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Contents

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Evidence-based medicine: A commentary

Walter Holland

Introduction

Almost every medical publication every week has an article devoted to evidence for, or against, some form of practice. Recent examples include evidence based well child care,[1] and experts versus evidence in hernia surgery.[2] Managers, politicians and journalists have become familiar with the term and concept of evidence-based medicine (EBM) – and now ask for evidence before advocating action. The movement for EBM has many advocates, some with great charisma, but the concept of EBM is not new and it is often forgotten that it is of limited application. Furthermore, for many areas of health policy it is forgotten or disregarded.

Ancient history

In the distant past, most medical knowledge was based on empirical evidence and religious beliefs – the former often based on sound, careful recording of observations. Examples of experimental evidence, such as the circulation of the blood described by Harvey in the 17th century, and the preventative efficacy of smallpox vaccination by Jenner in the 18th century, were in fact rare until the 19th century. The second half of the 19th century saw the flowering of the development of the scientific basis of medicine, largely through the isolation of bacteria (i.e. tubercle and cholera), which enabled hygienic principles to be developed for the prevention of these common scourges. Their treatment, however, had to wait on the development of chemotherapeutic agents and antibiotics in the 20th century.

With the developments in biochemistry, physiology and physics, physicians became interested in understanding the mechanisms of disease processes and thus understanding how changes in the various bodily systems could be modified to correct certain abnormalities, for example circulation in view of cardiac failure, endocrine deficiencies, or electrolyte disturbances. This enabled more rational methods of treatment to be introduced and a better understanding of the causation of some signs and symptoms. Eminent physicians such as Thomas Lewis led this development in the United Kingdom (UK). It was a great advance on the old anecdotal, observational methods used by most medical practitioners. It should also not be forgotten that before the middle of the last century (1960) post-mortems were performed on most patients dying in hospital in the UK, and it was expected that doctors attended the post-mortem of their patients to learn of errors in diagnosis and obtain a better appreciation of the pathological consequences of their observations/diagnoses.

Recent history

With the enormous advances in the development of effective drugs (i.e. antibiotics), better methods of diagnosis (i.e. imaging techniques), and understanding of metabolic disturbances as well as of surgical procedures – aided by the better anaesthetic techniques

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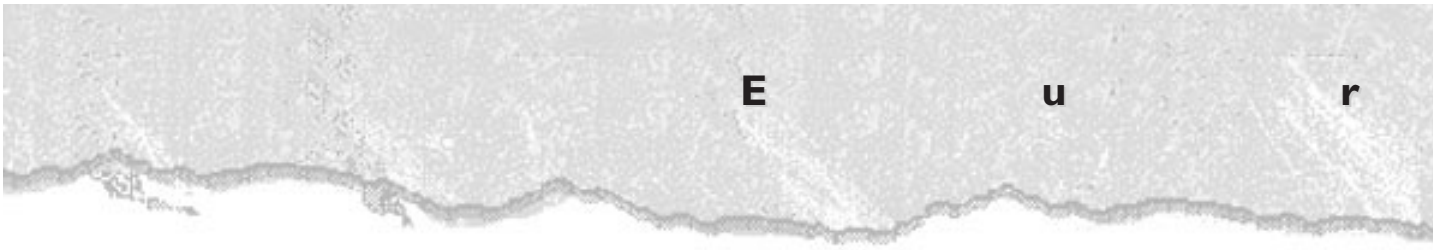

as well as new technical instruments (i.e. laser) – the possibilities for treatment and care became far greater.

The methods of the randomised controlled trial (RCT) introduced by Bradford Hill in the late 1940s for the treatment of pulmonary tuberculosis with streptomycin, enabled doctors to have far more reliable information available about the possibilities of treatment (as well as diagnosis) than case studies, or experience of treating 'suitable' patients which they had previously relied on. Professor Archie Cochrane, an eminent epidemiologist, in his Rock Carling Lecture in 1973 commented on the need for adequate scrutiny of medical procedures and making such critical summaries widely available.[3] As a result of these advances in knowledge the practice of medicine achieved a more rational basis, and methods of treatment and diagnosis became far more precise.

The growth in knowledge was accompanied by a great proliferation of medical publications. Since many trials are often performed on patients with similar conditions, and may lead to divergent results, statistical methods of analysing the meaning of such trials – in relation to treatment – have been developed (meta-analyses). The process of reviewing evidence has also been the subject of development with rules for analyses of published data (critical analyses) and systematic reviews on a subject – based on a comprehensive rather than selective choice of published information.

These changes and advances have been well summarised by Sackett and his colleagues.[4] There are, however, problems with EBM. Reliance on the RCT as the 'gold standard' for evidence of effectiveness is appropriate, but it is crucial to recognise that a RCT can only answer a specific, well-defined question. Moreover, it is time-consuming and resource intensive. There is, furthermore, a difference in the results obtained when the results of a RCT are applied in routine practice. It is thus essential to distinguish the results of a pragmatic trial from that of an experimental trial. Meta-analyses also have their problems, as do so-called systematic reviews. Both depend on exhaustive knowledge of the condition under scrutiny and valid, comparable data designs in the investigations. Unfortunately these prerequisites are not always met, so that some meta-analyses and systematic reviews are of inadequate quality. Of equal importance in the application of EBM is the proper search and appraisal of evidence. A recent study has shown that this does not always occur.[5]

Problems

The discipline of EBM has been accepted by most practising clinicians. It is thus unfortunate that the need for proper decisions has not been equally applied. There are innumerable examples of changes in policy or management that have been introduced on the basis of the opinions or feelings of policy-makers without consideration of either past experience or facts; not to mention without the benefit of proper evaluation which might provide guidance. Examples in the UK include fund-holding in general practice, the introduction of primary care trusts, and the abolition of district health authorities. The advent of EBM has been particularly welcomed by policy-makers who considered that this enabled them to make more rational policies. Unfortunately, in practice, the problem is more complex. Two recent events in the UK illustrate this from the policy perspective.

Breast cancer is the commonest cause of cancer in women. Mammography screening has for the past ten years been considered an important method to reduce women's breast cancer mortality. This was based on the findings of seven randomised-controlled trials. But a recent systematic 'Cochrane' review has questioned this based on a re-analysis of the data provided by the seven randomised controlled trials and upon which current policy is based.[6] This thorough review concluded that the studies were of unequal merit. Although the number of mastectomies and tumourectomies is increased when women are screened, no evidence was found for a reduction in either 'all cause' or 'all cancer mortality'. The authors also emphasise that flawed studies lead to exaggerated claims of benefit. The Department of Health (DoH), presumably for political reasons, continues to insist that this programme saves lives. A possible reason for this discrepancy in interpretation is that the programme is shown by the Cochrane reviewers to increase the number of breast operations.[6] The DoH interprets this as an improvement in prognosis – a jump in logic which the reviewers show to be wrong. Furthermore, although breast cancer mortality in women aged 55–69 has fallen by 21 per cent in the period 1990–98, there is no hard evidence that this can be attributed to mammographic screening.

Another recent example is the treatment of multiple sclerosis (MS) with Beta-interferon. The National Institute of Clinical Excellence (NICE), the body that advises on the clinical and cost-effectiveness of drugs, has recommended that Beta-interferon should not be funded by the NHS as they could not identify significant health benefits. At the same time the Department of Health has "confirmed that it is in discussions with four manufacturers of Beta-interferon and related products, as well as other stakeholders. Our discussions are looking at a range of options, including the possibility of a 'risk-sharing' scheme in which the drug would be funded for relapsing-remitting MS patients".[7] There are a number of possible reasons why the Department of Health should give a different view. The use of Beta-interferon for the treatment of MS has been the subject of a great deal of pressure from the MS Society, a patient group. Thus the use of this drug is politically highly emotive. Coupled to this is the pressure from the pharmaceutical industry which has for long advocated the use of the drug.

Final remarks

The use of 'evidence' in the practice of medicine and the formulation of health policy is welcome and crucial. It is not, however, a new phenomenon. The growth of academic knowledge has enabled practitioners to consult a far greater store of knowledge than available in previous years. But it still has difficulties in application. Most patients present

a problem or a symptom. Most academic 'evidence' is available on discrete diagnoses or syndromes. The synthesis of information is still a sapient skill. Whereas in the past we often had to rely on anecdotes or past experience, it is now possible to draw on the results of much more formalised knowledge. But it is important to recognise that this is often imperfect, misapplied, flawed or absent. It is unfortunate that the term EBM has become so evocative that we forget that most medical decisions have always been based on some form of evidence. Much more and better evidence is of course now available, but it still depends on careful, thorough collection, analysis and dissemination. And its interpretation is still subject to personal or political idiosyncrasies, as in the past!

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EU accession – is it healthy?

Elke Jakubowski and Laura MacLehose

Countries in the WHO European Region came together to discuss prospects for health in relation to enlargement of the European Union (EU) against the backdrop of the 51st session of the WHO Regional Committee for Europe, held on 11 September 2001. This was one of a number of other high profile meetings, such as the Gastein European Health Forum, where health issues arising from the enlargement process were also discussed. Twelve countries in the WHO European Region as well as Cyprus are among the current 'candidate countries' for EU membership (see Box). The enlargement process will increase the population of the EU by millions.[1] It will also bring together a very diverse range of health systems, with different structures, population health profiles, and levels and methods of funding. For candidate countries the potential health impacts of enlargement are wide-ranging, reflecting the broad range of new legislation that they must adopt as part of the accession process. There are also implications for the existing member states, and enlargement has encouraged many to take a further look at the existing body of EU legislation relating to health to assess whether it will meet the needs of a much larger and more diverse community.

CANDIDATE COUNTRIES IN ACCESSION NEGOTIATIONS FOR THE EUROPEAN UNION

Bulgaria

Cyprus

Czech Republic

Estonia

Hungary

Latvia

Lithuania

Malta

Poland

Romania

Slovak Republic

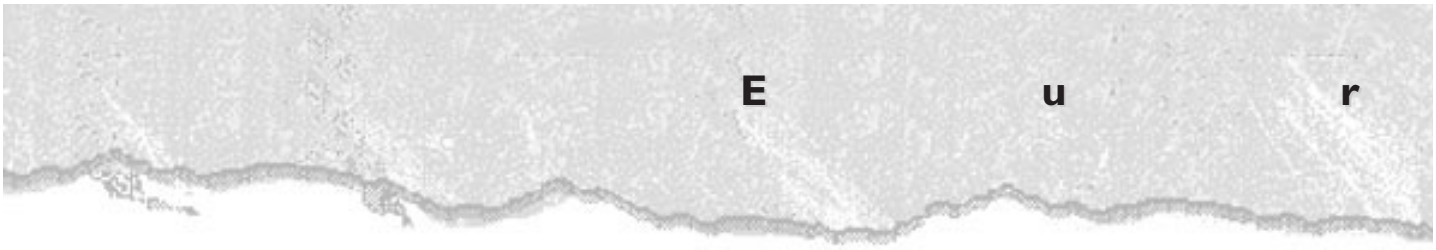
Slovenia

Turkey

Accession to the EU is conditional on countries complying with the 'Copenhagen Criteria'. The criteria cover the three areas of guaranteeing democracy, establishing a market economy with the capacity to cope with competitive pressure from forces of the internal market, and being able to take on the obligations of membership, including political, economic and monetary union. Countries must also adopt and implement all existing EU legislation which, in its entirety, is known as the *acquis communautaire.*

As the *acquis* is continually developing, completely adopting it is perceived by some as aiming for a moving target. In 1999 it was estimated that the total *acquis* formed about 80 000 pages.[2] It is divided into 31 'chapters' arranged by theme. For example, Chapter 23 covers 'Consumers and Health Protection'. Although health care is primarily a concern for national governments, throughout the 31 chapters there is an abundance of legislation which is either directly health-related (such as laws on blood products) or is likely to have an impact on health or health care arrangements (such as legislation on free trade).

Accession countries are working through the different chapters to bring their national legislation into line with EU requirements. They are assisted in this process by the European



Commission through the 'Europe Agreements', 'Accession Partnerships', 'National Programmes for the Adoption of the Acquis' (NPAAs), and with financial support from the EU PHARE and other EU programmes.

Although health care is generally the preserve of national governments, an explicit basis for EU action in the field of public health first emerged in Article 129 of the 1992 Maastricht Treaty. This was strengthened and replaced by Article 152 of the Amsterdam Treaty of 1997. Prior to 1992, however, there were some elements of cooperation in public health under the Treaty on the European Coal and Steel Community, the Euratom Treaty and the Single European Act.[3]

However, legislation relating to the fundamental freedoms of movement of people, goods and services, enshrined in the Treaty of Rome, has perhaps the greatest implications for health and health care. These implications, which are already a matter of concern amongst the current EU member states, are magnified as the EU begins the enlargement process. Indeed, questions such as: 'will more patients try to seek health care in other countries?'; 'what will the trends in health care professionals movement be after enlargement?'; and 'are the arrangements for cross-border communicable disease control adequate across the new enlarged EU?', have already arisen.

Movement of patients

Arrangements for EU citizens travelling in other member states to access emergency care have been established for some time. However, the right to travel to other member states for non-emergency health services (and be funded by their national health service or insurance fund) has long been uncertain.

Two 1998 rulings by the European Court of Justice clarified some issues.[4,5] A more recent Court ruling on accessing services in other member states has further clarified the patient movement issue although questions still remain.[6] This decision (12.07.2001) established that medical care provided in hospital is subject to European law on the free movement of services, regardless of the method of payment for the service. Although movement of patients between countries continues to be small, there is clearly potential for wide-scale patient movement between member states. The movement of patients across borders is therefore a key issue for those involved in health and enlargement.

Some candidate countries have expressed concern that the flow of their patients to existing EU countries may increase costs falling on their health insurance systems. Figures from 1999 showed that per capita real health spending in the EU was over EU €1 500 while it was below EU €300 in the then ten candidate countries. Yet, at the same time, some candidate countries see the benefits of reverse movement. For instance, some may be able to offer certain specialist services at a more favourable price than is presently obtainable in current member states. Along several border regions between the EU and candidate countries there is already evidence of movement for dental care, in particular, from Austria to Hungary.

Although some cross-border travel for health care is now allowed under EU legislation, the issues are complex and many remain unresolved. Health care systems differ in respect of payment and financing mechanisms (in some, one pays at the point of service, in others it is free at the point of care, and some have insurance financing mechanisms while others are tax-funded). Different health care systems also offer different levels of benefits and these are often determined by the level of funding of the system. As the EU enlarges, the need to resolve some of these issues raises questions about what is covered by different countries.

Professionals on the move?

Under EU legislation, EU citizens have the right to work in any EU member state and have their professional qualifications recognised. The enlargement of the EU will add many thousands of health care professionals to the current EU total. Several factors make the health care movement issue of key interest in terms of enlargement.

First, several of the existing member states have severe shortages of nursing and medical staff. These may be exacerbated by the Working Time Directive, which will limit hours worked.

Second, the wages of medical staff in the current member states far exceed those in most accession states.

Third, in most countries the tax-payer funds the training of health care professionals. Will enlargement attract health care staff from the candidate countries towards the current EU member states? Will countries that train few medical staff be able to recruit staff from other countries that have invested more in training? Will some countries lose the incentive to train medical staff altogether? Will lower priced services in some candidate countries put some specialists in current EU member states out of business?

These issues are amongst many which remain to be resolved and clearly pose challenges for health policy-makers in both current member states and candidate countries.

Public health

Joining the EU requires new members to take on a raft of health and safety legislation and to participate in some communicable disease surveillance arrangements. For some countries, taking on the EU legislation will help raise standards for worker and consumer safety. Yet for others, who already have stricter legislation than that required by the EU, there are concerns that joining will lower standards in some areas.

Finland, which joined the EU in 1995, provides an example of a country which has had to relax legislation as part of its accession process. Prior to joining, the government had put in place a restrictive alcohol policy which at the same time raised substantial amounts of funds for the national budget (between 5 per cent and 8 per cent). As part of the accession agreements, Finland had to relax its price controls on alcohol. It was given around six years to achieve this. In the coming

year, alcohol prices in Finland will be lowered substantially. Alcohol consumption in Finland is currently one of the lowest in the EU. However, it is highly likely that the decrease in price levels will result in increased consumption, leading to additional deaths annually, with wider consequences for the country's social and welfare structures.

Enlargement of the EU brings about important challenges for communicable disease control. Enlargement will result in the increased movement of people and goods across borders. In candidate countries, as in current EU member states, communicable disease surveillance and control is based on national systems. Yet, connected outbreaks may occur in more than one country (for example, through a contaminated food product sold around the EU).

Detection and prevention of outbreaks crossing borders depends on rapid and effective international cooperation, common case-definitions, laboratory procedures, investigation and control procedures. In 1998 it was decided that EU member states would cooperate in international disease surveillance and control through a 'network approach' – a computerised linkage of technical experts and laboratories in each of the member states. These networks have already started to produce benefits, detecting outbreaks that might otherwise have been missed.[7]

Communicable disease prevention is dependent to a large extent on the 'weakest link' in a free trade and movement zone. In the light of recent bioterrorist activities in the United States, the need for high quality national surveillance and control standards, based on effective international cooperation, has been reinforced.[8] The challenge now is to ensure that all candidate countries are supported technically and financially to enable their surveillance and laboratory systems to join in EU networks as soon as possible.

The potential impact of enlargement on levels of mental health has been raised by some commentators. It is estimated that in the rural populations of Hungary and Poland, only between one out of five and six citizens currently employed in the agricultural sector will be able to remain in this employment. The great majority will face major upheaval in their lifestyle and financial security, posing new pressures on their mental health.

What's next?

The candidate countries have been undertaking a large amount of work in preparation for accession. Some may join the EU as soon as 2004. The implications of enlargement for health are unclear. But as this short summary of some of the issues arising has shown, there remains much work to be done to ensure that the process brings benefits to the population of the new EU rather than problems.

To date the EU has tried to steer clear of becoming involved in health care policy. Yet, at the same time, a European health policy is evolving, albeit in a piecemeal fashion from disconnected rulings of the European Court of Justice. As discussed in a recent editorial by Mossialos and McKee, countries must now decide whether they wish to leave health policy-making in the EU to the courts or whether they want to address the policy issues directly.[9] As the enlargement process speeds up, it remains a challenge to ensure that policy-making across the EU effectively addresses the health needs of its population.

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In a study entitled 'Health and EU Accession: Managing the Transition', the European Observatory on Health Care Systems is looking at some of the health and accession issues highlighted here. For more information about the study, or to suggest contributions, please contact Laura MacLehose at the London School of Hygiene & Tropical Medicine; mail to: accession-study@lshtm.ac.uk or Telephone: +44-207-612-7808.

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Dubrovnik Summer School 2001:

'Public Health and Health Services: Managing the Interface'

Laura MacLehose

Delegates and teaching faculty at the Dubrovnik Summer School 2001

Eighty participants from twenty-seven countries attended the Observatory Dubrovnik Summer School 2001 which was held at the Hotel Croatia, Cavtat, between Saturday 25th August and Thursday 30th August 2001. The course theme was 'Public Health and Health Services: Managing the Interface' and was run by the European Observatory on Health Care Systems with the Andrija Štampar School of Public Health (Zagreb). The Summer School was funded by the Open Society Institute (OSI), New York, and supported by the partner organisations of the Observatory. The Health Development Agency of England also provided valued financial assistance.

The Summer School aimed to look at the links between the health service and public health sectors and to investigate if and how they can be improved. Teaching was carried out through lectures, group work exercises and an integrating 'mini-project'.

The programme began with an overview of health status and health systems in the European region and an introduction to the concepts of linkages between public health and health services. Lecture and group-work sessions then introduced the issues and methods of health needs assessment. The role of evidence in developing more effective health strategies and policies was also reviewed and this was complemented with a demonstration of the Cochrane Collaboration database. The course modules also looked at policy strategy: how to get hidden or less well known, but important, issues onto the health agenda and strategies for promoting a common public health agenda. The latter theme was usefully explored through two sessions on reporting the health of a population and developing health targets. Two lectures and a group exercise covered stakeholder analysis and involvement issues, and were accompanied by a case study from Latvia to highlight some of these stakeholder issues. The Summer School programme also touched on cost issues in developing a health strategy, complimented by a case study from Croatia. The session on 'health impact assessment' then focussed on the influence on health of non-health policies. Bringing together many of the issues and concepts covered in previous modules, there was a presentation session on a successful regional public health strategy in Spain. The course concluded with a look to the future and considered what issues new developments in genetics may pose for public health and health services.

The Summer School programme was complemented by three parallel sessions of participant presentations. Twenty-two excellent presentations were given on a range of topics under the general themes of health care reform, health needs assessment and health financing. In addition, a number of informal sessions occurred during coffee breaks and over lunch. These included a session on accessing the resources of the Observatory and an additional session on the Cochrane Collaboration data availability.

The venue of Cavtat, near Dubrovnik, provided both excellent course facilities and beautiful surroundings for informal activities. As part of the course activities, participants visited the city of Dubrovnik and Lokrum island. The annual staff versus students water-polo match also took place again in the Cavtat harbour. With a little assistance from the local Cavtat champion team, the staff team managed to fend off the strong participant team!

We are very pleased that the end-of-course evaluation showed a high level of satisfaction with the programme. Overall satisfaction with both course content and practical arrangements was high with 95 per cent of participants being either very satisfied or satisfied with the lectures and 97 per cent saying that they would recommend the course to others.

For further details on the Observatory Summer School 2002 programme and how to apply, please check the Observatory web-site: http://www.observatory.dk where information about the programme and scholarships will be available from January 2002.

Volume 3

Rapid transformation in Romania: Changes and challenges

Wendy Wisbaum

The Romanian health care system has undergone—and is still undergoing—rapid transformation, and health sector reform is part of the country's broader transition to political pluralism and a market style economy. The changes which have taken place to date largely reflect the country's history and influences by different actors.

History of the health care system

Romania has a long history of organised health care. For four decades, from 1949-1989, there was a *Semashko* health system, characterised by government financing, central planning, rigid management and a state monopoly over health services. The private sector had been abolished and all health professionals were salaried civil servants. In 1983, out-of-pocket payments were introduced for some services, but all services were still provided in state-owned facilities. The lack of competition, poor quality of health services, under-funding, inefficiency, inflexibility and inadequate health care equipment and facilities led to increasing pressure for change.

With the political transformation of 1989, a period of major change began in every sector in Romania. In the health sector, changes began in the early 1990s and, starting in 1995, important laws were passed concerning the structure and organisation of the Romanian health care system. These laws established the legal framework for the shift from an integrated, centralised, state owned and controlled tax-based system to a more decentralised and pluralistic social health insurance system, with contractual relationships between health insurance funds as purchasers and health care providers.

Context for change

Many different actors influenced and shaped the process of change. With regard to health care reform, the intention was to take into account positions of all concerned agents. This led to the existence of various coordination and advisory boards which fed into the health reform strategy. An indicator of the importance of health care reform in Romania is that the country's major financial bodies were actively involved in the process. At the same time, there was direct influence on the government by numerous international bodies. The resulting changes in the health sector show clear traces of influence from these different actors, such as the World Bank with regard to primary health care, Germany with respect to the health insurance system, and the United Kingdom regarding capitation payments. Finally, there were early demands from the medical profession to increase the role of the private sector and to introduce a health insurance system.

Developing new system

The process of decentralisation and moves to diversify the sources of funding started in the early 1990s. But the big change took place in 1997, when the Health Insurance Law transformed the Romanian health care system from a *Semashko* state financed model to an insurance based system.

The main features of the insurance based system are:

- Mandatory membership, linked to employment, with contributions as a percentage of income paid in equal proportion by the employer and the insured. Free access to health insurance for children, dependants with no income, the handicapped and war veterans.
- 42 autonomous district health insurance funds, one for each of the country's 41 districts plus one for Bucharest, which collect contributions, contract services from public and private providers, and reimburse providers. There are also 2 country-wide funds: one from the Ministry of Transportation and one from ministries related to national security.
- A National Health Insurance Fund (NHIF), which sets the rules and regulations for the district funds, redistributes 25 per cent of collected funds to under-funded districts, and negotiates the framework contract

This article is based on the Observatory's Health Care in Transition Report (HiT) on Romania, published in 2000. The HiT for Romania was written by Cristian Vladescu (Centre for Health Policies and Services), Silviu Radulescu (World Bank) and Victor Olsavsky (WHO Liaison Office in Romania), and was edited by Reinhard Busse (European Observatory on Health Care Systems). The Observatory is grateful to Dana Farcasanu (Institute for Health Services Management, Bucharest), Ioan Bocsan (Iuliu Moldovan Institute of Public Health, Cluj-Napoca) and Anca Dumitescu (WHO Regional Office for Europe) for reviewing the report.

with the Romanian College of Physicians. This overall framework contract provides the basis for the district funds' individual contracts with providers, and includes such areas as the benefits package, payment criteria and procedures, and indicative proportions for the allocation of funds for different kinds of care. The NHIF and the Ministry also compile a positive list for pharmaceuticals which determines which drugs are covered by health insurance funds.

– Free choice of doctor (GP and specialist) but the insured have to register with a family doctor, an independent practitioner who privately runs his/her medical office and is contracted by the district health insurance funds.

– A mix of weighted capitation and fee-for-service reimbursement to physicians, with hospital staff on salary, and global budgets for hospitals. Reimbursement is provided on a contractual basis with no distinction (after accreditation) between public and private family doctors.

Constraints and future challenges

Like any major reform, there have been problems and obstacles and future challenges remain. Coordination of the process has been complicated, in part due to the multiple actors involved, and in part due to turnover and change (for example, between 1996 and 1998, there were six different Ministers of Health and eight different Secretaries of State, and in the first six months of 1999, there were three different Presidents of the National Health Insurance Fund). Health legislation is complex and changes frequently. At the same time, in the 1990s, Romania spent very little on health as a percentage of GDP (2% – 3.5%), and while the introduction of social health insurance was seen as a solution for addressing this, it has been limited in doing so due to problems collecting contributions.

Romania needs to find the right balance between increasing expenditure and controlling unnecessary spending through its chosen forms of reimbursement. Equity remains of concern, social care is limited, and there is still overuse of hospital care. On a positive note, during the 1990s, lessons learned and specific circumstances led to changes in the reforms, for example, amendments in the Health Insurance Law. These changes are good indicators of the country's flexibility. This ability to adapt will continue to be needed as the new system unfolds and reforms are assessed.

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