracetamol, ibuprofen, naproxen, and diclofenac, all of which are available as over-the-counter (OTC) medicines in some part of the world. There is no good evidence for most branded combination products, though it is likely that additional analgesic effect is produced by codeine.

Background

A wide variety of OTC analgesics are available to buy, but the amount of high quality information about these treatments is limited. We set out to find evidence for the efficacy of a range of OTC analgesics, available in various parts of the world, in standard acute pain trials. Specifically we were looking for single dose data from four to six hour trials in post-operative pain models, and reporting standard outcomes.

Clinical trials measuring the efficacy of analgesics in acute pain have been standardised over many years. Trials have to be randomised and double blind. Typically, in the first few hours or days after an operation, patients develop pain that is moderate to severe in intensity, and will then be given the test analgesic or placebo. Pain is measured using standard pain intensity scales immediately before the intervention, and then using pain intensity and pain relief scales over the following four to six hours for shorter acting drugs. Pain relief of half the maximum possible pain relief or better (at least 50% pain relief) is typically regarded as a clinically useful outcome. For patients given rescue medication it is usual for no additional pain measurements to be made, and for all subsequent measures to be recorded as initial pain intensity or baseline (zero) pain relief (baseline observation carried forward). This process ensures that analgesia from the rescue medication is not wrongly ascribed to the test intervention. In some trials the last observation is carried forward, which gives an inflated response for the test intervention compared to placebo, but the effect has been shown to be negligible over four to six hours.

Single dose trials in acute pain are commonly short in duration, rarely lasting longer than twelve hours, allowing no reliable conclusions to be drawn about safety. To show that the analgesic is working it is necessary to use placebo. There are

clear ethical considerations in doing this. These ethical considerations are answered by using acute pain situations where the pain is expected to go away, and by providing additional analgesia, commonly called rescue analgesia, if the pain has not diminished after about an hour. This is reasonable, because not all participants given an analgesic will have significant pain relief. Approximately 18% of participants given placebo will have significant pain relief, and up to 50% may have inadequate analgesia with active medicines.

Systematic review and methods

For references to methods used, refer to Moore A et al, 2003.¹

We searched PubMed, Cochrane Central Library, and our own in-house databases in pain research for any double-blind, randomised controlled trials (RCTs) reporting pain relief, pain intensity, or patient global evaluation of efficacy as outcomes over 4–6 hours for single dose analgesic versus placebo. The search terms used included both trade names and generic names of the individual analgesic constituents, including combinations where appropriate. It is not likely that all OTC analgesics have been included, since sources for OTC analgesic names and availability are not easy to come by, and may change from time to time. OTC analgesic combinations, in particular, may change. The approach, therefore, was to work with combinations of drugs and doses of the combinations that appeared to be current in 2009.

From these trials we extracted outcome data, including pain relief measured as a TOTPAR (total pain relief) at four or six hours, and pain intensity measured as a SPID (summed pain intensity difference) at four or six hours. Mean TOTPAR or SPID values, for both the active analgesic and placebo, were then converted to %maxTOTPAR or %maxSPID by division into the calculated maximum value. The proportion of participants in each treatment group who achieved at least 50%maxTOTPAR was calculated using verified equations, and these proportions converted into the number of participants achieving

at least 50%maxTOTPAR by multiplying by the total number of participants in the treatment group. Information on the number of participants with at least 50%maxTOTPAR for active treatment and placebo was then used to calculate relative benefit (RB) and number-needed-to-treat-to-benefit (NNT).

Results

One hundred and twenty five RCTs were retrieved that matched the search criteria. After closer scrutiny, six head-to-head comparative trials were excluded due to lack of a placebo control, and two trials were excluded due to lack of analysable data. The remaining 117 trials were randomised, double blind and placebo controlled and were included in the efficacy analysis. The studies involved a mixture of dental pain and episiotomy pain.

The overall standard and quantity of data available was poor, particularly for studies specifically using the trade name OTC analgesics. To compensate for this we have included data on the equivalent dose generic named analgesics and their combinations. For some of the test analgesics (Anadin Extra, Askit, Codis, Dispirin, Dispirin Extra, Panadeine 15, Paracodol, Paramol, Pentalgin H, Sedalgin-neo, Solpadeine Max) no useable data could be found. In many cases, particularly those combination analgesics including codeine, this was due to differences in the doses of the constituent analgesics used in the available trials as compared with the OTC versions. In general, OTC containing codeine tended to use significantly lower doses of codeine and higher doses of other constituents; presumably to minimise codeine-related side effects. Information on combinations of paracetamol and ibuprofen is included since these newer combinations are likely to appear as OTC analgesics in several parts of the world.

Table 1 gives information about the included studies. Table 2 summarises data available for each of the analgesics along with its calculated relative benefit and number-needed-to-treat-to-benefit. Table 3 shows a sub-analysis of only those trials involving dental pain.

To summarise the findings of our investigation we produced comparative figures (Figures 1 and 2 for all data and just dental studies, respectively) showing the NNTs and their 95% confidence intervals for each analgesic where calculable.

Figure 1: NNTs (number-needed-to-treat-to-benefit) for all available data

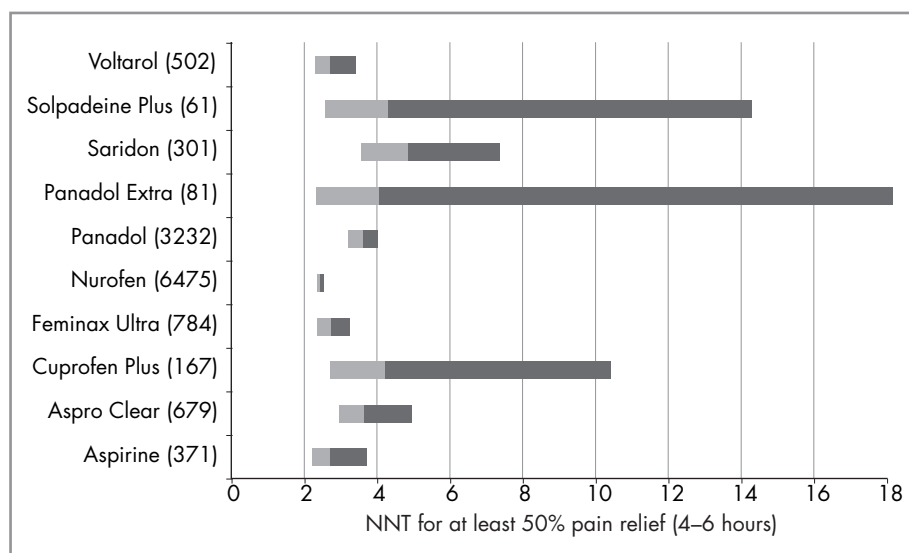
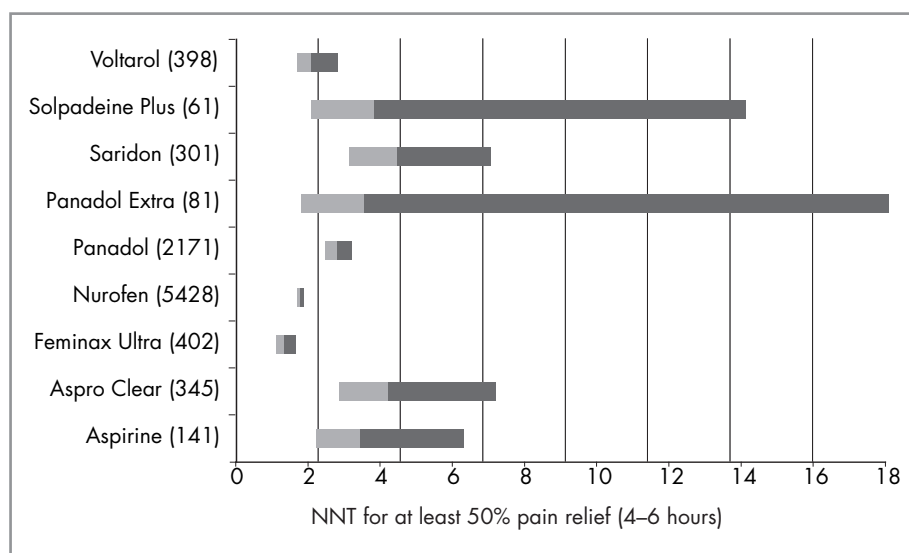


Figure 2: NNTs (number-needed-to-treat-to-benefit) for dental studies only



Comment

There are two main issues when looking at the evidence of acute pain efficacy of OTC analgesics. The first is the dearth of evidence in the public domain for some of these products. The second is what we are able to make of what evidence we have.

Dearth of evidence

Most of the OTC analgesics, including combination analgesics, were developed decades ago, as long ago as the 1950s, in times when trials were performed for registration purposes. Publication was infrequent. A good example is a review of 30 trials involving about 10,000 patients examining the analgesic efficacy of caffeine in combination with analgesics published in JAMA in 1984.² Most of the data was unpublished then, and has remained unpublished subsequently. We know more about OTC drugs like paracetamol and

ibuprofen from trials in which they have been used as active comparators than trials in which they themselves have been tested.³

The dearth of evidence is not, therefore, surprising. It is, however, frustrating. For several OTC analgesics we have no reliable data, and for others the data available are inadequate – leading to very wide confidence intervals in Figures 1 and 2. This is a shame, because OTC analgesics, properly used, are effective for many people.

It is also the case that the case for analgesic combinations can be developed using evidence from closely related studies. A case in point is the combination of paracetamol and codeine, where relatively small amounts of information for some dose combinations are bolstered with evidence from other dose combinations.⁴

Table 1: Details of available data

Drug	Details of available data	References of included studies
Anadin Extra	We found no trials comparing Anadin Extra (or a generic combination analgesic containing paracetamol, aspirin and caffeine in similar doses) to placebo	N/A
Askit	We found no trials comparing Askit (or a generic combination analgesic containing aspirin, caffeine and aloxiprin in similar doses) to placebo	N/A
Aspirine	We found two trials comparing a generic combination of aspirin and caffeine (ASA 650mg/caffeine 65mg in Forbes et al. and ASA 800mg/caffeine 65mg in Rubin et al.) against placebo. Both trials were relatively small and used different pain types: Forbes et al. (n=141) in dental and Rubin et al. (n=230) in episiotomy. The results reflect this with Forbes et al. reporting the % of patients achieving 50% pain relief on the active treatment as 27% and on the placebo as 1%; while Rubin et al. report 86% on the active treatment and 48% on the placebo	Forbes JA. <i>Pharmacotherapy</i> 1990;10(6):387-93 Rubin A. <i>J Int Med Res.</i> 1984;12(6):338-45
Aspro Clear	We found seven trials in a Cochrane review of single dose oral aspirin for acute pain (currently undergoing in-house update) comparing aspirin in any formulation (ASA 1000mg) against placebo	Edwards JE. <i>Cochrane Database Syst Rev.</i> 2000;(2):CD002067
Codis	We found no trials comparing Codis (or a generic combination analgesic containing aspirin and codeine in similar doses) to placebo	N/A
Cuprofen Plus	We found two trials comparing a generic combination of ibuprofen and caffeine (IBU 400mg/COD 30mg) against placebo. Both trials reported pain following episiotomy with similar results	Cater M. <i>Clin Ther.</i> 1985;7(4):442-47 Norman SL. <i>Clin Ther.</i> 1985;7(5):549-54
Disprin	We found no trials comparing Disprin (or a generic formulation of aspirin in a similar dose) to placebo	N/A
Disprin Extra	We found no trials comparing Disprin Extra (or a generic combination of aspirin and paracetamol in similar doses) to placebo	N/A
Feminax Ultra	We found five trials in an up-to-date Cochrane review of single dose oral naproxen for acute pain comparing naproxen or naproxen sodium (NAPROX 500mg or NAPROX SODIUM 550mg) against placebo	Derry C. <i>Cochrane Database Syst Rev.</i> 2009 Jan 21;(1):CD004234
Mersyndol	We found one trial comparing Mersyndol against placebo. The trial reported pain following dental surgery	Margarone JE. <i>Clin Pharmacol Ther.</i> 1995;58(4):453-58
Nurofen	We found 61 trials in an up-to-date Cochrane review of single dose oral ibuprofen for acute pain comparing a generic formulation of ibuprofen (IBU 400mg) against placebo	Derry C. <i>Cochrane Database Syst Rev.</i> 2009 Jul 8;(3):CD001548
Panadeine 15	We found no trials comparing Panadeine 15 (or a generic combination of paracetamol and codeine in similar doses) to placebo	N/A
Panadol	We found 28 trials in an up-to-date Cochrane review of single dose oral paracetamol for acute pain comparing a generic formulation of paracetamol (PARA 1000mg) against placebo	Toms L. <i>Cochrane Database Syst Rev.</i> 2008 Oct 8;(4):CD004602
Panadol Extra	We found one trial comparing a generic combination of paracetamol and caffeine (PARA 1000mg/CAF 130mg) against placebo. The trial reported pain following dental surgery	Winter L Jr. <i>Current Therapeutic Research</i> 1983;33(1):115-22
Paracodol	We found no trials comparing Paracodol (or a generic combination of paracetamol and codeine in similar doses) to placebo	N/A
Paramol	We found no trials comparing Paramol (or a generic combination of paracetamol and dihydrocodeine tartrate in similar doses) to placebo	N/A
Pentalgin H	We found no trials comparing Pentalgin H (or a generic combination of naproxen, codeine, caffeine, dipyrrone and phenobarbital in similar doses) to placebo	N/A
Saridon	We found one trial comparing Saridon against placebo. The trial reported pain following dental surgery	Kiersch TA. <i>Curr Med Res Opin.</i> 2002;18(1):18-25
Sedalgin-neo	We found no trials comparing Sedalgin-neo (or a generic combination of paracetamol, caffeine, codeine, dipyrrone and phenobarbital in similar doses) to placebo	N/A
Solpadeine Max	We found no trials comparing Solpadeine Max (or a generic combination of paracetamol and codeine in similar doses) to placebo	N/A
Solpadeine Plus	We found one trial comparing a generic combination of paracetamol, codeine and caffeine (PARA 1000mg/COD 16mg/CAF 30mg) against placebo. The trial reported pain following dental surgery	Cooper SA. <i>Anesth Prog.</i> 1986;33(3):139-42
Voltarol	We found four trials in an up-to-date Cochrane review of single dose oral diclofenac for acute pain comparing all generic formulations of diclofenac (DICLO 25mg) against placebo	Derry P. <i>Cochrane Database Syst Rev.</i> 2009 Apr 15;(2):CD004768

Table 2: Summary of data available for each analgesic showing calculated relative benefits (RB) and number-needed-to-treat-to-benefits (NNT)

Drug	Constituents	Number of trials	Number of patients	Percentage with active	Percentage with control	RB (95% CI)	NNT (95% CI)
Anadin Extra	Para400 + Asa600 + Caf90	0					
Askit	Asa530 + Caf110 + Aloxiprin140	0					
Aspirine	Asa650 + Caf65	2	371	65	28	2.3 (1.8–3.0)	2.7 (2.2–3.7)
		Forbes 1990	141	17	0	39.8 (2.4–648)	3.9 (2.7–6.7)
		Rubin 1984	230	86	48	1.8 (1.5–2.2)	2.6 (2.0–3.7)
Aspro Clear	Asa1000	7	679	43	16	2.6 (2.0–3.5)	3.7 (3.0–5.0)
Codis	Asa1000 + Cod base 16	0					
Cuprofen Plus	Ibu400 + Cod base 20	2	167	55	31	1.8 (1.2–2.6)	4.1 (2.6–10.3)
Disprin	Asa900	0					
Disprin Extra	Asa600 + Para400	0					
		Margarone 1995	76	21	8	2.7 (0.8–9.3)	7.6
Feminax Ultra	Naprox500	9	784	52	15	3.4 (2.7–4.4)	2.7 (2.3–3.2)
		Winter 1983	81	48	22	2.2 (1.1–4.2)	3.9 (2.2–18.0)
Mersyndol	Para1000 + Cod base15 + Doxylamine succinate10	1	76	21	8	2.7 (0.8–9.3)	Not calculated
Nurofen	Ibu400	61	6475	54	14	4.0 (3.6–4.4)	2.5 (2.4–2.6)
Panadeine 15	Para1000 + Cod base23	0					
Panadol	Para1000	28	3232	46	18	2.5 (2.2–2.9)	3.6 (3.2–4.0)
		Cooper 1986	61	29	4	6.2 (0.9–45.0)	4.2 (2.5–14.2)
Panadol Extra	Para1000 + Caf130	1	81	48	22	2.2 (1.1–4.2)	3.9 (2.2–18.0)
Paracodol	Para1000 + Cod base13	0					
Paramol	Para1000 + Dihydrocodeine tartarate15	0					
Pentalgin H	Naprox100 + Cod base8 + Caf50 + Dipyron300 + Phenobarbitol15	0					
Saridon	Para500 + Caf100 + Propifenazone300	1	301	23	2	9.2 (1.3–64.5)	4.9 (3.6–7.4)
Sedalgin-neo	Para600 + Caf100 + Cod base20 + Dipyron300 + Phenobarbitol30	0					
		Norman 1985	74	53	29	1.8 (1.0–3.3)	4.2 (2.2–48.5)
		Cater 1985	93	57	32	1.8 (1.1–2.9)	4.1 (2.3–19.8)
Solpadeine Max	Para1000 + Cod base20	0					
Solpadeine Plus	Para1000 + Caf60 + Cod base13	1	61	29	4	6.2 (0.9–45.0)	4.2 (2.5–14.2)
Voltarol	Diclo25	4	502	53	15	3.6 (2.6–5.0)	2.6 (2.2–3.3)

Para = paracetamol, Asa = aspirin, Caf = caffeine, Cod = codeine, Naprox = naproxen, Diclo = diclofenac, Ibu = ibuprofen.

Table 3: Sub-analysis of only those trials involving dental pain

Drug	Constituents	Number of trials	Number of patients	Percentage with active	Percentage with control	RB (95% CI)	NNT (95% CI)
Anadin Extra	Para400 + Asa600 + Caf90	0					
Askit	Asa530 + Caf110 + Aloxiprin140	0					
Aspirine	Asa650 + Caf65	1	141	17	0	39.8 (2.4–648)	3.9 (2.7–6.7)
Aspro Clear	Asa1000	3	345	32	11	2.9 (1.8–4.8)	4.7 (3.4–7.6)
Codis	Asa1000 + Cod base 16	0					
Cuprofen Plus	Ibu400 + Cod base 20	0					
Disprin	Asa900	0					
Disprin Extra	Asa600 + Para400	0					
Feminax Ultra	Naprox500	5	402	62	7	8.9 (5.3–14.9)	1.8 (1.6–2.1)
Mersyndol	Para1000 + Cod base15 + Doxylamine succinate10	1	76	21	8	2.7 (0.8–9.3)	Not Calculated
Nurofen	Ibu400	49	5428	55	12	4.7 (4.2–5.2)	2.3 (2.2–2.4)
Panadeine 15	Para1000 + Cod base23	0					
Panadol	Para1000	18	2171	40	9	4.4 (3.5–5.5)	3.3 (3.0–3.7)
Panadol Extra	Para1000 + Caf130	1	81	48	22	2.2 (1.1–4.2)	3.9 (2.2–18.0)
Paracodol	Para1000 + Cod base13	0					
Paramol	Para1000 + Dihydrocodeine tartarate15	0					
Pentalgin H	Naprox100 + Cod base8 + Caf50 + Dipyron300 + Phenobarbital15	0					
Saridon	Para500 + Caf100 + Propife-nazone300	1	301	23	2	9.2 (1.3–64.5)	4.9 (3.6–7.4)
Sedalgin-neo	Para600 + Caf100 + Cod base20 + Dipyron300 + Phenobarbital30	0					
Solpadeine Max	Para1000 + Cod base20	0					
Solpadeine Plus	Para1000 + Caf60 + Cod base13	1	61	29	4	6.2 (0.9–45.0)	4.2 (2.5–14.2)
Voltarol	Diclo25	3	398	51	11	4.6 (3.1–7.1)	2.5 (2.1–3.2)

Para = paracetamol, Asa = aspirin, Caf = caffeine, Cod = codeine, Naprox = naproxen, Diclo = diclofenac, Ibu = ibuprofen.

What can we make of the evidence we have

The best evidence we have is from ibuprofen 400mg (Nurofen), paracetamol 10,000mg (Panadol), naproxen 500mg (Feminax Ultra), diclofenac 25mg (Voltarol), and aspirin 1,000mg (Aspro), though the evidence is likely not to have come from testing of any particular product. All of these analgesics have usefully low NNTs in the range of about 2–4.

The evidence for combination analgesics is less clear, with predominantly no trials, or too few trials and patients available to make any judgement. This is a shame,

because there is evidence elsewhere (Smith et al, 2001⁴, for example) that combinations of analgesics can produce very good results.

Consumers can make up their own minds whether the expense of branded analgesics is worth it compared to the often much lower cost of unbranded – though that is a UK view, and certainly analgesics like paracetamol and ibuprofen are available in quantity and at low cost in the USA.

REFERENCES

1. Moore A, Edwards J, Barden J, McQuay

H. *Bandolier's Little Book of Pain*. Oxford: Oxford University Press, 2003.

2. Laska EM, Sunshine A, Mueller F, Elvers WB, Siegel C, Rubin A. Caffeine as an analgesic adjuvant. *Journal of the American Medical Association* 1984;251(13):1711–18.

3. Barden J, Derry S, McQuay HJ, Moore RA. Bias from industry trial funding? A framework, a suggested approach, and a negative result. *Pain* 2006;121(3):207–18.

4. Smith LA, Moore RA, McQuay HJ, Gavaghan D. Using evidence from different sources: an example using paracetamol 1000 mg plus codeine 60 mg. *BMC Medical Research Methodology* 2001;1:1.

Mythbusters

Myth: Whole-body screening is an effective way to detect hidden cancers

Whole-body screening is promoted as a one-stop shop for painlessly detecting hidden cancer and preventing cancer-related deaths. It is big business in the United States.¹ In Canada, private clinics have begun offering full-body diagnostic procedures for a fee.^{2,3} The tests and procedures are often marketed to healthy people as a way to scan for hidden abnormalities or cancers, affording people the peace of mind that they are in good health.^{2,3} When used in this manner, the evidence shows that whole-body cancer screening offers no proven health benefits and that it, in fact, exposes people to a number of unnecessary health risks.

Sound screening is sensitive and specific

Using Computerised Tomography (CT), Magnetic Resonance Imaging (MRI) technology or, at times, Positron Emission Tomography (PET), whole-body screening involves scanning the body from different depths and angles to compile an image that can be examined for abnormalities. When these tests are used to make, confirm or refine a diagnosis in patients with cancer symptoms, or to monitor patients undergoing cancer treatments, the benefits outweigh the risks.⁴ Screening to detect abnormalities or possible cancers can lead to one of four outcomes:

- normal test result and no cancer (true negative)
- normal test result, but an undetected cancer (false negative)
- abnormal test result, but no cancer (false positive)
- abnormal test result and actual cancer (true positive).⁵

False positives in particular often lead to a cascade of additional testing and biopsies, which can bring additional costs to the health care system as well as further risks to the patient, not the least of which are anxiety,

worry and medical complications.⁶ A good screening test is sensitive and specific, producing a low rate of false negatives and false positives. It should also reduce the number of deaths from the disease tested for, while not subjecting people to unacceptable harm.⁷ Generally, recommended cancer screening tests – for example, a mammogram – meet these criteria. A mammography for women 50 to 69 years of age may decrease breast cancer deaths by up to 30%,⁸ while a fecal occult blood test for individuals 50 to 74 years of age can decrease colon cancer deaths by 15%.⁹ As well, since the introduction of Pap tests more than 25 years ago, cervical cancer mortality has declined by 60%.¹⁰

In contrast, there is no evidence that whole-body screening of healthy people prevents cancer-related deaths. In fact, evidence shows that whole-body screening – which is neither sensitive nor specific – poses a number of serious risks to patients, including unnecessary examinations, overexposure to radiation, and high false positive and false negative rates.^{11–13} Whole-body screening also increases the rate of over-diagnosis – the diagnosis of diseases or ailments that would not have caused any problems in a person's lifetime or for which therapy is not known to be effective.¹⁴

Risky business

No screening test is free of risks, but some screening procedures are more harmful than others. It is estimated that whole-body CT screening, for example, uses 500 to 1,000 times the radiation levels of a routine chest x-ray.¹² Radiologists have expressed concerns about exposing patients to this level of radiation, given the unproven benefits of whole-body screening and the potentially life-threatening risk in causing radiation-induced cancer.¹⁵ Concerns about exposing patients to unnecessary radiation have been raised related to PET scanning, too.⁵ Although MRI scanning doesn't use ionising radiation, it poses its own risks: its magnetic field can pull on or heat up metallic implants such as pacemakers or pins, causing soft-tissue tears or burning.¹²

Given the potential risks, assessments of the effectiveness of whole-body screening should

This issue of Mythbusters is based on an article written by Kathleen Decker, recipient of the 2009 Mythbusters Award. Kathleen is a PhD candidate at the University of Manitoba and a research coordinator for the Manitoba Breast Screening Program at CancerCare Manitoba in Winnipeg.

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be based on robust evidence. However, there are no randomised controlled trials of whole-body screening and only a handful of retrospective reviews.¹⁶⁻¹⁷ These report that the percentage of people who had an abnormal test result from a full-body scan ranged from 33% to 52%.¹⁶⁻¹⁷ This is compared to an abnormal rate of 6% for a mammogram¹⁸ and 2% for a fecal occult blood test.¹⁹

The evidence suggests that whole-body screening is neither sensitive nor specific, and that it can lead to a high rate of false positives and negatives. A study that examined the abnormalities arising from whole-body screening, for example, found that the overwhelming majority – up to 97% – were benign and not clinically significant.¹⁵ A 2006 study also showed that whole-body PET screening alone failed to spot 29% of cancers detected in a population of over 3,400 healthy individuals who were subjected to multiple screening procedures; in other words, it also had a significant rate of false negatives, indicating that those who have received a whole-body scan should not forego recommended screening tests.¹⁹ The same study found that more conventional screening tests, like endoscopy, were successful in leading to correct cancer diagnoses.¹⁹ A number of false positives were also reported in a small, pilot, randomised controlled trial on whole-body screening of healthy subjects conducted in the US: 64% of the experimental (screened) group participants had an abnormal test result, but there were no confirmed cases of cancer.²⁰ In addition, the medical costs were more than twice as high for participants in the experimental group than for those in the control (non-screened) group.

The cost-effectiveness of whole-body screening has been further called into question by a 2006 analysis of the potential effect of whole-body screening on health and health care costs, which estimated that providing full-body screening to a group of 500,000 healthy people at age 50, at a cost of \$2,513 per person, would lead to an average gain in life expectancy of only six days in 26.3 years.²¹ False-positive results accounted

for more than 30% of the total costs.²¹

Conclusion

Whole-body screening for healthy people offers the promise of early cancer detection and reduced cancer-related deaths. Despite the claims, such screening has not demonstrated any positive effects on life expectancy. Instead, it is tied to significant risks, costs and anxiety for clients, as well as to substantial costs and unnecessary service use on the healthcare system. Cancer screening recommendations and decisions should be based on reliable data and careful weighing of all of the potential benefits and harms.

REFERENCES

1. Scandirectory.com. Updated 12 July 2007; Accessed 8 July 2009.
2. EcuMedical. *What you need to know about full body scans*.
3. Canada Diagnostic Centres. *How can preventative health scans help me?* <http://www.canadadiagnostics.ca/private/preventative-health-scans.php>
4. Schmidt GP et al. Whole-body magnetic resonance imaging and positron emission tomography-computed tomography in oncology. *Magnetic Resonance Imaging* 2007;18(3):193–202.
5. Schoder H, Gonen M. Screening for cancer with PET and PET/CT: Potential and limitations. *Journal of Nuclear Medicine* 2007;48(1):4–18s.
6. Rosenfeld EL, Duggan AE. Colorectal cancer screening; ensuring benefits outweigh the risks. *Medical Journal of Australia* 2008; 188(4):196–97.
7. Wilson JM, Jungner YG. Principles and practice of mass screening for disease. *Boletín de la Oficina Sanitaria Panamericana* 1968; 65:281–393.
8. Gotzsche PC, Nielsen M. Screening for breast cancer with mammography. *Cochrane Database of Systematic Reviews* 2006;4:1–61.
9. Hewitson P et al. Screening for colorectal cancer using the faecal occult blood test, Hemoccult. *Cochrane Database of Systematic Reviews* 2007;1(Art. No.: CD001216):1–25.
10. *Canadian Cancer Statistics 2006*. Toronto: Canadian Cancer Society, 2007.
11. Cassels A, van Wiltenburg J, Armstrong W. *What's in a scan? How well are consumers informed about the benefits and harms related to screening technology (CT and PET scans) in Canada?* Ottawa: Canadian Centre for Policy Alternatives, 2009.
12. Health Canada, Public Health Agency of Canada. *Whole-body screening using MRI or CT Technology. It's Your Health*. Ottawa: Health Canada, 2003. Available at <http://tinyurl.com/y9h9cz3>
13. Salman RAS, Whiteley WN, Warlow C. Screening using whole-body magnetic resonance imaging scanning: who wants an incidentaloma? *Journal of Medical Screening* 2007;14(1):2–4.
14. Modic MT, Obuchowski N. Whole-body CT screening for cancer and coronary disease: does it pass the test? *Cleveland Clinic Journal of Medicine* 2004;71(1):47–56.
15. Ghotbi N et al. Cancer screening with whole-body PET/CT for healthy asymptomatic people in Japan: re-evaluation of its test validity and radiation exposure. *Asian Pacific Journal of Cancer Prevention* 2007;8:93–97.
16. Furtado CD et al. Whole-body CT screening: spectrum of findings and recommendations in 1192 patients. *Radiology* 2005;237:385–94.
17. Obuchowski N, Modic MT. Total body screening: predicting actionable findings. *Academic Radiology* 2006;13:480–85.
18. Decker K, Harrison M, Watters K. *Manitoba Breast Screening Program Biennial Report 2004–2006*. Winnipeg, Manitoba: Cancer Care Manitoba, 2007.
19. Ono K et al. The detection rates and tumor clinical/pathological stages of whole-body FDG-PET cancer screening. *Annals of Nuclear Medicine* 2006;21(1):65–72.
20. Obuchowski NA et al. Total-body screening: preliminary results of a pilot randomised controlled trial. *Journal of the American College of Radiology* 2007;4:604–11.
21. Beinfeld MT, Wittenberg E, Gazelle GS. Cost-effectiveness of whole-body CT screening. *Radiology* 2005; 234:415–22.

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www.euro.who.int/Document/E93312.pdf

This publication provides an overview of WHO's activities in the Regional Office for Europe over the last sixty years. The report begins with a look at how Copenhagen was chosen as the base for operations, and then provides a historical analysis of the attributes of each of the five former directors, their major achievements and projects. This information is placed within the context of changing socioeconomic and health challenges, particularly in the 1960s. A substantial proportion of the report is dedicated to outlining major events of the past ten years. For example, the Health and Stability Pact of 1999 and WHO's increased efforts to contain the impact of humanitarian disasters upon health. Cases discussed include: avian influenza in Turkey; abnormally cold weather in Tajikistan; lead poisoning in Kosovo; mass immunisation in Ukraine; and polio eradication.

The report also serves to summarise milestones created by WHO European conferences. In addition to the 2008 WHO Ministerial Conference on Health Systems, six others are discussed in terms of goals set and achieved. Important international partnerships and internal changes are presented. Additional information pages, references and web links are chronologically provided.

Contents:

Introduction
The road to Copenhagen
1949–1956: Dr Norman Begg: the First Regional Director
1956–1966: Dr Paul van de Calseyde: the Second Regional Director
1966–1985: Dr Leo A. Kaprio: the Third Regional Director
1985–2000: Dr Jo E Asvali: the Fourth Regional Director
2000–2010: Dr Marc Danzon: the Fifth Regional Director
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The socioeconomic impact of interoperable electronic health records (EHR) and ePrescribing systems in Europe and beyond

Alexander Dobrev, Tom Jones, Karl Stroetmann, Yvonne Vatter, Kai Peng



Brussels: European Commission, DG Information Society & Media, 2009

54 pages

Freely available online at:
www.ehr-impact.eu/

EHR IMPACT is the last element of an EU commissioned study that comprised nine quantitative and two qualitative independent evaluations of good practice cases on interoperable electronic health record and ePrescribing systems in Europe. The study aimed to improve awareness and provide evidence on the socioeconomic and financial impact of EHRs. To this end the report presents a conceptual framework within which practice can be analysed. Study sites include systems implemented over the last twelve years from all over Europe (UK, Switzerland, Bulgaria, Spain, Czech Republic, France, Italy), in addition to the USA and Israel.

Cost benefit analysis and sensitivity analysis are used as the methodological foundation for the report, which indicates that EHRs are beneficial but need net cash injections to be effective. In all cases it is shown that socioeconomic gains outweigh costs and typically take between four and nine years to produce net returns. Health care providers shoulder the majority of costs but are also the main winners. Crucially, the importance of information sharing – 'interoperability' – forms a vital backbone of EHR and ePrescribing systems, with continuous engagement a necessary precursor to successful implementation. The report provides advice for policymakers, with strategic recommendations of note.

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Spanish EU Presidency

<http://eu2010.es/en/unioneuropea/politicas/empleo/>

January 1, 2010 marked the beginning of Spain's presidency of the European Union. The Employment, Social Policy, Health and Consumer Affairs (EPSCO) council site brings together objectives, policies and external resources. A calendar directs users to search for upcoming events. Links to the main EU site and the Spanish presidency in focus are also accessible, including a detailed list of specific health priorities. A search facility for downloads is available for documents, news and key agenda items. The site is available in Spanish, Catalan, Galician, Basque, English and French.

Health Services Research – Europe

www.healthservicesresearch.eu

Health Services Research-Europe is an European Commission funded consortium, coordinated by the Netherlands Institute for Health Services Research (NIVEL) and involving four other major health services research institutes, which aims to identify, evaluate and improve the contribution of health services research (HSR) to the health policy process both at the national and EU levels. This focuses on five areas: health (care delivery) systems; health care organisations and professional practices; health technology assessment; benchmarking & performance indicators; and relationships between research & policy. One major activity is a forthcoming conference in the Hague on 8–9 April 2010, where the HSR community and decision makers will meet to set an agenda for European HSR and strengthen the research-policy infrastructure. The website also has a dedicated members-only area and search box. Users are able to subscribe to a newsletter.

Social Dialogue

www.socialdialogue.net/en/index.jsp

Social Dialogue offers information on European employment and disability issues. The site is sponsored by the European Commission and aims to raise awareness of innovative policies and practices across Europe to support people with disabilities. Information on policies, legislation and affiliated organisations are listed on the site under five main sections – IT & social dialogue; corporate social responsibility; lifelong learning; social inclusion and disability, and economic & social change. Recent news items are outlined on the homepage, whilst a library and project databases allow users to search for relevant documents. A members' only area is available. The site is accessible in Greek, English, French and German.

Health and Environment Alliance (HEAL)

www.env-health.org/a/2837

The Brussels based HEAL aims to raise awareness of how environmental protection improves health. It represents sixty-five social and professional organisations across Europe. Issues of particular concern include the environment and health policy; mercury and health; chemicals; pesticides; climate change; air quality; public participation and environmental diseases. The website has a dedicated members' only area, and resources which include media coverage, book reviews, publications and photos. Users can sign up for environmental health news and news feeds. Contact details and external links can be found online.

European Policy Centre (EPC)

www.epc.eu

The EPC is an independent think tank comprising over four hundred international members which aims to provide policy makers with high quality information on a range of issues including health and long term care. It organises a series of events, reports of which are subsequently made available on the website. Key publications and some keynote speeches are also available. A calendar allows users to search for future events.

CALL for InterOPERability, (CALLIOPE)

www.calliope-network.eu

CALLIOPE is a network of collaborating organisations mandated with the planning and implementation of eHealth. It has representatives from national governments, eHealth competence centres and eleven EU-level stakeholder organisations of health professionals, patients, health insurers and industry. The web site identifies and outlines key priority areas and encourages knowledge sharing and collaborations amongst stakeholders. Those interested can join Calliope online and consequently subscribe to newsletters and remain informed of future events. Event reports, newsletters and other material are downloadable. There is also a frequently asked question section.

NEWS FROM THE INSTITUTIONS

European governments adopt plan to reduce environmental risks to health by 2020

The Fifth Ministerial Conference on Environment and Health: “Protecting children’s health in a changing environment”, organised by the World Health Organization (WHO) Regional Office for Europe and co-hosted by Italy’s Ministry of Health and Ministry for the Environment, Land and Sea took place in Parma, Italy on 10–12 March 2010. Focused on protecting children’s health, the Conference aimed to drive Europe’s agenda on emerging environmental health challenges over the next ten years.

More than ever, children’s health is at risk from a changing environment. The health impacts of environmental risk factors – inadequate water and sanitation, unsafe home and recreational environments, lack of spatial planning for physical activity, indoor and outdoor air pollution, and hazardous chemicals – are amplified by recent developments such as financial constraints, broader socioeconomic and gender inequalities and more frequent extreme climate events. They pose new challenges for health systems to reduce deaths and diseases through effective environmental health interventions.

Evidence is growing that climate change is contributing to an increase in the frequency of natural disasters, such as heat-waves, floods and droughts. Since 1990, the International Disaster Database (EM-DAT) has recorded more than 1200 natural events in the WHO European Region, affecting over 48 million people and causing more than 112,000 deaths, at an estimated loss of more than US\$ 241 billion.

Pledge to reduce health impact of environmental threats

All 53 Member States of the WHO European Region adopted a declaration pledging to reduce

the adverse health impact of environmental threats in the next decade. Future work will be based on a new European regional framework for action, entitled “Protecting health in an environment challenged by climate change”. The document provides a comprehensive roadmap laying out steps and priorities for coordinated international and national action.

Through the Declaration and Commitment to Act, participating governments agreed to implement national programmes to provide equal opportunities to each child by 2020 by ensuring access to safe water and sanitation, opportunities for physical activity and a healthy diet, improved air quality and an environment free of toxic chemicals. Governments also pledged to place health at the centre of socioeconomic development through increased investment in new technologies and green jobs. Stefania Prestigiacomo, Italian Minister for the Environment, Land and Sea, noted that “environment and health objectives can also serve as an engine to boost innovation and competitiveness”.

Delegates also underlined that the health sector, one of the most energy-intensive sectors in all countries, should lead moves to reduce greenhouse gas emissions in the public sector by rationalising energy use. They also agreed to strengthen early-warning surveillance and preparedness systems for extreme weather events and disease outbreaks.

“We need a radically new vision for European health policy to address the biggest health challenges of our Region. This Conference has opened an exciting new chapter in the way European governments work on environment and health, helping to push these closely inter-related issues higher up the political agenda,” stated Zsuzsanna Jakab, WHO Regional Director for Europe. In the meantime, John Dalli, European Commissioner for Health and Consumer Policy promised that the European Commission will

“play its part by continuing to focus attention across European Union policies on environmental impacts on health.”

In September 2010, Member States will gather in Moscow for the sixtieth session of the WHO Regional Committee for Europe to endorse the outcomes of the conference through a resolution. Governments gathered in Parma also agreed to strengthen political coordination between regular ministerial conferences, and will now involve ministers directly in steering the process to ensure that cross-sectoral issues are given the highest possible political profile.

More information on the conference is available at www.euro.who.int/parma2010

EU ministers outline 2020 vision for eHealth

The eighth Ministerial eHealth Conference, co-organised by the Spanish Presidency of the European Union and the European Commission, in cooperation with the Regional Government of Catalonia and the Foundation Tic-Salut, was held in Barcelona on 15–18 March 2010. EU ministers outlined a joint vision and policy priorities on how to make eHealth more accessible, interactive and customised to patients over the next ten years.

Their Declaration called for policy coordination amongst the various areas where eHealth can have an impact on citizens’ health, in order to enhance benefits for patients, health care systems and society. It also recognised the need for stronger synergies with policy areas like competitiveness, research and regional development, both at European and national levels.

The importance of eHealth, they noted, should be underlined in the framework of the future EU 2020 Strategy and the European Digital Agenda. They noted that information and communication technology (ICT) tools for health should be used to scale up benefits to patients, health care systems and society. Large scale ac-

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

tions at European level to link research, innovation and deployment were therefore welcomed. The Commission should report on progress in this area. The signatories also underlined the importance of involving all stakeholders in the strategic planning, validation and implementation of eHealth.

The Ministerial Conference is the latest step in more than two decades of support from the European Commission during which time more than 450 projects, at a cost of €1 billion, have been funded. Since 2007 the European Commission has been supporting eHealth deployment via the Competitiveness and Innovation Programme and over the last year through the Public Health Programme.

More information on the High-Level conference and World of Health IT conference can be accessed at www.ehealthweek2010.org/

New legislation to reduce injuries for health care workers in Europe

EU Employment and Social Affairs Ministers on 8 March 2010 adopted a Directive to prevent injuries and infections to health care workers from sharp objects such as needle sticks. This is one of the most serious health and safety threats in European workplaces, estimated to cause one million injuries each year. The legislation specifically addresses one of the priority objectives of the EU's current strategy for health and safety at work, which aims to cut workplace accidents by 25% by 2012.

The Directive translates into Community law an agreement negotiated by the European social partner organisations in the sector, which employs around 3.5 million people. Speaking at the Council of Ministers meeting, László Andor, EU Commissioner for Employment, Social Affairs and Inclusion said that "the health care sector is one of the biggest employers in Europe and needles represent a real risk to workers, both in terms of injuries and increased rates of life-threatening infections like HIV or hepatitis". He added that the "new Directive will better protect workers and their families while reducing the burden of injuries on European health services."

The new Directive implements in law a framework agreement on prevention from sharp injuries in the hospital and health care sector signed in July 2009 by the European Public Services Union (EPSU) and the European Hospital and Healthcare

Employers' Association (HOSPEEM) – European Social partner organisations. It aims to achieve the safest possible working environment for employees in the sector and protect workers at risk, as well as patients; prevent injuries to workers caused by all types of sharp medical objects (including needle sticks); and set up an integrated approach to assessing and preventing risks as well as for training and informing workers.

More information at www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/113210.pdf

One in seven sunbeds in breach of UV radiation safety limits

Consumers need to be more aware of the potential risks associated with using sunbeds according to the results of a market surveillance check of sunbeds and sunbed services, published on 12 February 2010 by the European Commission.

In a project led by the Dutch Food and Consumer Product Safety Authority, market surveillance authorities in ten Member States (Belgium, Cyprus, Czech Republic, Denmark, Finland, Germany, Hungary, Latvia, the Netherlands and Poland) examined safety information and advice provided to consumers, the labelling of sunbeds, and the availability of eye protection and ultra-violet (UV) radiation emitted by sunbeds.

They inspected more than 500 sunbeds at over 300 locations (mostly tanning salons and wellness centres) between September 2008 and September 2009. Three main problems were found: UV radiation limits for sunbeds were violated in one in seven sunbeds made available at tanning services; consumer guidance, including on the hazards of UV radiation or prohibiting their use by under 18s was not provided; and there were insufficient warnings on the sunbeds themselves (for example, that UV radiation may cause injury).

As a result of their findings the project participants recommended that: there should be more enforcement at the source of entry onto the market; further alignment of the interpretation of the legal requirements; making consumers better informed about the hazards of tanning and how to avoid them; and to increase the number of UV radiation checks for a more representative measure of non-compliance (expected to be higher with more testing).

Member State authorities are now intensifying their work to ensure compliance

with all relevant safety legislation and the results of the 2008/2009 check will feed into a follow up project launched by authorities in twelve Member States to train more inspectors and improve information for consumers. The outcome of this project should be available at the end of 2011. The authorities are also working with the sunbed industry, which is itself developing training material for service providers such as tanning studios.

More information at http://ec.europa.eu/consumers/citizen/my_safety/sunbeds/index_en.htm

NEWS FROM THE EUROPEAN COURT OF JUSTICE

ECJ Opinion states UK prescribing incentives schemes are illegal

On 11 February, the European Court of Justice (ECJ) provided an Opinion (C-62/09) to the High Court of Justice in England and Wales stating that prescribing incentive schemes operated by Primary Care Trusts (PCTs) in England were illegal under EU law. In his Opinion, Advocate General Nilo Jääskinen stated that the schemes have the deliberate and direct intention of promoting certain medicinal products within the National Health Service (NHS) at the expense of others, and that the schemes therefore amount to promotion. This relates specifically to Article 94(1) of European Directive 2001/83, which covers the provision of human-use medicines, including their advertising and promotion.

The ECJ Opinion was in response to action by the Association of the British Pharmaceutical Industry (ABPI) against the Medicines and Healthcare Products Regulatory Agency (MHRA) in the English High Court challenging the practice of rewarding doctors financially for prescribing specific medicines. On 3 July 2006, after the ABPI wrote to the MHRA expressing concern about the incentive schemes being implemented by PCTs, the MHRA had replied that, in its opinion, Article 94 covered incentive schemes "of a commercial nature" only. The ABPI disputed this interpretation and sought a review of the legality of the MHRA's position in the High Court, which in turn asked the ECJ for an interpretation of Article 94 before it could give judgement.

Furthermore, the UK had claimed that

the industry group was “not concerned...with preserving the independence of doctors or with patient safety, but wishes instead to maximise the prescription, and therefore the sale, of branded medicinal products manufactured and marketed by its members.” However, the Advocate General responded that, in his view, “the self-regarding nature of ABPI’s motives is legally irrelevant.” Moreover, he stated that the UK appears to be the only Member State with prescribing incentive schemes involving the substitution of specific medicines, compared with other countries that provide other forms of financial incentive schemes to reduce pharmaceutical costs.

Jääskinen emphasised that his proposed interpretation of the law does not mean that the NHS is precluded from controlling expenditure on medicines. He did though suggest that it may need to think about other measures, such as government price freezes, price reductions and the promotion of generics. This is not a full judgment, although the Opinion of the Advocate General will be considered as part of a final decision on the issue, which is expected later this year.

The full text of the Opinion can be accessed via www.curia.europa.eu

Legislation in France, Austria and Ireland fixing minimum retail prices for cigarettes infringes EU law

On 4 March the ECJ ruled that legislation in France, Austria and Ireland fixing minimum retail prices for cigarettes infringes European Union law. The Commission had brought infringement actions before the Court of Justice against France (C-197/08), Austria (C-198/08) and Ireland (C-221/08), because it considered that the legislation of these Member States concerning the fixing of minimum prices for some manufactured tobacco products, namely cigarettes and other tobacco products in the case of France, cigarettes and fine-cut tobacco for the rolling of cigarettes in the case of Austria and cigarettes in the case of Ireland, were contrary to Directive 95/59 which lays down rules on excise duty affecting the consumption of those products.

The directive obliges Member States to impose excise duty on cigarettes consisting of a proportional element calculated on the maximum retail selling price, and a specific element, the amount of which is fixed by reference to cigarettes in the most popular price category but which may not

be less than 5 % or more than 55 % of the amount of the total tax burden. The rate of the proportional excise duty and the amount of the specific excise duty must be the same for all cigarettes. The directive also provides that the manufacturers and importers of manufactured tobacco are to be free to determine the maximum retail selling price for each of their products (Article 9(1)).

According to the Commission, the legislation of those three Member States, which imposes minimum prices corresponding to a certain percentage of the average prices of the manufactured tobacco concerned (95 % in the case of France, 92.75 % for cigarettes and 90 % for fine-cut tobacco in the case of Austria and 97 % in the case of Ireland) undermines the freedom of manufacturers and importers to determine the maximum retail selling prices of their products and, correspondingly, free competition. That legislation is therefore contrary to the Directive.

In its judgement the Court recalled, first, that the directive seeks to ensure that the determination of the tax base of the proportional excise duty on tobacco products is subject to the same rules in all the Member States but also to maintain the freedom of manufacturers and importers to make effective use of the competitive advantage resulting from any lower cost prices.

It considered that the imposition of a minimum retail selling price means that the maximum retail selling price determined by manufacturers and importers cannot, in any event, be lower than that obligatory minimum price, and is therefore capable of undermining competition by preventing some of those manufacturers or importers from taking advantage of lower cost prices so as to offer more attractive retail selling prices.

The Court therefore held that a system of minimum retail selling prices for tobacco products cannot be regarded as compatible with Article 9(1) of Directive 95/59 unless it was structured in such a way as to ensure, in any event, that the competitive advantage which could result for some manufacturers and importers of those products from lower cost prices is not impaired.

It concluded that national legislation did not make it possible to ensure, in any event, that the minimum prices imposed do not impair the competitive advantage which could result for some manufacturers and importers of tobacco products

from lower cost prices.

The Court rejected the arguments advanced by each Member State in order to justify its legislation. Its conclusion had no bearing on the Framework Convention on Tobacco Control of the World Health Organisation (WHO), since it did not impose any actual obligation on the Contracting Parties with regard to the price of tobacco products which would allow them to act contrary to the provisions of the directive. Moreover, the health protection objective laid down in Article 30 EC can be relied upon only to justify the quantitative restrictions on imports and exports and the measures having equivalent effect envisaged by Articles 28 EC and 29 EC. However, the Commission did not base its action on those provisions of the EC Treaty.

Finally, the Court considered that Directive 95/59 ensures health protection and does not prevent the Member States from combating smoking. It pointed out that fiscal legislation is an important and effective instrument for discouraging consumption of tobacco products and, therefore, for the protection of public health, since the objective of ensuring that a high price level is fixed for those products may adequately be attained by increased taxation of those products, the excise duty increases sooner or later being reflected in an increase in the retail selling price, without undermining the freedom to determine prices.

The Court added that the prohibition on fixing minimum prices does not prevent Member States from prohibiting the sale of manufactured tobacco at a loss, so long as the freedom of manufacturers or importers to determine the maximum retail selling prices for their products is not undermined. Those economic actors would not be able, in that case, to absorb the impact of the taxes on those prices by selling their products at a price below the sum of the cost price and all taxes.

The full text of the judgements can be accessed via www.curia.europa.eu

COUNTRY NEWS

Swedish regulator proposes environmental restrictions on pharmaceutical manufacturing

In December 2008, the Swedish government commissioned the Swedish Medical

Products Agency (MPA) to identify different possibilities for strengthening the environmental requirements involved in the manufacture of pharmaceutical products. The MPA was instructed to undertake this project in consultation with the Swedish Environmental Protection Agency and the Swedish National Chemicals Agency, and to focus on both national and international perspectives.

In its final report published at the end of 2009, the MPA makes proposals for environmental measures designed to limit the adverse environmental effects of pharmaceuticals manufacturing. The *Report of the Government Commission on strengthening environmental requirements in the manufacture of pharmaceutical products and active substances* proposes that environmental protection measures be encompassed into marketing authorisation legislation at an EU level and into the pharmaceutical reimbursement system at a national level.

It also proposes that an environmental risk assessment be included in the EU legislation on the authorisation of pharmaceutical products. The MPA also proposed that an environmental certification be introduced to the EU legislation on Good Manufacturing Practice (GMP) and that at a national level the review of the pharmaceutical reimbursement system should include environmental dimensions

In the 21st century, results from this Swedish research indicate that emissions from the manufacture of medicinal products in India might seriously affect human and animal health, as well as their environment. Pharmaceuticals are found in both ground- and drinking water. Current studies show that levels of pharmaceuticals in 'purified' waste water are above the level of a normal dose of a drug in a human being. With this background, the discharge of substances from the pharmaceutical production in the third world is of serious concern.

A significant part of the current manufacture and production of raw materials or intermediate products takes place in low income countries and many large companies are planning to place even more of their production there. National legislation is insufficient and these measures are better met with harmonised EU legislation, since the level of requirements also may affect conditions outside the EU.

The MPA therefore proposes, as a first priority, that a requirement for an envi-

ronmental certification of production facilities, with respect to the production of medicines and active pharmaceutical ingredients, be introduced to the legislation on GMP. This will ensure an environmental perspective in the legislation for improved cleaning technology at production facilities.

In order to better reflect sustainable development in accordance with the EC Treaty, the MPA proposes that the current EU legislation for the authorisation of medicinal products for humans should be changed so that an environmental risk assessment is also included in the approval.

Today, authorities may not include environmental risk assessment in the risk/benefit analysis when assessing whether a drug will be approved for marketing authorisation. This means that current legislation does not allow a denial of authorisation of medicinal products for humans due to any risk of negative environmental effects. The Swedish government is now considering the MPA's proposals and potential actions.

The report is available in Swedish, with an English summary, at <http://tinyurl.com/y8unnwvm>

Czech Republic: New cardiovascular care system introduced

The Ministry of Health, together with experts from professional associations and health insurance companies, recently introduced a new cardiovascular care system in the Czech Republic. As a result, a new complete network of Complex Cardiovascular Centres will be established. They will become the guarantors of care for especially costly or complex cases, including cardio-surgery, invasive cardiology and heart transplants. The list of individual centres and the level of care being provided at each will be part of the Ministry of Health Bulletin to be published in 2010.

Cardiovascular diseases are the number one cause of death in the Czech Republic. Every year over 50,000 people die of heart and circulatory system diseases, which represent over half of overall mortality. Minister of Health, Dana Jurásková, said that "the concentration of personal and technical capacities for these diseases is a rational step also recommended by the European Union". The First Deputy Minister of Health, Marek Šnajdr, added that "concentrating care into a number of centres is a key systematic step towards securing top cardiovascular care for all pa-

tients in the Czech Republic. It does not mean that centres will be closed down – instead, some will be selected to play the role of a guarantor of services for especially costly and complex cases. In addition, the centres in the network will play the role of regional coordinators, which have to actively carry out research and apply new knowledge in day to day practice."

All the cardiovascular centres were carefully evaluated by the Ministry of Health, experts from relevant specialisations (i.e. cardiology, cardio surgery, angiology, vascular surgery and interventional radiology) in August and September of 2009, focusing especially on human resources, technical and material equipment, efficiency, accreditation of doctors in different specialisations, participation in research and publications. The decision about which centres will be included in the network was made in November 2009.

The Ministry of Health will support the essential modernisation of the new centres by helping to secure financial resources for standard equipment from the structural funds of the European Union as a part of the Integrated Operational Programme. The call for proposals was announced on 16 February 2010.

Source: <http://www.mzcr.cz>

Slovakia: Reference pricing for pharmaceuticals

The reference pricing of pharmaceuticals is considered to be the most important achievement of the Slovak health care system in 2009, according to both the Minister of Health, Richard Rasi, and the Health Policy Institute, an independent health care think tank in Slovakia. The economic crisis has significantly affected the health care sector and deprived health insurance companies of important revenues. Therefore, a 1.2% decline in pharmaceutical expenditures in the first half of 2009 (a figure which is likely to remain constant by the end of the year and is the same as in 2008) was considered to be a major achievement. This is particularly the case given that drug expenditures in Slovakia represent approximately 30% of total health care expenditure. According to the Ministry of Finance, savings in 2009 totalled €71 million and are projected to be €86 million in 2010. The former figure represents approximately 7% of total drug expenditure in 2008.

This accomplishment can be mainly at-

tributed to the Ministry of Finance which proposed and implemented three rounds of reference pricing for pharmaceuticals. Slovakia is one of the first countries to have implemented this reference pricing system. The system compares the six lowest prices in the European Union, takes the average, and sets prices in Slovakia accordingly. "This approach should bring about important savings which can be redirected towards new drugs with proven effectiveness", said a spokesman from the Ministry of Health. The first three referencing rounds have indicated that branded drugs, the top 100 drugs according to consumption, and drugs for cancer and autoimmune disorders, were the most overpriced. Referencing will continue to take place twice a year, in April and October.

Sources: www.hpi.sk and www.tasr.sk

Ireland: HSE National Service Plan 2010 approved

The Minister for Health and Children, Mary Harney, on 8 February announced her approval of the Health Service Executive (HSE) National Service Plan 2010. The Plan outlines how the HSE plans to deliver health and personal social services within its 2010 current budget of €14.069 billion. It projects service activity levels for 2010 which are broadly in line with 2009 levels. The Minister said "I welcome the fact that the Plan commits to treating people in a more effective way with no reduction in access to appropriate services. By reducing costs, and reforming the way services are provided, I am confident the HSE will deliver the services people expect and continue to improve health outcomes for the population."

The Chairman of the HSE, Liam Downey, has welcomed the Minister's approval. Despite current resource pressures, other than the changes to the delivery of hospital based care, the same level of service as 2009 will be maintained in 2010 within the context of health service reform, a rapidly changing economic environment and a climate of reducing resources. The HSE's budget allocation for 2010 includes a reduction of over €500 million in respect of pay, this is in line with government pay policy outlined in the national budget.

Acute hospital activity in 2010 will reflect the continuing shift from inpatient to day case activity, with an increase in day cases of 6.5% and a targeted reduction in the level of inpatient care provided of 5.6% over the 2009 targets. This will be achieved through a combination of continued re-

form in how health services are delivered through measures such as minimising length of stay in hospital and more day case procedures. Alternatives for people, who at present have to be admitted to hospital though emergency departments (ED) for very short hospital stays, will be met through the provision of more services within communities. The emphasis is on a continued move towards treatment on a day case basis where this is clinically safe and in line with international best practice.

While the number of people who visit an ED in 2010 is expected to remain constant, the HSE intends to reduce the numbers who are admitted through EDs by 33,313. This will be achieved by increasing access to the specialist skills and senior clinical decision making available in EDs and in current and planned Medical Assessment Units, which will mean that people do not need to be admitted to hospital unnecessarily. In addition, by increasing access to diagnostics for the 10,000 people who are admitted to hospital annually solely for this purpose, the reduction in admissions can be achieved in 2010.

Speaking about the Service Plan, Professor Brendan Drumm, Chief Executive Office of the HSE, said "our challenge this year is to keep on enhancing the quality of the services we provide, which can only be achieved by improving our effectiveness and in so doing, reducing costs".

The National Service Plan 2010 can be accessed at www.hse.ie/eng/services/Publications/corporate/NSP2010.html

England: Better NHS access to drugs and treatment for very rare conditions

Patients with very rare conditions will be given access to drugs and services not previously available on the national health service (NHS) in England, Junior Health Minister Mike O'Brien announced on 19 March 2010.

The proposals follow two consultations and mean that a small number of drugs and treatments for very rare conditions, that are not yet appropriate for the National Institute for Health and Clinical Excellence (NICE) appraisal process, can now be considered for use in the NHS.

Access to these drugs and services will be increased through two initiatives that are supported by patient groups, NICE, the NHS and industry. The first is the creation of a three-year £25 million (€27.8 million) Innovation Pass pilot, as outlined in the Office for Life Sciences (OLS) Blue-

print, to help patients with rarer diseases access highly innovative new drugs which are not yet appraised by NICE. The OLS Blueprint, published in July 2009, put forward a package of measures to help maintain a competitive life science sector in the UK.

A Government notice of procurement will be published in the Official Journal of the European Union formally inviting expressions of interest for the pilot. Drugs included on the Innovation Pass pilot scheme will be licensed and NICE will play a key role in developing and applying the drug eligibility criteria for the Innovation Pass. All drugs included on the pilot will be submitted for NICE appraisal at the end of the three years.

A new expert advisory group will be set up to strengthen existing arrangements for commissioning services nationally for extremely rare conditions and to ensure that the system is more transparent and robust. The group will have a wide range of expertise to take into account both clinical and commissioning issues when assessing all treatments to be funded nationally. It will replace the National Commissioning Group in its current form, incorporating the strengthened system.

Minister O'Brien said that he was extremely pleased to see support for proposals that will make a real difference to patients with very rare and extremely rare conditions by helping improve access to drugs and services not previously available to them. "Exciting, innovative new drugs which will be included in the Innovation Pass pilot scheme will mean that, with the help of NICE, the small number of patients suffering from rarer diseases will be able to get access to a wider range of drugs and contribute to the collection of important data on their impact."

More information available at www.dh.gov.uk/en/MediaCentre/Pressreleasesarchive/DH_114325

England: NHS to provide more services at home

Measures to shape NHS services in England around individual patients were set out on 18 February by Health Minister Andy Burnham. Transforming how the NHS treats patients with long-term conditions, by providing more support in people's homes and local community settings, means that people are able to better manage their health and avoid unnecessary hospital visits. The Department of Health

have estimated that improvements in the management of long-term conditions have already led to efficiencies and savings of £2.1 billion.

Focussing on providing care at home can also have a significant impact for social care. A report published on 18 February by the Audit Commission indicated that older people who have the opportunity to be looked after in their own homes if they want, are happier and there are less costs to the taxpayer. There are already examples of how being innovative can have significant outcomes and save money – for instance, for the cost of just one month’s care package a home can be equipped with sensors and pagers to help a family look after a relative with dementia. Other measures include providing more services at home for children and young people who have acute or long-term conditions or disability or palliative care needs, and giving more people the option to die at home if they wish to.

More dialysis at home and chemotherapy in the community would mean patients can benefit from more convenient services that help produce better outcomes and can be more efficient. Around 7,000 patients across England could benefit from home dialysis. Providing haemodialysis at home means that patients can tailor their dialysis sessions around their lifestyle, which can lead to benefits such as better blood pressure control, fewer admissions to hospital and less reliance on medication. As well as benefits to patients, the annual costs of home haemodialysis could be up to 25% less than providing dialysis in a hospital or renal centre, and can lead to long-term savings once initial set-up costs are recovered.

Health Minister Andy Burnham said that “the time has come for the NHS to make a decisive shift in providing more care out of hospitals and in the patient’s community and home. For too long, services have been organised to fit the convenience of the system. A great NHS will put the convenience of the patient first, and move services towards them where it is safe to do so. But care in the home can also achieve better results and save money.”

Jane Macdonald, President of the British Renal Society and Lead Nurse for Renal Services at Salford Royal Foundation NHS Trust said that the need for long term dialysis undertaken either thrice weekly or in some cases daily has a significant impact on the lives of dialysis pa-

tients, their families and carers. To be offered the choice, if clinically appropriate, to undertake dialysis at home is a major factor in eliminating frequent travel, maximises time spent with family, and plays an important role in remaining in employment.”

The Department of Health has also published a guide for the NHS on developing chemotherapy services closer to home. Giving cancer patients the option of having chemotherapy at or closer to home where clinically appropriate, can benefit patient experience and contribute to better outcomes. This follows the recent announcement that all cancer patients will have one to one support within five years.

Children and young people who have acute or long-term conditions, or disability or palliative care needs, should be able to spend less time in hospital and receive care at home or in the community instead. Providing services for children and young people at home can mean fewer unplanned visits and shorter stays in hospital, reducing distress for children, young people and their families.

As a next step, the Department of Health will be publishing the final version of the National Framework for Children and Young People’s Continuing Care very shortly. This will help in assessing the continuing health care needs of children and young people, and in considering the bespoke packages of care that will be required to meet those needs. The Health Minister also confirmed plans to review progress on End of Life Care by 2013, with the intention of setting out proposals for a right to choose to die at home in the future. The non-governmental organisation, Marie Curie Cancer Care, is already piloting a range of models through their ‘Delivering Choice’ programme.

More information at www.dh.gov.uk

Spain: New law permits abortion without restriction up to 14 weeks

On 24 February the upper house of the Spanish Parliament voted in favour of legislation permitting abortion without restriction up to 14 weeks into pregnancy. The Senate approved the law tabled by Prime Minister Jose Luis Rodriguez Zapatero’s Socialist government with 132 votes in favour, 126 against and one abstention.

The law had already been approved by the lower house of Parliament in December 2009. The expansion of legal access to

abortion – which takes effect in June 2010 – is part of a comprehensive law aimed at improving universal access to sexual and reproductive health services and information, especially for young people. The new law grants 16- and 17-year-olds abortion access, provided that they notify at least one parent or legal guardian. Notification is not required if they believe it would result in “domestic violence, threats, coercion, abuse, or a situation of uprooting or helplessness.” It also allows abortion up to 22 weeks if there is a serious risk to the health of the mother or if the foetus has serious abnormalities.

Spain’s new law also requires that public policies related to health, education and social issues promote universal access to sexual and reproductive health services and programmes – including family planning services – and makes comprehensive sexuality education mandatory in schools. Additionally, it requires public health facilities to provide pregnancy-related care and effective family planning methods to all women and their partners.

Since 1985 abortion has been decriminalised in Spain, but only in matters of rape, or when the health of the child or mother is at risk. Abortions have doubled in the past decade in the traditionally Roman Catholic country, from nearly 54,000 in 1998 to 115,000 in 2009. The law faces strong opposition from Catholic and pro-life groups and from the conservative Popular Party, the main political party in the opposition. Popular Party leaders have announced that they will repeal the new law if they win the next election.

Scotland: Free prescriptions a year away

Further progress towards abolishing prescription charges in Scotland will benefit 600,000 people in low-income households. Regulations introduced to Parliament recently will see prescription charges fall to £3 (€3.34) from April 2010, if approved, on the road to full abolition in 2011.

Around 600,000 adults in households with an income of less than £16,000 (€17,800) are benefiting from the reductions, with hundreds of thousands more on modest incomes also finding prescriptions more affordable. Since the first reduction in charges in 2008, sales of Prescription Pre-Payment Certificates bought by people with long-term conditions who need medicines over a period of months have soared by more than 150%. In the first six months of the 2009/10 financial year

alone, 236,000 were dispensed, compared to just 93,000 in the same period of 2007/08.

The regulations to further reduce prescription charges from £4 to £3 (€4.45 to €3.34), which will also see four-month and twelve-month Prescription Pre-Payment Certificates fall from £13 (€14.47) and £38 (€42.31) to £10 (€11.13) and £28 (€31.17) respectively, were introduced to Parliament on 6 January 2010. The Health Committee were expected to vote on the regulations in February. Under Parliamentary rules, the regulations must remain in Parliament for 40 days, during which time any Member of the Scottish Parliament can lodge a motion suggesting the proposals are rejected by Parliament.

Speaking ahead of her appearance at the Health and Sport Committee on 3 February 2010, Public Health Minister Shona Robison said “we’re committed to scrapping prescription charges and removing this tax on ill-health, which hits those on low incomes hardest. We want our national health service to be restored to its founding principles – free at the point of delivery and based on clinical need, not ability to pay.” She added that “with Scotland’s record of ill-health and our appalling health inequalities, it’s vital that we do all we can to help people get the health help they need – not put further financial hurdles in their way.”

Germany: Tension over health care reforms in coalition government

On 17 March, under the auspices of the Federal Health Ministry, the first meeting took place of the new Government Commission on the Sustainable Financing of Health and Social Care. The Commission, which consists of eight government ministers, must put forward proposals on reforms to the insurance system at a time when the country must contend with ever increasing costs and, according to the German Federal Insurance Office, an estimated €15 billion deficit in funding by 2011. Overall German health care costs are estimated to be some €250 billion per annum.

Germany’s health care system instituted a new universal premium in January 2009. Set at 15.5% of an individual’s gross pay, it has turned out to be insufficient to maintain the budgets of the country’s statutory insurers. Many have begun putting extra fees on subscribers.

Major proposals for reform have now

been set out by Minister of Health, Philip Roesler of the junior coalition government partner in 2011, the Free Democratic Party (FDP). Controversially he has proposed a flat rate contribution to health insurance irrespective of income. The system would break the link between health costs and labour costs. Keeping control of Germany’s high labour costs has formed a key part of recent government efforts to bolster the nation’s international economic competitiveness.

Under the plan, the state would also subsidise the contributions made by the less well off, and anyone wanting more than the basic coverage could then top up with private health insurers. But critics have warned that the reforms would mean a two-class health system with patients covered by basic insurance forced to pay for extra treatment out of their own resources.

Combined with tensions over tax cuts, Roesler’s proposals have led to cracks emerging in Chancellor Angela Merkel’s conservative-led coalition. Horst Seehofer, who heads up Merkel’s Christian Democrats’ (CDU) associate party, the Bavarian-based Christian Social Union (CSU), has threatened to veto the move to replace the existing wages-linked contributions scheme with a flat contribution. Despite support for the Roesler reforms emerging from the ranks of Merkel’s CDU, Bavarian CSU Health Minister Markus Soeder dismissed the proposal for a flat-rate contribution as “unfair and unaffordable”.

Defending the proposal however, Volker Kauder, parliamentary leader of the CDU party, emphasised the need to implement a health care premium, explaining that this was agreed as part of the coalition agreement. German Chancellor Angela Merkel has also provided her support for the Health Minister, and has urged the coalition to put an end to the futile bickering and feuding, and to allow the government’s commission time to carry out its role.

Other mooted reforms include a plan that pharmaceutical companies should negotiate prices for pharmaceuticals with the health insurance funds. This the Minister contends could reduce the costs of pharmaceutical expenditure by €2 billion per annum. The German daily newspaper *Süddeutsche Zeitung* also ran a story on 20 March, suggesting that the government may impose a three year freeze on the price of pharmaceuticals. The price freeze

on drugs would be put in force quickly, according to the *Süddeutsche Zeitung* report. Mandatory discounts and a broad comparison of German medication prices with the international standard would begin next year.

The government’s commission is due to present its proposals in the summer, in order that the anticipated reform can take effect from 2011.

More information on the work of the Commission is available in German at www.bmg.bund.de/cln_178/nm_1168682/DE/Gesundheit/Kommission/kommission__node.html?__nnn=true

Poland: plans for electronic health cards announced

In an effort to radically reform and improve the national health system the Polish government is planning to introduce an electronic health management system, which it is claimed will facilitate easier access to health care services.

The main directions for the development of e-Health have been set out in the *e-Health Strategy for Poland 2009–2015*. The e-Health Strategy includes four main objectives: facilitation of the access of citizens to information on health care; improvement in the effectiveness of electronic documentation flow; modernisation of the health services demand analysis system; and the establishment of an ‘interoperational’ electronic health record.

Starting in 2013, Poland will embark on issuing every citizen with an electronic health card that will contain information about their health condition, medical diagnosis and any prescription given. The medication data will be capable of being read at a pharmacy, thus reducing risks arising from the difficulty of reading a doctor’s handwriting. A draft law on information systems in health care is being prepared. It will constitute the basis of a stable information system and help clarify issues related to collecting, processing and using information.

The new system is expected by the government to yield savings of about 4 billion zloty (approx. €1 billion) on an annual basis. They claim it will eliminate phenomena of identity fraud. The reforms are expected to cost 800 million zloty (approx. €197 million), 85% of which will be financed with EU support.

News in Brief

Former WHO Regional Director for Europe Dr Jo E. Asvall dies

It was announced with great sadness that Dr Jo Eirik Asvall, the WHO Regional Director for Europe from 1985 to 2000, died on 10 February 2010. Born in Norway in 1931, his time as Regional Director was spent promoting and implementing the Health for All strategy in the Region. This called for a fundamental change in countries' health development and outlined four main areas of concern: lifestyles, risk factors affecting health and the environment, the reorientation of health care systems and the political, management, technological, human resources, research and other support necessary to bring about the desired changes in the first three areas.

Remaining active during his retirement, his last public engagement was at the WHO Regional Office for Europe in January 2010. "WHO was his life, his world, his passion. He was a true leader in European health policy and public health. We owe him so much," said WHO Regional Director for Europe, Zsuzsanna Jakab. Dr Asvall is survived by his wife, Kirsten Staehr Johansen.

Tributes can be sent by email to condolences@euro.who.int

Up to 40% of cancer cases could be prevented, says WHO

Marking World Cancer Day on 4 February 2010, the WHO Regional Office for Europe highlighted the importance that changes in lifestyle and improved prevention and screening policies can have in preventing up to 40% of all cancer cases.

It was noted that people can significantly reduce their cancer risk by avoiding risk factors (such as tobacco use, heavy alcohol consumption, excessive sun exposure and obesity) and adopting healthier lifestyles. Moreover, as cancer incidence rates continue to rise, governments have a crucial role in raising awareness and putting in place comprehensive early detection measures.

"Well-conceived, effective national cancer control programmes are essential to fight cancer and to improve the lives of cancer patients," said Zsuzsanna Jakab, WHO Regional Director for

Europe. She urged governments to "rigorously implement the four basic components of cancer control – prevention, early detection, diagnosis and treatment, and palliative care."

More information on World Cancer Day at www.worldcancercampaign.org/

European Quality of Life Survey: Subjective well-being in Europe

Drawing on findings from the second European Quality of Life Survey carried out by the European Foundation for the Improvement of Living and Working Conditions in 2007, a new report explores factors that give rise to a feeling of satisfaction with one's life and how these vary from country to country.

Written by Dorothy Watson, Florian Pichler and Claire Wallace, the report looks at different aspects of an individual's life – such as income, age, employment, marital status and health – and their impact on quality of life. In doing so it gives a wide-ranging picture of the diverse social realities in Europe today.

The report is available at <http://www.eurofound.europa.eu/pubdocs/2009/108/en/1/EF09108EN.pdf>

Scotland: Alcohol abuse costs every taxpayer £900 a year

A new report, commissioned by the Scottish Government and authored by a team from the University of York, has revealed that alcohol misuse could be costing Scottish taxpayers up to £4.6 billion a year in costs to health and social welfare services. The report indicates that crime-related costs resulting from alcohol misuse can be as much as £727.1 million, while the human costs caused by suffering through premature death were estimated to be £1.46 billion.

The report is available at www.scotland.gov.uk/Resource/Doc/297819/0092744.pdf

European Medicines Agency consultation

The European Medicines Agency is engaged in a public consultation on its future strategic vision, set out in the document *The European Medicines Agency Road Map to 2015: The Agency's contribution to Science, Medicines,*

Health. Building on the achievements made by the previous Road Map initiative between 2005 to 2010, the focus of the new Map is on continuous high-quality delivery of the Agency's core business in an increasingly complex regulatory and scientific environment. In addition, the document proposes three priority areas – addressing public health, facilitating access to medicines, and optimising the safe use of medicine – for future actions to strengthen the Agency's role in protecting and promoting human and animal health in the European Union. Comments on Road Map should be sent to the Agency by 30 April 2010.

More information on the Road Map and consultation at www.ema.europa.eu/btms/general/direct/roadmap/roadmapintro.htm

Snapshot on the health of women

A new report prepared for the European Commission by the Faculty of Medicine Carl Gustav Carus, the Research Association Public Health Saxony and Saxony-Anhalt, the Technische Universität Dresden, Germany, provides a snapshot of the health of women across the EU and some additional countries in the European Economic Area.

Key findings include the recognition that breast cancer remains the most common form of cancer and cancer-related death amongst women. Depression, Alzheimer's Disease, arthritis, osteoporosis and diabetes are also of concern. The report concluded that, despite much work in recent years, not enough reliable and relevant data is available by gender. It recommended more investment in the implementation of standardised gender-specific data collection across the EU.

The report is available at http://ec.europa.eu/health/population_groups/docs/women_report_en.pdf

Additional materials supplied by
EuroHealthNet
6 Philippe Le Bon, Brussels.
Tel: + 32 2 235 03 20
Fax: + 32 2 235 03 39
Email: c.needle@eurohealthnet.eu

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