

# eurohealth

A Northern Light  
on EU Health Policy

*Finnish Presidency of  
the European Union*



The European Investment Bank and healthcare

Globalisation and public health risks

Housing – the front line in public health

Health in the "New Scotland"

Measuring the burden of disease

I am very pleased to report that there has already been a tremendous response to the readers' questionnaire included with the last issue of *eurohealth*. I would urge those of you who have not responded to send your replies in the near future as your views will be taken into account. Although the survey is not yet complete, we have received extremely positive comments and expressions of support for our goal of creating a bridge between the various players involved in developing health policy.

Such a resounding endorsement from our readers is a fitting tribute to the excellent work of Robert Wood who has now stepped down as Editor of *eurohealth*. On behalf of LSE Health, I would like to take this opportunity to thank him for the significant contribution he has made to ensure the journal's continued success. A notable symbol of Robert's achievement is the substantial increase in the readership that has taken place since he joined the Editorial Team and the positive reactions received to the changes introduced with the last issue. Robert will be leaving *eurohealth* to diversify and further his journalistic career by taking up a senior position to launch a major national publication for the British music industry. While we are sorry to lose him, we are confident that he will bring the same success to his new publication that he has brought to *eurohealth*.

I would also like to express my considerable gratitude and thanks to Govin Permanand who will step down shortly as Editorial Assistant and EU News Editor to concentrate on his PhD studies at LSE Health. Over the last three years, Govin has provided invaluable support to *eurohealth* and has established himself as an experienced and skilled editor in his own right through his central role in producing the special issue of *eurohealth* on Central and Eastern Europe. This has proved to be a resounding success and I know from the many comments received that my personal thanks and respect for his work are shared by readers and the rest of the editorial team. I wish him well with his studies.

*Paul Belcher*  
*Senior Editorial Adviser*

# eurohealth

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# Public health at the dawn of a new Millennium

*Eva Biaudet*

*Minister, Ministry of Social Affairs and Health, Finland*



With Finland assuming the Presidency of the European Union on 1st July, the main proposals in the EU public health framework established in 1993-94 have been carried out. This enables us to concentrate on future policies and actions. Before the start of the new Millennium we must discuss the most important questions regarding European Community action on public health. These include:

- giving practical effect to the new provisions in the Treaty;
- promoting a quick decision on the new EU public health programme;
- the health impact of all Community policies; and
- health beyond the borders of the present Union.

In addition, EU leaders must make the Treaty obligations to improve public health, prevent diseases and obviate sources of danger to health, more visible to European citizens. Health is a central resource for individuals and societies. We need a clear statement on the key health challenges faced by the European Union and the Member States and how they will be addressed as a priority for the Community.

The Treaty of Amsterdam strengthened the Community's powers in the field of public health in several ways. I think that the interpretation of this new situation depends more

on political will than on legalistic considerations. Giving practical effect to the amendments is a task that spreads over several EU Presidencies.

The discussion on a new health strategy has been fuelled by the Commission's 1998 Communication, and discussions in the Health Council and the European Parliament. Building on the work of the previous EU Presidencies, the development of the future strategy for public health will be a central topic for the Finnish Presidency agenda. In this context, the Presidency will draw particular attention to mental health as a key feature.

The Treaty gives new emphasis to ensuring a high level of human health protection in the definition and implementation of all Community policies and activities. For me this provision serves as a basis for a horizontal approach to health. Health should be seen as a horizontal issue in a similar way to environmental issues.

While the external dimension of the European Union is more the focus for political discussions, I do not think that health questions can be left out of this development.

## **Programme for public health**

In the Amsterdam Treaty, the scope for Community action was expanded to improving public health, preventing human illness and diseases, and obviating the sources of danger to human health. In particular, the Treaty mentions the major health scourges and provides for research into their prevention. These principles are important when designing the health strategy of the new Millennium.

The Commission's Communication on future action in the field of public health has been subject to a thorough public discussion and evaluation. The Council and the European Parliament have supported the main findings of the Commission.

The Member States advocated focused action to achieve the greatest health gains for citizens in three areas: tackling major health scourges; reducing mortality and morbidity; and fostering equality. Finland stresses that the functional and working ability of the population is especially important as life expectancy is increasing.

The Commission suggested three strands of action, which are all needed to create a balanced health strate-

gy. I think that improving information for the development of public health (first strand) should concentrate on making use of the data and translating it into practical policy proposals.

Communicable diseases respect no national boundaries, therefore, combating them is a natural part of the Community's work. The Finnish Presidency wants, as a priority, to

***"For a long time mental health has taken second place in health policy, health services and health promotion, despite the fact that in some European countries the total cost of mental ill-health exceeds 3% of GDP".***

contribute to building up the communicable diseases network that will ensure rapid reaction to health threats (second strand).

Tackling health determinants through health promotion and disease prevention (third strand) continues to be a cornerstone for improving public health in the Union. We have learned a lesson during the past five years that disease-specific programmes at European level are not effective enough. A broader approach is needed. The successful German EU Presidency conference in Potsdam suggested a focus on a limited number of broad themes. Each theme could involve a cluster of health determinants, settings of everyday life, risk factors and target groups.

The mid-term evaluation of the current EU action programmes gives us an opportunity to analyse the advantages and disadvantages of European action on various health determinants. This will give us valuable information on how the third strand needs to be structured. The Parliament called on the Community to introduce a broader health information campaign while avoiding the provision of direct health education. The Community can indeed draw attention to health issues and provide impetus. It is necessary to develop a European model of how national and regional efforts can be brought together to achieve added Community value to

national efforts. All Community activities must be based on strategic planning and the best available evidence regarding their effectiveness. As I have stated before, policy consists of norms and laws, taxation, influencing attitudes and a dialogue with businesses.

The Commission has suggested that issues related to EU enlargement and to the health impact of all

not be promoted or mental ill health prevented. As a public health concern, I think that mental ill health is clearly as serious as physical ill health.

In 1998, Council emphasised both the physical and mental aspects when it discussed how to achieve the maximum health benefit for citizens. The European Parliament highlighted mental health during its public hearing on public health and in its recent resolution on women's health.

Encouraged by this positive feedback, Finland decided to include mental health in its EU Presidency programme. The European Union priorities in mental health will be developed at the high level Conference on Promotion of Mental Health and Social Inclusion in October. I hope that this leads to at least two practical outcomes, namely intensifying networking on mental health and developing a first report on the state of mental health in the European Union.

### **Health as a horizontal theme**

Health issues are scattered throughout the EC Treaty. Focusing only on Article 152 on public health is clearly too narrow. Instead, one has to study the Community's basic tasks and activities as well as specific provisions in other Treaty articles. Special attention needs to be given to articles on the internal market, working environments, consumer protection and environment.

The Commission has published three reports on the protection of health in all Community policies. The Council has discussed the reports but satisfactory solutions have not yet been found. Addressing the health impact of all Community policies, as underlined by the new wording in the Treaty, requires new policy instruments.

There is a continuum from those measures that directly influence human health to those that do not influence human health. Therefore, a mechanism has to be developed that enables various levels of Health Council involvement. For example, the important resolution on the fight against antibiotic resistance was first discussed in the Agricultural

***"The Health Council should deal with legislation and initiatives directly linked to public health, regardless of the legal base of the policy instrument."***

Council and then finally in the Health Council – showing the value of coordination of different Council groupings. The current discussion on ways to review the work of the Council offers an opportunity to look at how the health impact of all policies can be approached.

The environmental sector has provided a model for how a horizontal theme can be dealt with in the European Union. Environmental issues have been discussed in several Councils and political impetus has been received from the European Council of heads of government.

I strongly recommend a similar approach to health issues. The Health Council should deal with legislation and initiatives directly linked to public health, regardless of the legal base of the policy instrument. It would be equally important to coordinate and stimulate discussions on health in other Councils and to develop tools for evaluation of the health impact of various measures.

Numerous proposals in the field of veterinary medicine and plant health have been introduced under former Articles 43 and 101a. Some of them have been brought under Article 152 since the Amsterdam Treaty came into force. They can be better discussed and decided upon in other Councils than the Health Council and bringing all of them to the Health Council would not provide any major benefit for human health strategy.

On the other hand, many issues deserve treatment at the Health Council even if they are not based on Article 152. The directive on tobacco advertising highlighted this. It was based on the Treaty article dealing with the internal market but had, at the same time, a considerable human health dimension, and consequently was decided upon in the Health Council.

There seems to be a broad consensus that many pharmaceutical issues could benefit from greater attention by the Health Council. In fact this is nothing new, in 1995 the Health Council approved four resolutions on different aspects of pharmaceuticals, namely orphan drugs, mutual recognition of medical prescriptions, medicinal plant preparations and generic medicinal products. In autumn 1998, the Health Council took note of the report on homeopathic medicines. Currently, Council working groups are studying a regulation on orphan drugs, a directive on good clinical practice in the conduct of clinical trials, and an amendment of the directive on medical devices.

The unclear relationship between Community action in the fields of consumer health protection and public health needs to be resolved. There are several proposals for consumer protection with health implications, one covering health and environmental claims used in marketing. Nutrition is a very important issue for consumer protection and public health. It is a broad theme that runs from the technical safety of foodstuffs to culture-related eating habits. I definitely see a need to discuss this theme much more thoroughly in the future.

Finland is also seeking to strengthen the social dimension of the European Union. There are several aspects that need to be studied here, for example the challenges to the funding of social security caused by Economic and Monetary Union and demographic changes. The Presidency will organise a conference on this topic in November.

### **Health beyond the Union's present boundaries**

Finland welcomes the discussion on health determinants, health status and health systems in the EU applicant countries. The poor health situation in many applicant countries is

linked to the major determinants of health – health behaviour and social environment. Our experience suggests that only determined multi-sectoral action can improve the situation in relation to diverse health problems, such as cardiovascular disease and cancer, poor eating habits, smoking, traffic and occupational accidents.

Only a small part of the problems facing the applicant countries is due to the obvious shortcomings of the health care system. Therefore, it can be expected that the applicant countries would benefit most from participating in activities dealing with health determinants. While the applicant countries can benefit from the experience of the present Member States, they need to find solutions that fit their own economic and social background.

The future EU programme on public health must include elements that support both the pre-accession phase and the early years of EU membership of the applicant countries. I think that the Treaty obligation to ensure a high level of health protection must also be kept in mind in relation to EU enlargement negotiations.

The enlargement process shows that we cannot build our health strategies in a vacuum. The world of interdependence and globalisation provides a new perspective on health, too. The Euro-Mediterranean process, the initiative on the Northern dimension and the common strategy on Russia belong to the external dimension of the Union's health strategy. At the European Council in Vienna, the Commission reported on the Northern dimension of the European Union's policies. The report, as well as the strategy on Russia, also discussed health issues. The immediate tasks include health and social policy measures, especially the fight against communicable diseases and drugs.

The Conference of the Euro-Mediterranean health ministers later this year in France will also focus on communicable diseases, highlighting their cross-border character. In addition, I recall the cooperation between the EU and the United

States in the form of a Task Force concentrating on communicable diseases.

I am convinced that the public health sector of the European Union has a role in helping the health situation of migrants and refugees, both within and beyond the borders of the Union. All external activities must be carried out in good cooperation with international organisations, especially the World Health Organization.

### **Cooperation with WHO**

The World Health Organization has a major role in the development of health policies but it also works in many fields that are common to the public health sector of the European Union. Common interests range from the control of communicable diseases and tobacco products to alcohol and mental health.

These are all topics where the European Union has considerable possibilities for influence. Through cooperation, the WHO and the EU can both benefit from each other's advantages, their different remits, working methods and organisations. The benefits of this cooperation are so clear that the official exchange of letters for cooperation should be a top priority.

### **Health of young people**

I am personally very concerned to promote the health of children and young people, a topic that has not yet been discussed widely in the European Union. The Commission's forthcoming report on the health of young people will be an important boost for defining action. Initiatives on alcohol, drugs and tobacco use are important elements in protecting children and young people. The Commission's proposal on alcohol and youth will be a very welcome opening in the process of viewing alcohol from a public health perspective.

There is a need to follow-up the Commission's excellent 1997 communication on tobacco strategy. Community action on tobacco is a good example of how actions in the 'third strand' could be formulated: they should be a mix of information

activities, networking and legislative initiatives. The directive banning tobacco advertising should be followed by further legislation on tobacco products. Tobacco taxation can be seen as a health tax, following the model of environmental taxes. The Council should use the Commission's forthcoming report on smoking and smoke-free environments as an opportunity to give new impetus for action. Our experience shows that occupational safety requirements can, and should, include a working environment free from tobacco smoke. I stress the need to use the European Community Fund on Tobacco Research and Information in a proactive way to promote a better European public health response to tobacco. The WHO initiative for an International Framework Convention on Tobacco requires active support from the European Union.

Another important multi-sectoral issue is combating narcotic drugs. Input from the public health perspective is needed to find a right balance between repressive and demand reduction measures. The Council will soon adopt the new strategy on drugs for 2000–2004. A practical first step we will need to take is to improve information exchange between the health sector and the Horizontal Drugs Group.

### **Healthy ageing**

1999 is the UN Year for the elderly. In Finland we have launched a national initiative to highlight the event. Our message is 'Adding more life to years'. I want to emphasise the positive aspect: the ageing of the population is a consequence of, and an indicator for, our success in promoting health. When people live longer we must make sure that their health and working and functional ability is promoted to keep them economically and socially active, thus relieving the otherwise inevitable economic burden.

Ageing might prove to be a suitable theme for action in future Community measures on public health. It has links with the work of several Councils. An informal Labour and Social Affairs Council will discuss ageing of the labour

force and employment, working ability, social security, reorganisation of work and age discrimination in the context of employment guidelines for the year 2000. Enabling independent living of the elderly and disabled people will also be studied by a Presidency Conference in October.

### **Violence and its consequences**

Violence and fear of violence can be regarded as a major health scourge. Violence ranges from inconspicuous acts in the home and everyday life to high profile cruelties attracting much media coverage. Violence, especially in its more limited forms, is very common and causes much human suffering. Violence in all its forms deserves a multi-sectoral approach.

I fully support the proposal for the Daphne programme that addresses important aspects of violence: violence towards children, young people and women, including violence in the form of sexual exploitation and abuse. Because violence has many aspects that go beyond health, the scope of the Daphne programme should not be limited to the field of public health. Implementation of the programme must bring together several policy sectors, actors and countries in each project to achieve maximum impact.

A decision about the programme is needed urgently to secure the uninterrupted continuation of pilot action implemented in 1997–1999.

### **Partnership at the start of the new Millennium**

The present situation in the European Union provides an opportunity for us to shape the future of public health. Many exciting and important questions await a solution. The Commission's right of initiation puts it at the top of this process. One EU Presidency is only a link in a longer chain. Therefore, I have been very pleased with the good cooperation with previous and future Presidencies and other Member States. As a parliamentarian, I attach much weight to working with the European Parliament, and the institutional changes introduced by the Amsterdam Treaty provide a good opportunity to do just that.

# Towards an integrated health care policy in the European Union?

*“Despite the omission of the health care market from the Rome Treaty, harmonisation in other product and service areas is, de facto, leading to the integration of health care policies.”*



*Alan Maynard*

*“Harmonising the EU physician market to improve free movement of practitioners whose skills may become redundant (and dangerous) is insufficient.”*

A market is a network of buyers and sellers. Whilst the concept of a ‘free market’ is part of the political rhetoric of Member States of the European Union, the reality is that markets always and everywhere are regulated by both public and private organisations. The purpose of the processes of European harmonisation is to reduce these public and private barriers to trade and ensure a more efficient use of scarce resources within the Union.

Such policies in the health care sector may produce considerable gain for the population. Despite the omission of the health care market from the Rome Treaty, harmonisation in other product and service areas is, *de facto*, leading to the integration of health care policies. Thus integration of labour markets has led to the harmonisation of physician, nurse and dental markets. Integration of product markets, with the development of European competition and safety policies, has led to the integration of pharmaceutical markets. Integration of service markets creates an opportunity for issues such as consumer protection to be expanded to include private health care insurance. The challenges inherent in such integration processes are considerable.

## **Integration of health care labour market**

To facilitate the freer movement of labour, the training requirements for health care professions have been harmonised. However, there are noticeably deficiencies in these policies.

With the rapid development of health care technologies, the skills of practitioners rapidly become redundant. Airline pilots are tested every six months to ensure physical and mental fitness, as well as continuing competence to fly their planes. Physicians are appointed for life and their practices may become out-of-date and dan-

gerous quite rapidly. Thus a cardiac surgeon in Bristol, England, has been held responsible for killing 29 children over a period of five years by poor technical competence.

The nice challenge for the professions and Government is how to protect the consumer from such deficiencies in practice. Harmonising the EU physician market to improve free movement of practitioners whose skills may become redundant (and dangerous) is insufficient and requires supplementing with vigorous policies of reaccreditation of practitioners every five years; a policy now advocated by the UK medical profession.

Furthermore, market integration is having only limited effects on physician remuneration. There is a surplus of doctors in Germany and Spain. In Germany the surplus has not led to pay reductions. This absence of pay reductions to reflect market surplus implies that the monopolistic power of German medical trade unions is distorting the market mechanism. Throughout the Union, physicians are highly unionised and restrict pay flexibility.

These two examples, pay inflexibility and consumer protection from physician redundant skills, require national and EU wide action if the principles of the European Union are to be translated into practice.

## **Integration of the market for pharmaceuticals**

There is now a European mechanism to assess the safety, efficacy and quality of new pharmaceuticals and determine whether a product licence can be issued; without such a licence companies cannot market their products.

This is a welcome development but incomplete. The first obvious policy omission is that such regulation does not extend to medical devices (which range from bandages to scanners in scale) and foods. Many foods (e.g. cholesterol reducing products to

replace butter) have significant effects (e.g. reductions in cholesterol of 10-15 per cent). Why is there limited national regulation of foods (e.g. no obligation to conduct appropriate clinical trials) and an absence of EU regulation of such products, whose potential to damage health is similar to pharmaceuticals?

Another obvious limitation to European integration is the 'fourth hurdle'. Since 1993, pharmaceutical companies in Australia have been able to get a product licence after demonstrating the safety, efficacy and quality of their new product (the first three hurdles). However, reimbursement for the product in the Australian public health care sector (Medicare) is given only when companies produce evidence to demonstrate cost effectiveness (the fourth hurdle).

Several European governments are emulating the Australians. For instance, from April 1999, the National Institute for Clinical Excellence in England will begin to issue mandatory clinical guidelines which will be based on evidence of 'clinical cost effectiveness'. Thus pharmaceutical companies in England, like those in Australia, will not get reimbursement from Government sources unless the new product is demonstrably cost effective.

Rather than let individual States replicate economic evaluation of new products, is there scope to develop an integrated mechanism and ensure that purchasers of pharmaceuticals throughout the EU are informed about the 'value for money' characteristics of often over-hyped pharmaceutical and medical products?

### **The market for private health care insurance**

Throughout the world, regulatory agencies are concerned about benefit plan transparency and the proficiency of private insurers to provide 'value for money' to consumers.

The Clinton proposals for health care reform, reform proposals in Chile and the regulatory concerns of the UK Office for Fair Trading all identify the fact that a purchaser of

insurance is always uncertain about the precise extent of coverage from private health insurance. This lack of transparency in the nature of the insurance product is similar in life as well as health care policies.

The European Commission has developed insurance policies to protect the consumer but, as yet, its regulation of the health care market is limited. Furthermore, it has also failed to develop policies to ensure 'value for money' for consumers.

Private health care insurers worldwide have traditionally been passive 'price takers' rather than vigorous 'price makers', i.e. they have accepted, and paid, like obedient bank clerks, the prices and volumes demanded by providers and have failed to exert their purchasing power. With managed care in the United States, the extraordinary wasteful and inefficient purchasing policies of insurers there are being reformed. Insurers throughout the world are becoming interested in adopting such techniques as they facilitate both cost control and the stabilisation of premia.

Such interest needs to be translated into regulatory practice. The insurers can self regulate, although they have failed to do this with respect to transparency and are slow in doing this to enhance purchasing rigour. Alternatively, the European Commission might extend the use of its existing powers and develop new controls, to protect better the European consumer from the inefficiencies of the private health care insurance industry.

### **Where next?**

The processes of European integration in healthcare labour, product and service markets have been innovative, slow and incomplete. The scope for further action is considerable.

The integration of the market for physicians and other professionals has been developed with, and sometimes with resistance from, these groups. Continuing market imperfections across the Union ensure continuing variations in the quality of performance and the protection of markets to benefit the producer

rather than the consumer (for example, the restrictive practices of physician trade unions to pay flexibility) and the protection of restrictive practices at various levels in the pharmacy market (for example, condoning, by inaction, resale price maintenance for over the counter pharmaceuticals in the UK).

The integration of the market for pharmaceuticals in the EU has also been circumscribed by provider interests to the detriment of the taxpayer and consumer. National governments have sought to control pharmaceutical expenditure and enhance 'value for money' by a range of policies which have failed to control adequately prices, volumes and quality (i.e. in terms of whether such products enhance the length and quality of life). The EU could usefully supplement these efforts, particularly in relation to the development of policies to demonstrate that expensive new products are cost effective. Such regulation should also be extended to medical devices and health enhancing foods.

The tardiness of national and EU policy makers to remedy the manifest and obvious deficiencies of the market for private health insurance has ensured that costs inflate (and fuel premia increases which raise employers' production costs; employers, after all, pay their workers' insurance premia) and resources are used wastefully. The failure of EU consumer lobbies to press for reform to protect European citizens is noteworthy and regrettable.

Improved regulation of such markets is overdue and the scope for Union action appears to be considerable. Such integration is a precursor for developing trade in health care services across the EU. For instance, might Member States and insurers purchase in future well defined, evidence based health care services, particularly in elective care, across political boundaries from EU registered centres of good practice?

An innovative, radical and scientifically based approach to the further integration of the EU healthcare market would erode trade barriers and bring considerable benefits to the European consumer.

# Financing healthcare capital investment: the role of the European Investment Bank

— Sir Brian Unwin —



I imagine that many banking colleagues outside Luxembourg, on hearing that I had been invited to write for Eurohealth, would have assumed that I would be contributing to a report on the health of the new single currency. However, despite the important role the European Investment Bank (EIB) has played in the gestation and birth of the euro, the subject matter of this article is not currency but health. I therefore much welcome this opportunity to set out how we see the development of the EIB's activities in healthcare in Europe and to discuss the challenges we will need to meet as EIB becomes an increasingly important player in the finance of European healthcare investment.

## The European Investment Bank

EIB was created by the Treaty of Rome in 1958 as the financing institution of the European Union. The Bank's shareholders are the Member States; and its mission is to promote the balanced economic development of the Community by making long-term and highly cost effective finance available for sound investment projects. The Bank does this on a very large scale. In 1998, the Bank made long-term loans amounting to nearly EUR 30 billion, 90% within the European Union, with the rest going to prepare Eastern European countries for possible Union membership or to support the development needs of over 100 other countries outside Europe. By any criterion of size, the EIB is a very significant world-wide lender.

The EIB's funds are raised on the

world's capital markets. The Bank is one of a small number of institutions which has a triple A credit rating. This is a distinction which even many governments do not enjoy. It gives the Bank access to capital on the most favourable possible terms. The EIB is a non-profit institution and so is able to pass this advantage directly to borrowers. Maintenance of the triple A rating has the highest priority for the Bank and this requires the application of strict banking criteria to all loans.

But EIB is more than a bank; it is also an institution of the European Union, and as a public institution, it

*“... healthcare as such was a new sector for the Bank and one in which we had no track record and no in-house expertise on which to draw. We make no apology, therefore, for having approached the sector cautiously.”*

has a duty to ensure that its projects are not only financially sound but also socially worthwhile and help to promote European Union policy objectives. This is an important distinction which underpins much of the Bank's work in the identification and appraisal of projects. To a purely commercial bank the primary concern in appraisal is whether there is an income stream to meet the financing requirements. To EIB, this is a necessary condition, but not sufficient. The concern to limit investment to worthwhile projects is one the Bank takes extremely seriously. It commits a considerable effort to project appraisal and, in many areas, project improvement. This raises particular issues for us in the context of our work in healthcare.

## The EIB's involvement in healthcare

It was not until the autumn of 1997, when they approved the Amsterdam Special Action Programme (ASAP), that the Bank's Board of Governors agreed to an extension of the Bank's mandate to cover lending for investment in the delivery of healthcare (and education). ASAP was established following the Amsterdam European Council which requested the EIB to extend its lending to health and education as part of a wider programme to promote growth and employment across the EU. The mandate was limited to EU countries and applied only when the project in question also met other eligibility criteria. In practice, this means that to date we have been limited to healthcare projects in areas with regional development priority

*"The challenge to health managers and policy makers is to find ways of using EIB's resources for innovative projects which promote better integration across the primary, secondary and tertiary levels of care."*

or which have a substantial teaching component (so making them eligible under an 'education' criterion). This may sound rather restrictive, but in my view, the reasoning, certainly for an initial phase, was soundly based. Although the broader consideration of health impacts has long featured in the Bank's appraisal work (for example, a part of the case for a new road scheme may be the accidents and injuries prevented) healthcare as such was a new sector for the Bank and one in which we had no track record and no in-house expertise on which to draw. We make no apology, therefore, for having approached the sector cautiously.

The Bank's *raison d'être* is to improve resource allocation across the EU by supporting sound investment projects and programmes. It was clear at the outset that healthcare projects in general, and hospital projects in particular, have not always been required to address properly the economic case for their development. Whilst there are areas of good practice, society has not always applied the same critical scrutiny to hospital schemes as to roads, power stations and other parts of the physical infrastructure. This was, therefore, an area in which it was incumbent on EIB to tread carefully.

During the past 18 months we have begun to establish a track record. We have already committed loans of some EUR 3 billion. In health, this covers six projects in Greece, Berlin, Mecklenberg and Thüringen in Germany, Padua in Italy and Santiago in Spain. We are currently appraising projects in the United Kingdom, Sweden, Austria, the Netherlands and Germany. We have not, however, proceeded with all the projects that have been brought to us by promoters. Projects can fail to meet the stringent appraisal tests we apply to them. In health, given that

most projects are in the public sector, this is less likely to be because the project cannot guarantee a revenue stream than because the project cannot demonstrate its social value. In other words, projects can fail if they do not offer a good return in terms of 'health gain'. We recognise the difficulty in applying this test; it is important that we are reasonable in the information we require from promoters and pragmatic in our definition of health gain. So, for example, a hospital reconfiguration designed to eliminate spare capacity in acute beds can release resources for re-investment in other services elsewhere; this could well pass the 'health gain' test. In contrast, a project which duplicates services, adding to capacity without good cause, would not. In practice, this factor almost always lies behind any decision of the Bank not to proceed with an investment. We also, of course, have to be conscious of particular national circumstances in this context.

Appraisal designed to ensure the quality of projects, therefore, takes centre stage. In relation to health and education we have geared ourselves up for this work with a carefully targeted programme of staff recruitment. In addition, we have established a series of strategic partnerships with individuals and organisations at the 'leading edge' in this field. It is within this context that the Bank made its recent investment in the European Observatory on Health Care Systems. Later this year we will be hosting a major conference on the appraisal of healthcare capital investment in collaboration with the World Health Organisation and the European Healthcare Management Association. In essence, we are building a momentum in healthcare, focussing on an active selection of projects which fit the mandate given to the Bank.

## Looking ahead

I see an exciting future for the Bank as a major provider of capital for healthcare modernisation and development across Europe. But this vision is not without its challenges. Arguably the most demanding comes from the recognition that, in much of Europe, the most pressing need for healthcare capital comes not from acute hospitals but for the supporting, often community based, infrastructure needed to secure efficient use of hospital beds.

There will also be challenges associated with the development of appropriate facilities, again often in the community, for a growing elderly population and for groups such as people with mental health problems. The substantial costs associated with capital market operations and our approval system make it unlikely that the Bank could directly finance, for example, a single health centre or small community hospital (although we also establish lines of credit with commercial banks, so-called global loans, through which smaller schemes could be taken on board).

The key point, however, is that a decision to invest in a new hospital is a decision to commit to a stream of operating costs often significantly greater than the original capital cost. We recognise that if the Bank's role were *de facto* limited to making 'privileged' capital available for large hospitals, there would be a risk that our intervention might not improve the overall allocation of healthcare resources.

The challenge to health managers and policy makers is to find ways of using EIB's resources for innovative projects which promote better integration across the primary, secondary and tertiary levels of care. This may require the development of new ways of sponsoring or 'bundling' projects; perhaps even a new concept of healthcare investment which recognises the multi-agency nature of the services (in other words, beyond the purely clinical) necessary to secure health improvements. We look forward to engaging the support of the healthcare community across Europe in meeting this challenge.

# Health and risk - an emerging field



*Paul Anand*

The growing attention to risk in medicine and the rise of social science in public health are inextricably linked though, at one level, there is something paradoxical about this. The dramatic improvement in life expectancy through better public health measures is one of the major achievements of the 20th century and yet Western populations seem even more sensitive and concerned about the risks that remain. This brave new world, in which death and disease are not seen as inevitable throughout most of the life-span is not one well served by institutions that were developed in an age when the control of infection was *a*, if not *the*, central objective of the public health system.

The new mandate which increasingly centres around the promotion of health and well-being is quite a different project though one which still depends on the clinical, statistical and scientific expertise traditionally found in the epidemiological model. But experience in the post-war period shows that there are other issues and disciplines that need to be integrated into public health if the new public health

*"The dramatic improvement in life expectancy through better public health measures is one of the major achievements of the 20th century and yet Western populations seem even more sensitive and concerned about the risks that remain."*

model is to address health risks appropriately. Indeed if the first international conference on Health and Risk held at Oxford last year is anything to go by, the new paradigm may even give rise to a new set of disciplinary interests.

The way in which public policy, health risks and a wide variety of issues from socioeconomic inequalities and social infrastructure issues through accidents, violence, stress right up to the health and economics problems associated with ageing populations have already turned this into a truly multidisciplinary field of endeavour. In this brief overview, I want to pick out five issues that I believe will be central to how we think about and address public health risks, defined in the widest sense, as we look to the next millennium.

## Profound uncertainty

Traditionally, we have thought of statistics as providing the numbers that help quantify risk. However, a litany of public health issues around the world including GMOs, Creutzfeldt-Jakob disease (CJD) and AIDS has shown that we are increasingly confronted with decisions that need to be made before some fundamental uncertainty has been resolved. Whether some new chemical or food product should be allowed or banned depends on scientific information that often we just don't have or could have, possibly for decades.

We may want to have more research but everyday practices from eating beef to having unprotected sex are subject to societal approval before we really know what the risks are really are.

Good decision-making at the individual level or social level is normally thought to be about integrating consequences with an assessment of their likelihoods yet in many of the health scares that hit the headlines, we can only say something about possible consequences. Good decision-making when nothing is known about probabilities has to fall back either on making subjective guesses about likelihoods or examining more closely the different consequences that could follow from various courses of action. Banning the sale of UK beef might have prevented some deaths from CJD but it would also have done untold damage to thousands of individuals and livelihoods. These are the tradeoffs we have to make, and it is not always clear that politicians are best placed to make them.

This may seem like a simple point but it requires a fundamental change in how we approach these kinds of decisions. In a sense this lesson has been learned for BSE in the UK: Sir Richard Southwood said his committee felt under pressure to minimise their estimate of risks to humans while senior scientists in the UK today feel able to say that there is just no way of telling yet whether deaths from the human equivalent will be large or small.<sup>1</sup> Likewise there is evidence that the media has grown tired of playing off experts against each other – "in BSE there are no experts" is how one writer rather crudely put it. But what is not clear, even in the UK, is that institutional structures are being changed in a way that reflects this experience, which brings us to

my second point which is about how we organise to address these issues.

### **Organisation**

The UK's Salmonella in eggs scare, which in part brought about Edwina Curry's move to the European Parliament, provides a model for how not to manage a food scare. So, interestingly, does the Mad Cow Disease crisis that followed it. So why did government not learn and apply the messages of the first to the second? Well in a sense, there was learning but because they were without any theoretical foundation, the lessons that were learnt were the wrong ones.

In their review of MAFF's handling of the UK's Agriculture Committee of the House of Commons suggested that MAFF was too industry oriented and not sufficiently science driven in its handling of the eggs scare. The Commons' backbench committee was concerned with which groups had most influence but the problems if diagnosed from a decision analytic view are somewhat different. From such an angle, the main difference between the two food scares was that Salmonella posed a quantifiable risk while BSE illustrates what I have called profound uncertainty (others use terms like 'ambiguity' or phantom risk): the point is that information about consequences and likelihoods often comes from quite different sources.

Debate over the remit of the new food standards agency has not, however, centred around questions about how best information on consequences can be brought into the picture or integrated with likelihood information when the latter is available. Questions that have predominated, such as how much fundamental science research such an agency should do are important but of secondary relevance to the design of a regulatory body that could just as easily contract out any such needs. My point is that we need to think of institutional design issues within some theoretical framework – that the existence of profound uncertainty should play a key role in our thinking about the design of relevant regulatory institutions and that decision analysis, broadly defined, provides a good but still underutilised framework for doing this.

### **Communication**

Though essential, decision analysis is not comprehensive: for one thing it has little to say about what we say to people about risk and health. Risk communication is itself a developing field<sup>2</sup> but it is one with a histo-

ry that has been peppered with comparisons that illustrate just how unhelpful saying things that are true can be at times. The fact that "radiation emitted by the Three Mile Island disaster is no more than would be received by a passenger during the course of a cross-Atlantic flight" just confirms what those are sceptical about the nuclear power industry thought all along, whether it is true or not.

When it wasn't busy inventing them, the media has jumped on the facile comparison with some cause: for one thing, the perceived 'voluntaryness' of a risk is crucial to determining when it will be seen as acceptable. On the other hand, the extent to which people accept legal restraints on their freedom to voluntarily take risks should not be underestimated either as the widespread acceptance of seat-belt legislation indicates.

Even more importantly, in this context, we now have access to a number of richer models in which communication is seen either as a two-way process or even something broader. Health risk communication is no longer captured by the simple one way sender-receiver model but both at the individual and at group level it hinges on some form of negotiation or accommodation. Possibly even the word communication fails to capture the deliberative nature of this activity.

### **Government vs. private sector**

Given that we live in a world where even socialist governments seem keen on market based institutions, the way in which public health addresses risk cannot fail to be affected.

Economists tend to have a technical view of how markets operate which can make them seem to have political views when they do not, and the management and control of public health risks is no exception.

For example, work by John Graham and colleagues at Harvard shows that the value of life implied by various health and safety regulations ranges from nearly nothing to billions of dollars. In theory, this figure should be the same in all areas. This isn't necessarily an argument for reducing the

*"... we need to think of institutional design issues within some theoretical framework - that the existence of profound uncertainty should play a key role in our thinking about the design of relevant regulatory institutions"*

*“... the transparency and openness that increasingly characterises public sector decision-making means that different views about entitlements and appropriateness have to be melded together in the priority setting process.”*

amount of regulatory legislation but it suggests that a more rational approach is warranted and that some policy resources are going, for whatever reason, to projects of little benefit.

A second point to note here is that incentives do matter, though not always in the simple and stylised way that appears in certain 'economic' theories of public sector behaviour. Experience in the management of AIDS helps highlight the point. Many HIV and AIDS coordination activities appear to merit cooperation between multiple agencies. However, HIV and AIDS coordinators note that inter-agency collaborations are difficult not least of all because many of the organisations involved find themselves in head to head competition with each other for scarce research and project funds. Competition is not the preserve of the private sector and healthcare planning needs to take that fact on board. Sometimes the fact can be turned to advantage – in countries like Thailand, the private sector has a good record of importing condoms and as one AIDS worker noted, learning to work with the motivation rather than fight it, was on occasion a useful way forward.

### Rationing and the integration of competing claims

Though rationing is not limited to public health, nor even always most keenly felt there, it illustrates rather clearly the array of competing claims that will determine public attitudes to the treatment of healthcare risks. Health economists have argued that the quality adjusted life year be used as a form of utilitarianism in health – the greatest health for the greatest number. However there are two camps and the one that I think will attract more support from outside is the view that says a measure of healthcare benefit is just one consideration that needs to be put into the pot.<sup>3</sup> Individuals have rights too and if an increasing number decide to assert these and avoid immunisations, say, then we need to consider the implications. People also point to historically grounded social contracts that set up expectations which are not acknowledged by abstract measures of

health gain. Again some people believe there are duties to take adequate precautions (insurance if you ski, quit if you smoke). All of these constitute a set of competing moral claims on healthcare budgets that public health officials need to consider every time they seek to tackle high profile risks that are constantly on the edge of politicisation.

### Conclusion

If I had to pick one issue that the public health system has to tackle and is common to the various themes identified above, it would be the management of diverse stakeholder groups that range from senior politicians through healthcare professionals to patients and citizens who simply happen to have a view about the ethics of certain kinds of medical activity. Healthcare professionals are increasingly aware that the days of deference are past and that health and well-being depend on the establishment of consensus at a social level as well the development of consent at an individual level.

Benefit and cost information is now becoming part of the evidence base, especially in clinical trials. However, the transparency and openness that increasingly characterises public sector decision-making means that different views about entitlements and appropriateness have to be melded together in the priority setting process. Rights, social contracts, public consultation and communitarianism are just some of the types of moral claim that underpin demands on healthcare resources. They are conflicting both with each other as well as with other views that emphasise simple outcome measures like healthcare gain and we need some mechanism that pulls these concerns together. The keyword is integration but the social mechanisms by which this is achieved are still being constructed.

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# Risk Communication: new challenges for European health policy

*Risk communication in one form or another is probably as old as democratic government itself. However, the question of how and when to engage in systematic dialogue about health and environmental risks with the public and other stakeholder groups has only in the last decade become a central concern of many institutions,*

*regulators and administrators, at both national and European Union levels.*



*Nick Pidgeon*



*Karen Henwood*



*Tom Horlick-Jones*

gest ways forward in framing health risk communications.<sup>1</sup>

## **Risk perception research**

As a field of science policy research, the study of risk communication evolved out of early work by psychologists in the 1970s and 1980s on risk perceptions, which aimed to map the cognitive and social processes underlying both lay and expert conceptualisations of risk. The initial focus was on explaining public understandings of, and in some cases opposition to, one particular technology – that of nuclear power – although over time a much wider range of technological and health risks have been studied. This work has clearly demonstrated that members of the public have a fairly good idea of the relative chances of death in any one year from a particular technology or health hazard. For example, individuals are generally quite well aware that, in any normal year, heart disease kills more people than does botulism. One immediate implication of this finding is that whether people ignore, or conversely are overly concerned with, a risk is not necessarily due to ignorance about the chances of death.

Therefore, alternative explanations for their behaviour must be sought. This becomes clear if we look at judgements about perceived risk and its acceptability. Such judgements have been found to vary as a function of a number of factors, including (a) qualitative aspects of hazards, such as levels of perceived control and voluntariness (risks which are difficult for the individual to control, and which are believed to be imposed upon people without their consent are judged less acceptable) (b) demographic characteristics, individual attitudes, and cultural/ institutional affiliations and (c) societal values and beliefs concerning, for example, the equity of activities for which the benefits and risk burdens are unevenly distributed across society. Accordingly, two hazards with ostensibly similar risks in epidemiological terms might still differ widely on some of these other

characteristics, and hence provoke differing public responses in terms of acceptability.<sup>2</sup>

A first lesson here, particularly for health professionals who are used in their working lives to thinking about risks solely in statistical terms, is that risk communication involves far more than just 'getting the numbers right',<sup>3</sup> and indeed may fail if the frames of reference of the intended audience are not explicitly considered and addressed by a communicator well in advance.

*"The public have a fairly good idea of the relative chances of death in any one year from a particular technology or health hazard... whether people ignore, or conversely are overly concerned with, a risk is not necessarily due to ignorance about the chances of death."*

### Risk perception and trust

Sociological work in particular has highlighted a further complex aspect of risk concerns, that of trust (or distrust) in regulatory and risk managing institutions. This issue is often discussed in relation to certain highly politicised societal risks (for example, hazardous waste disposal and storage), but has also been central to recent public health concerns in Europe over food risks such as irradiation, BSE, and most recently Genetic Modification (GM). Some sociologists would go so far as to argue that reliance upon expertise and institutionalised risk management has become one of the defining features of our modern globalised 'risk society',<sup>4</sup> with people becoming increasingly distanced in terms of direct understanding or control from many of the sources of risk that impact upon their lives.

It is hardly surprising therefore to find a healthy degree of lay scepticism, and in some cases profound alienation, when expertise is found wanting, is uncertain or contested, or is unable to articulate sound theoretical scientific principles and risk assessments that allow appreciation of the actualities of risk management in a complex and messy world. For example, some of the very best approaches to numerical risk assessments remain vulnerable to, and in many instances just cannot accommodate, the all pervasive influence of human or organisational error.<sup>5</sup> People, on the other hand, have a fairly good appreciation of such human fallibilities, from the direct experience of their everyday lives.

In the case of the BSE crisis the tragic deaths from the human variant, nvCJD, have sometimes seemed overshadowed by the secondary economic impacts, felt right across Europe, against a backdrop of profound distrust in newer 'industrial' methods of livestock farming and of the system for food safety regulation. Recent research evidence also shows us that the distrust generated by the BSE crisis has also spilled over into the current public debate in

Europe about GM safety. Arguably the most important lesson to take away from the BSE/GM debates is that individual members of the public will not approach new risk issues as a tabula rasa, since historical precedents, images, and informal communications from friends and family, alongside other contextual factors, will almost always enter into people's understandings of any novel risk issue.

### Methodological issues

For governments and regulators at the present time, understanding the dimensions and dynamics of trust seems to be a particularly burning issue. However, in the face of many of the known complexities of risk communication it is one that should not be taken to be a panacea or as the sole concern in approaching the goal of effective risk communication. What is more, research findings can often be heavily dependent upon the methods used to measure trust, with social science researchers now beginning to favour mixed-method approaches which triangulate the richness of qualitative data (e.g. from focus groups) with the representativeness of quantitative survey data to illuminate this complex social phenomenon. In this way a more complete picture can be obtained than by working with any one methodological approach alone. For example, in research recently completed for DGXII under the EU 4th Framework environment and climate programme,<sup>6</sup> we have investigated the perceptions of risk, and the effects of existing risk communication, amongst communities living in close proximity to major chemical accident hazards (so called 'Seveso' installations). The post-Seveso major accidents legislation was one of the first European examples to include formal risk communication to the public as mandatory – in this instance in the form of emergency response information to communities who might be directly affected by offsite hazards. Our own study was designed to take into account the fact that such industrial sites are often seen as highly complex entities in people's minds, and that communication within communities occurs at a variety of both formal and informal levels. In the UK quantitative survey – conducted at Seveso-designated sites in London and in South Wales – we found that institutions such as the emergency services, local health authority, and local community groups were accorded much higher levels of trust (in relation to decisions about siting or the impacts of the local chemical industry) than were the industries themselves, local councils, or government agencies.

While these quantitative results are unsurprising in that they mirror the findings from other similar surveys conducted in the UK and elsewhere – particularly in the low ratings accorded to ‘government’! – in the follow up qualitative focus groups conducted in the UK, Spain and Italy a more complex pattern emerged. Our conclusion was that participants were not prepared to give unreserved trust to any party (health professionals included) where they were seen to have a self-interest in the issue at hand. This has profound implications for health risk regulation and communication, in that people clearly wish for institutions that are genuinely dedicated to the public interest while at the same time being independent of the risk generating process. Interestingly, in some of the focus groups there was enthusiasm for the idea that regulatory institutions might eventually fulfil such an ‘honest broker’ role.

### Risk communication and trust

Trust issues will impact upon the design and delivery of health risk communications in a number of ways, and these can only be noted briefly here. Most obviously, results from persuasive communication research show that at the individual level the credibility of a communicator is critically dependent upon the trust placed in him or her. If we do not trust the source of a message then we will not trust the message itself! It is also the case that in many, although by no means all circumstances, trust is both hard to gain but very easy to lose. Institutional trust may be lost following a serious incident or disaster if a previous or ongoing cover-up is suspected, or if the responsible authorities are not believed to be learning from the event in an open and public way. It is for these reasons, amongst others, that many commentators advocate that early, on-going, open and above all honest interaction with stakeholders is a prerequisite for trust as well as for effective, ethical communication about risks. Evolving the institutional mechanisms for achieving genuine openness in communicating about public health risks across Europe would appear to set a major policy challenge for EU legislators in the future.

Such challenges will also need to be met within a framework stressing multi-agency working and an interdisciplinary understanding of the issues involved. Many current public health risks arise from a complex interaction of environmental, lifestyle and technological factors, and it is no surprise therefore to find lay beliefs in relation

to say, the impacts upon health of environmental pollution, encompassing a range of such issues. Many of the new Quality of Life research priorities in the Commission’s Framework 5 Research Programme appear to have explicitly recognised the importance of these linkages. For risk communication it is important to recognise that approaches which become compartmentalised along administrative or disciplinary lines are also unlikely to fully meet public concerns.

### Public participation in health risk decisions

As we approach the end of this millennium it is clear that we have moved away from the simple (essentially unworkable) model of risk communication as a one-way transmission of scientific information from ‘experts’ to a passive audience, to one that recognises that risk communication is both contextually framed and an explicit part of the wider democratic processes of empowerment that operate (or ought to operate) within a civic European society.

Here risk communication can be viewed as an essential strategy in enabling risk-bearing groups in society to participate more effectively in decision-making about their own health and safety, and in addressing a range of existing health-risk inequalities. This in turn sets the research community a significant challenge, since it is far from clear how these objectives will be met in practice, or which participation vehicles will suit which forms of health risk communication issue. We also know very little about the unintended consequences such wider participation might bring. At one end of the scale it may simply be a case of individual health professionals taking more seriously their dialogue with their clients, as is increasingly the case with decisions to conduct genetic testing. With regard to resolving some of the more conflicted risk issues in the public health domain (such as the future of GM foods) we may need more complex forms of analytic/deliberative process,<sup>7</sup> such things as citizens juries and consensus conferences, that allow for open interrogation of the basic science of the matter and which are both fair and inclusive for all stakeholders involved.

Whatever the vehicle and issue, we must recognise that effective risk communication and decision-making will always have to involve a judicious blend of sound scientific knowledge and public values. Bringing the two together is the real European public health challenge for the new millennium.

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# The European Commission, risk management and the precautionary principle

*“The absence of scientific evidence does not mean that action to prevent the realisation of a postulated hazard-harm relationship has to await conclusive evidence.*

*Appropriate action can be taken pending the availability of the evidence, and this at its most basic level is what is meant in practical terms by the Precautionary Principle.”*



*Michael D. Rogers*

## **The regulator's lot**

Imagine the following scenario. A manufacturer of wallpapers introduces a new product range with innovative characteristics that rapidly generate a large demand. The characteristics, which prove so attractive to consumers (at least initially), are long-life perfumes (released by touch) and built in (contact) insecticides to keep the home free of unwanted guests! A year or so after the product launch, consumer organisations point out that if the active ingredients (perfume and insecticide) are fed in large quantities to laboratory rats, then the rats suffer serious health damage (such as cancer inception in various organs). At this point, plausible hazard-harm relationships for both humans and the environment are promoted by the consumer organisations. Firstly, it is suggested that children find the perfume of the wallpaper so attractive that they spend long periods in very close proximity to the walls and absorb the carcinogenic chemicals in sufficient quantities to produce cancers in later life. Secondly, it is suggested that the wallpapers will one day be disposed of in the environment and will produce detrimental impacts on beneficial insects.

Please remember that this is an invented

scenario. However, the essential elements are realistic. Here is a product embodying a technology for which a plausible hazard-harm relationship can be postulated. The harm (to human health or the environment) is certainly serious if realised. However, there is insufficient knowledge to carry out a formal risk assessment and thus the normal precursor for risk management is missing. It is under such circumstances that the Precautionary Principle (PP) is invoked. We should be clear about what is meant by this ‘principle’ particularly because it appears in international treaties from which legal obligations flow. It has been an integral part of the European Regulatory System since 1992, when Article 130(r) concerning the environment was modified to include the words; “*Community policy...shall be based on the precautionary principle and ....*”<sup>1</sup>

The rules of the World Trade Organisation make it clear that the absence of scientific evidence does not mean that action to prevent the realisation of a postulated hazard-harm relationship has to await conclusive evidence. Appropriate action can be taken pending the availability of the evidence, and this at its most basic level is what is meant in practical terms by the PP.<sup>2</sup>

So the Principle is invoked when there is an absence of conclusive evidence to the contrary. There is a clear analogy in the trial in Lewis Carroll’s ‘Alice’s Adventures in Wonderland’ when the Queen demands “*Sentence first – Verdict afterwards*”. Unfortunately the PP has come to mean different things to different actors. To the consumer and ‘green’ organisations it means the banning of products which are under suspicion of producing harm. To the regulator it should represent a range of policy options designed to minimise the chances of the postulated hazard-harm

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This paper results from a series of studies carried out or sponsored by the Forward Studies Unit of the European Commission. The views expressed are the author's. They do not necessarily represent the official position of the European Commission

relationship being realised to a significant extent. This lack of common understanding of the application of the PP is having profound implications at local, regional and international levels and thus is of major concern to the European Commission in its role as risk regulator and defender of the international (and EU) trade rules. Events in recent years (from BSE to phthalates in children's soft plastic toys), and current trade and health issues (from hormones in beef to the use of antibiotics in animal rearing), have ensured that the PP and risk management (and health) are high up on the European Commission's current agenda.

### **The Forward Studies Unit's contribution**

The Forward Studies Unit (FSU) has a strong interest in this field for three overlapping reasons. The first reason is that risk assessment is by its very nature a *prospective* exercise. It is a process which uses current knowledge (no matter how limited or imprecise) to predict possible future harms. It depends on *a posteriori* arguments. It takes particular facts about (technological) hazards and develops these into general principles, which enable control decisions to be taken regarding the postulated hazard. For this process to be effective the *a posteriori* facts must provide the basis for a 'dose – effect' (or 'input – output') relationship, i.e. a relationship which allows one to calculate the *proportion* of the population under consideration which when exposed to a given level of the *hazard agent* suffers the *hazard realisation*, or *harm*. This is of course a probabilistic relationship that uses past knowledge to predict future effects, i.e. we are concerned with prospective risk assessment, in a process which forms the basis of *risk management*.

The second reason concerns the changing interaction of science and technology and society. On the one hand we see science and technology playing an increasing role in societal development and on the other hand we see society opposing many technological developments. It is self evident that technological progress has brought enormous rewards as well as often-unintended adverse consequences. Regulators, such as the European Commission, have a responsibility to minimise the adverse impacts without inhibiting the benefits of technological progress. However, the impacts of a regulatory decision are very complex with potential effects on research, employment, health, industrial location,

and so on. These crosscutting effects of regulatory decisions are another of our research interests.

Lastly, it has become clear that in many issues of current concern to regulators there is insufficient knowledge to carry out a risk assessment. It is clearly necessary to develop better ways of dealing with such uncertainty. This brings us into the area of governance, the need for new instruments, for greater transparency (and trust) and for the involvement of all concerned actors.

One of our first major studies in this field concerned the intercomparability of risk assessment carried out on genetically modified organisms (GMOs).<sup>3</sup> In effect, Directives set the Community ground rules for a particular area of policy. They are binding as to the result to be achieved but leave the form and method of implementation to the Member States. Nevertheless, the concept of the Single Market is incompatible with significant differences in the conditions of competition in the different Member States. Consequently, there are two strong reasons for asking questions about the comparability of risk assessments carried out under the 'Deliberate Release' Directive (90/220). The first concerns environmental safety and the second the operation of the Single Market. From a small number of case studies involving three Member States we concluded that the current methodologies for carrying out such risk assessments do not readily allow the quantitative comparison of the risks related to the introduction of different GMOs. This conclusion is broadly accepted and there is a great deal of work going on which is addressing the risk assessment methodology problem in this field.

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Risk assessment is, strictly speaking, a process involving the application of data from the relevant quantitative sciences. However, because of the various sorts of uncertainty and value-commitments that enter into many decisions on risks, the scientific side of the work has increasingly to be complemented by other considerations, deriving from its policy aspects. Hence, it necessarily involves the question of governance. Society has to cope with technological changes of all sorts that occur with increasing intensity and rapidity, and the trust that governments require for their management is made problematic by unresolved debates and difficulties with the assessment of the related risks.

To explore the governance aspect we studied three cases, GMO maize, BSE and

‘Seveso’.<sup>4</sup>

In one sense, the risks arising from GM maize are ‘post-modern’ in that there is no palpable or even demonstrable injury. It is not merely a question of different ways of conceiving potential harms – some participants say that there are no harms at all! The uncertainties of the problem (necessarily viewed more or less subjectively) are more critical in the argument than many of the facts of the case. The debate is as much at the methodological level as at the scientific. How should we weight possible future

*“...with distrust of official expertise now well established, and consumer militancy ready to be aroused at any time, the predictability of the European style of governance can no longer be taken for granted.”*

hazards? How much is the credibility of an applicant damaged by faulty procedures? How far is it legitimate for policy and commercial concerns to affect the evaluations of risks?

The case of BSE highlights the way in which traditional systems of governance are put in question by the new sorts of risks.

The system, which is under challenge, is one of procedural manoeuvrings around a regulatory body (the European Commission) with decisive rule-making powers. However, it is also subject to conflicting pressures, commercial and political, at local and international levels. It seems self evident that Europe needs decision-making procedures which are proof against being derailed. However, with distrust of official expertise now well established, and consumer militancy ready to be aroused at any time, the predictability of the European style of governance can no longer be taken for granted.

In summary, our first field of research concerned risk assessment and regulations; the second revolved around risk assessment, risk management and governance (society); and the third is focussed on risk management and scientific uncertainty (governance). This third area (our current research focus) brings us back to my opening scenario. Put most simply we are trying to provide some answers to the following questions.

- How should a regulator apply the PP while paying due regard to the balance between risk and benefit?
- How should a regulator take account of the need for stakeholder involvement without unduly compromising administrative efficiency?

### Sectoral actions

I must emphasise that the FSU has no specific sectoral responsibilities in this field. By far the major part of the Commission’s work on risk management is carried out by the concerned General Directorates. DGV is concerned with health; DGXI with the environment; DGIII with industry; DGXXIV with the consumer; the Legal Service with legal advice; and so on. However, the FSU is essentially neutral and thus can help to promote horizontal coordination in fields falling within our mandate. In this connection we are co-chairing (with DGXXIV) an inter-service network on risk regulation. One of the aims of this network is to ensure a greater coherence in our approach to such difficult questions as the effective application of the Precautionary Principle.

### The way forward

The recent decision by the UK to create a surveillance group for adverse health effects of GM foods highlights the major problems associated with the PP. There is apprehension (if not fear) of possible health impacts among many consumers but no evidence (let alone plausible hazard-harm relationships). If there is an effect on health in the long-term (such as the inception of cancers), it will be almost impossible to separate the proportion which is caused by eating GM food from that arising from the ‘natural’ incidence. Such programmes would also depend on monitoring detailed diets of large numbers of people over long periods of time.

It may be possible to find chronic effects by using laboratory animals. However, this is difficult and will require large numbers of animals and long experimental programmes. This leads to the question of the optimum (in terms of health benefit) use of resources. I am not attempting to suggest that there is no problem. There may be, but testing the hypothesis will consume significant resources and will take a long time. In this sense the temporary nature of the application of the PP begs the questions “*How long is temporary?*” and “*What should we do now?*” Clearly there have to be better ways of dealing with questions of

risk management that involve large scientific uncertainties (often because the effects are small).

The growth in the current demand for the application of the PP is the clearest evidence of the difficulties faced by regulators in dealing with uncertainty. However, as with all regulatory actions, risk management has to be proportionate and balances have to be struck between the costs and the benefits, etc. Some actors consider that the strict application of the Principle involves the banning of a product or process. However, there are alternatives for the regulator that are introduced below.

The normal approach to managing uncertainty is through some form of insurance. If the uncertainty is high the premiums are also high. As an example, permission to continue with trials of a new product (involving technological risk uncertainty) might be dependent on the firm concerned taking out some form of insurance against the realisation of specified postulated hazards. (This insurance could be simply a designated sum of money in the reserves of the company sufficient to correct the problem or involve cover from the insurance industry itself.)

A second possible response (also from the world of financial risk management) concerns portfolio investment. Sensible portfolio investment should ensure that losses in one holding are counteracted by gains in another. Of course such an approach will not lead to spectacular gains but it will in general avoid spectacular losses! In the same way a sensible technological risk regulator should avoid over exposure to one technology in a particular sector. Such a concentration in one technological area would occur if agricultural competitive pressures lead to extensive monocultures involving limited genetic diversity.

Transparency is an overworked word in the current bureaucrat's lexicon. However, increased transparency might help to resolve some of the issues involved in the management of technological uncertainty. An example is provided by the 'beef on the bone' ban in the UK. The recommendation of the risk assessment experts was just that, namely, to publish the evidence with the uncertainties and to leave the public to decide. However, the government decided to ban beef on the bone. (Labelling is one form of transparency, but this could become meaningless if used extensively in a weak form such as the formulation "may damage your health".)

The active involvement of industry is obviously critical. Industry has not only a vested interest in improving the management of technological uncertainty but also considerable experience in this field. The pharmaceutical industry, for example, has a long history of managing uncertainty in the introduction of new drugs with a well-established procedure for pre-clinical and clinical evaluation processes. However, relations between regulators and industrialists in Europe tend to be rather formal. We need to find a mechanism for a much less formal and more intimate relationship with industry which would provide the sort of benefits enjoyed by for example the Japanese administrations (such as MITI) without compromising the regulator's role.

Other responses to uncertainty include technological intelligence systems and decision support systems. We also need to establish international benchmarking in this field. It is clear that some countries have managed technological uncertainty rather well, whether by design or accident, and others have done less well even with extensive regulatory systems.

I must stress that this is a field that is the focus of a great deal of current attention by many actors and that the above review is obviously somewhat partial. Uncertainty is a crucial aspect of risk management, which affects policy responses to such diverse scientific problems as climate change and plastic teething rings! The application of the PP is playing an increasing part in industrial trade negotiations and we can expect significant changes in our approach to uncertainty and risk management in the coming years.

*"...as with all regulatory actions, risk management has to be proportionate and balances have to be struck between the costs and the benefits..."*

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# Application of risk assessment and management in EU policies and measures



*George Gouvras*

*"Decision-making in the European Community has, for a long time, been characterised by a mixture of political, economic, and technical factors without an explicit or formalised conceptual distinction between assessment of risks and the consideration of risk management alternatives"*

Decisions by individuals and societies, whether or not in the context of a system of laws governing behaviour, relationships or activity, have always been characterised by the notions and processes of risk assessment and risk management at various degrees of sophistication. The relationship between risk (chance of an adverse outcome) and opportunity (chance of a beneficial outcome) has long been known to humankind and indeed is known intuitively or learned at an early stage in the life of an individual.

The growth in formalism and vocabulary concerning these and related concepts, such as hazard, detriment, harm, uncertainty etc., and our ability to articulate better these notions and measure their attributes, has certainly gathered pace over recent years. Generally it has followed the march of technology, the advance of science and the increased sophistication of economic and legal systems. The latter includes not only the courts and legislatures, but also the regulatory agencies and treaties - the whole process of governance which apportions power, responsibilities, rights and obligations.

Health risk, as opposed to economic, political, social advancement, career risks etc., is a particularly sensitive and problematic area of decision-making by the individual and for public policy. I do not intend to discuss here those areas of health risk where risk concepts are in regular use such as security, military and intelligence systems and insurance. The reader should, however, be aware that these are fundamental areas for the processes of risk assessment and management and would, by any standard, gain prominence over other health risks in the selection of priorities for action or allocation of resources, whether by the individual or by government.

Underpinning our ability to function as individuals and as society in terms of

assessing, managing, and communicating risks is our system of values and the way they combine to produce subjective or collective judgements. Science has a preponderant role in this which is not, however, always determinant. The attributes of risk, i.e. voluntariness, distribution of detriment and benefit (health or other) among particular groups in space and in time, degree of personal control, familiarity, reversibility of effects, visibility, uncertainty over and severity or fear of effect, lack of scientific information, contradictory or insufficient evidence and the possibility of refutation of claims, are all key factors in the decision-making process and the object of legislation and regulatory action.

Legislative and regulatory action aims at setting the conditions and limits of human activity which will eliminate or reduce to tolerable or acceptable the levels of health risk. This activity can take many forms, including economic, social, leisure or societal, e.g. protective countermeasures in natural disasters and radon exposure, etc. In doing this, regulatory or legislative measures must be effective, efficient, equitable with respect to the distribution of harm and benefit, consistent with respect to what has been done in other areas of exposure to health risks, procedurally sound, and economically, technologically and politically feasible, especially in terms of compliance and enforcement.

Last, and perhaps most importantly, there is the question of the burden of proof and the attendant issue of liability. The benefits and detriments of an activity involving human exposure to health risks may or may not be completely known. More often than not, the benefits are known, or claims about benefits are made by the proponents of the new practice or source of potential risk. Detrimental effects and the associated risks are not so well known. Both benefits and risks are established by the proponent of a potential source of risk on the basis of current knowledge. This is gathered in a variety of ways involving experimentation and testing, modelling, probability calculations, and may include significance and/or Bayesian testing for therapies and medicinal products and epidemiology for disease prevention and health care interventions.

The law may veer from the permissive to the restrictive, depending on the onus it places on the proponent to prove the benefits and establish the acceptability of risks and degree of safety required, or to refute claims about risks that have not been con-

sidered either by the authorities or by objectors. The law may also place a varying emphasis on the penalties, redress requirements, and insurance obligations it imposes on the proponent should there be faults or a realisation of harm which is different in nature or degree from the one previously established in the assessment and management of health risk. The law may also impose generic limitations on the justification for the introduction of sources and practices and the conduct of activities, such as a generic ban on narcotics or the use of certain plastics because they are not biodegradable, without any further consideration of the benefits and risks from the introduction and use of relevant sources and practices. These risk benefit considerations reflect a system of values and public interest particular to the status and temporal development of the society concerned.

### **Learning the hard way**

Policy in the European Community is slowly coming to terms with the notion and attributes of risk. Implicitly, however, risk considerations underlie some key concepts of the Treaties establishing the European Communities and are the object of fundamental and wide-ranging provisions in several articles of the EC Treaty (see Box for some examples).

Decision-making in the European Community has, for a long time, been characterised by a mixture of political, economic, and technical factors without an explicit or formalised conceptual distinction between assessment of risks and the consideration of risk management alternatives. With a legal obligation to implement Treaty provisions, regulatory action in the European Community was influenced mainly by existing Member State provisions and international guidelines (e.g. those of the World Health Organization or the International Commission on Radiation Protection) or obligations (e.g. GATT and WTO agreements, CODEX standards or international transport regulations) and by assumptions about what may be acceptable or feasible in prevailing political circumstances.

Although not unreasonable in terms of the desirable law-making characteristics described earlier, such a method of managing (and influencing the magnitude and distribution) of risks had the distinct disadvantage of failing to keep pace with technology and changes in the forces which control the introduction and exploitation of technology. In some areas, such as ionis-

ing radiation and health and safety at work, law-making and legislation was and remained sound in terms of desirable characteristics from the risk assessment and risk management point of view. In other areas, these characteristics were not evident, and it took three major crises, plus two highly-charged controversies, to usher in the new era of acceptance of the distinction between the scientific and policy basis for decisions, and the admission of public perception, participation of all stakeholders in decision-making, and need for effective communication about risks, as key determinants in law-making and risk management.

These three crises were the Seveso accident, the Chernobyl accident, and the BSE epidemic. The controversies, still raging, are over genetically modified organisms (and biotechnology, more generally) and hormones and other residues in beef and other foods and the application of the precautionary principle in areas other than where it appears as a requirement in the Treaty, i.e. Article 174 (ex-Article 130R) on the environment. The main difficulty lies in extending the application of the precautionary principle from situations where an effect or detriment is known and there is uncertainty over the existence or magnitude of causative relations with particular sources or practices (e.g. greenhouse effect), to situations where sources and practices are introduced and the benefits and the risks to health cannot all be determined and/or managed (e.g. non-ionising radiation and cancer, GM foods and immunisation system defects).

### **Changes for the better**

The changes in legislation, practices, and attitudes in response to the pressure generated by these events have been profound and are still unfolding. Coherent and consistent terminology and rationale over "high level of protection", "acceptable or tolerable level of risk", "failure or burden to prove harm or benefit", "evidence or lack of evidence", and "uncertainty of outcome" or "uncertainty due to lack of knowledge" are still in the process of formulation and integration into an overall policy. This will have far-reaching consequences for the further implementation of the provisions of the Treaties and the position of the EU in international standard-setting fora, particularly the WTO and the UN specialised agencies. It will undoubtedly influence governance, international trade, and day-to-day decision making. Hopefully for the better.

### **RISK ASPECTS OF EC TREATY**

**Articles 30 (ex-Article 36) and 49 (ex-Article 59)** which may be used by EU Member States to invoke health protection requirements to justify restrictions on the free circulation of products and services.

**Article 95 (ex-100A)** used for the establishment of the Single Market.

**Article 137 (ex-118A)** on the health and safety of workers.

**Article 152 (ex-129)** on Public Health.

**Article 153 (ex-129A)** on Consumer Protection.

**Article 174 (ex-130R)** on the Environment.

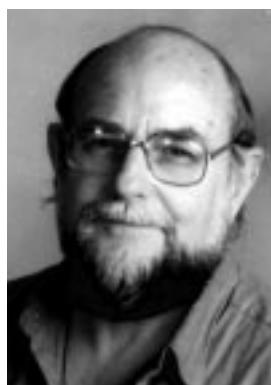
**Articles 30 and 37 of EURATOM Treaty** used for the setting of standards for the protection of workers and the public against the risks of ionising radiation.

*"Risk benefit considerations reflect a system of values and public interest particular to the status and temporal development of the society concerned."*

# The health costs of bad housing

## Report on a five year research programme in the UK

In 1992 the author was commissioned by the UK Foreign and Commonwealth Office 'Know How Fund' to form a team of British housing practitioners and academics to advise the Bulgarian Government on how best to reform their housing policies and practices. The team included urban regeneration specialists, senior officials from the public and voluntary sectors, finance experts, a lawyer and an architect in private practice and several academics. In 1994, on completing the task, it was decided that there was important research to be undertaken in Britain.



Peter Ambrose

Team members were well aware from long practical experience that poor housing conditions were clearly associated with higher rates of ill-health and with related adverse outcomes such as a higher incidence of crime and under-achievement by children in school. All these outcomes shared the characteristic that they seriously affected well-being and thus increased costs on budgets in non-housing, as well as housing, sectors.

A research project on Cost-effectiveness in Housing Investment (CEHI) was therefore initiated at the University of Sussex. The Research Management Committee was chaired by Stephen Hill of Capital Action Ltd. The aims were:

- to show that investment in better quality housing will produce more than commensurate reductions in 'cross-sectoral' costs (costs falling on budgets other than housing)
- to identify, systematise and where possible evaluate these cost savings
- to identify what forms of additional investment in housing quality will be most cost-effective
- to promote a more informed debate at all levels on these issues

A wide range of public, private and voluntary organisations, and several professional institutions, showed immediate interest in these aims and funding to initiate the project was quickly raised.

Time was spent defining what was meant by 'better quality housing' and a fully worked out definition was arrived at.<sup>1</sup> A brief and cross-culturally acceptable ver-

sion of this definition was found in work by Seedhouse (*Health, The Foundation for Achievement*, 1986):

"A satisfactory housing standard is one that provides a foundation for, rather than being a barrier to, good physical and mental health, personal development and the fulfilment of life objectives."

### New urban policies in Britain

The broad approach inherent in this definition accorded well with the 1990s trend in British urban regeneration policy. It was seen that there was a need for strategies to tackle the problem of poor housing quality on a more holistic basis. None of the regeneration policies during the 1980s had attempted to deal with the problem of decaying inner suburbs in this way. The new move was away from the 'bricks and mortar' approach of targeting housing per se and towards local economic and social regeneration as a whole.

Moreover it was realised that there had been insufficient inter-agency collaboration in setting-up and implementing earlier improvement schemes. The introduction of the Single Regeneration Budget (SRB) policy was a shift of ethos and represented the first opportunity to plan investment strategies to produce benefits which cross departmental boundaries.<sup>2</sup> This placed a greater premium on research, such as the CEHI Programme, which sought to evaluate the costs of not working in a cross-departmental and holistic manner.

### Poor housing quality and 'exported costs'

In recent years considerable research has focused on the interface between housing quality and health status. The interface is a complex one and there are no simple 'cause/effect' relationships. But evidence gathered from many studies shows clear patterns of association between poor housing conditions, for example cold, damp, infestation and overcrowding, and an increased incidence of ill health. A com-

hensive collection of essays on the subject has been published.<sup>3</sup> It is evident that an increased incidence of ill-health must increase costs for health services which are already under increasing strain in Britain and other EU countries as a result of various factors including ageing populations.

But poor living conditions generate additional costs not only to health services but also to other service providers. These include:

- the education service (because children in poor and overcrowded home conditions cannot learn as effectively)
- the police and judicial services (because poor housing design and construction is associated with a higher incidence of some crimes)
- the emergency services (because poor housing conditions and 'secondary heating' increase accident and fire risks)
- the energy supply services (because poorly designed housing uses excess energy and produces ecological damage).

Over three hundred research studies examining these issues were reviewed as an early part of the CEHI programme of work.<sup>4</sup> It was evident that these links implied additional costs for a wide range of service providers. The CEHI team termed these costs 'exported costs' because they are generated by under-investment in one sector (housing in this case) and then 'exported' to others.

### **The effects of poor housing in Stepney**

Early in 1995, in view of the progress they had made, the CEHI team were commissioned by the London Borough of Tower Hamlets to carry out a 'health gain' study to compare the health status of a population before and after a major housing improvement scheme. The housing to be improved was on two estates in central Stepney, the Limehouse Fields and Ocean estates, then some of the worst housing in London. The housing renewal was part of the Central Stepney Single Regeneration Budget improvement programme. Apart from the interest of the local authority in evaluating some of the benefits of housing improvement the project came at an opportune time to test the central propositions of the CEHI Programme with some empirical evidence.

The 'before' element in the study was carried out over five months in the winter of

1995/6. A total of 107 households (525 residents) were interviewed using an intensive survey methodology. The technique was to collect data on the health of all household members using unstructured interviews and several call-backs per household. The work was carried out by bilingual pairs of interviewers since 83% of the population spoke Sylheti as a mother tongue. The response rate was about 95%. The 'after' survey, on the same households following re-housing in improved conditions, will be carried out in the winter of 1999/2000.

*"... poor living conditions generate additional costs not only to health services but also to other service providers."*

The housing conditions encountered in the 'before' survey were extremely bad (see Ambrose P, 1996<sup>1</sup> for a full account of the findings). Over 47% of the rooms were damp and 69% of the population reported that the heating did not keep them warm enough. Over one third of households suffered from infestation from cockroaches and pharaoh ants and the room density was well over the legal limit at 1.43 people per room. The 107 households reported 280 illness episodes over the survey period and there was a total of 29,114 illness days, about 37% of the total person/days. The main ill-health suffered was coughs and colds, aches and pains, asthma and bronchial problems, digestive disorders and depression.

The relationships between (a) dampness, (b) lack of warmth and (c) accommodation needing repairs on the one hand and the incidence of coughs and colds on the other were all significant at the 99% level. Damp households and cold households experienced over twice the rate of illness episodes than dry and warm households. Residents themselves overwhelmingly regarded illness episodes as 'very closely related' to housing conditions.

The evidence of a link between poor housing conditions and poor health gained from residents was fully substantiated by a second survey - a round of interviews with over fifty providers of health, education and law and order services to the central Stepney population. Almost without exception these professionals working in the area also considered that poor housing conditions greatly increased the call on their services or reduced their capacity to deliver as good a service as they wished.

These two surveys, one of residents and one of service providers, enabled the team to conclude that very direct associations existed between poor housing and a number of adverse outcomes. They also identified a number of 'indirect' processes that

*"There is now increasing urgency to improve inter-agency working because future increases in national health and welfare spending may well be politically dependent on showing an increased degree of cost-effectiveness in service delivery."*

affected the health status of populations in very poor and stress-laden housing conditions. These included:

1. Lowered resistance to illness from long exposure to poor conditions.
2. Adoption of health-threatening habits such as smoking as a means of coping with the stressful conditions rather than as a chosen life-style.
3. Reduced self-organising capacity, for example in accessing health and other services and complying with courses of treatment.
4. Diversion of professional expertise (for example the time spent by doctors in writing 'housing letters' or by teachers in giving 'social work' support).

#### **The incidence of ill-health in a comparator area**

It was found that the increased use of primary care and hospital services appeared to be adding substantially to National Health Service (NHS) costs compared to those generated in a comparator area of improved housing in Paddington (an inner urban area of west London). Here, using identical survey methodology but on a smaller sample, the reported illness rate was about one seventh that in Stepney. An exploratory assessment of the differences in costs generated (in primary and hospital care only) indicates that the annual healthcare costs per household were £515 in the Stepney sample and £72 in the Paddington sample.<sup>5</sup> Part at least of the difference can be regarded as costs exported from the housing sector to the NHS.

#### **Post-1997 developments**

Shortly following their election to power in 1997, the Blair Government initiated a series of 'New Deal' programmes to reduce inequalities in Britain. The New Deal for Communities (NDFC) programme incorporated some welcome new thinking on the problem of decayed inner suburbs. It sought to approach the problems posed by the persistence of urban social, economic and physical rundown by targeting a num-

ber of 'pathfinder' areas marked by multiple deprivation. The programme further developed the SRB approach by promising a ten-year time-scale, allowing greater local freedom in defining and measuring indicators of 'success', requiring greater degrees of community participation and above all stressing the need for a more holistic approach involving not just physical but also social and economic regeneration.

This necessitates developing new and broadly based partnerships between public, private and voluntary organisations in the pathfinder areas. There is now increasing urgency to improve inter-agency working because future increases in national health and welfare spending may well be politically dependent on showing an increased degree of cost-effectiveness in service delivery. In this context CEHI team members were commissioned to advise the London Borough of Hackney on drawing up the New Deal for Communities programme in the local pathfinder area in Shoreditch. They were just completing a follow up survey of the health and other benefits of the urban renewal initiative in the Holly Street area of the borough carried out under a previous government programme. This regeneration, in an area just to the north of the Shoreditch pathfinder area, is widely regarded as a success and was the chosen location from which the Prime Minister launched the NDFC programme.

The follow up report on Holly Street<sup>6</sup> found that the benefits had indeed been considerable but that there were still serious obstructions to better inter-agency cooperation in service delivery and continuing difficulties in the measurement of 'exported costs'. The report suggests a number of steps that can be taken to improve inter-agency working. It also focuses on a limited number of 'exported costs' where progress in measurement and cost reduction can now be made as the cost databases of agencies get more sophisticated. As example:

- 11% of bed-spaces are lost in a local hospital because poor housing conditions delay the discharge of some patients
- accidents in the home can be much reduced by adequate sized kitchens
- more investment in crime prevention at the design stage can reduce personal stress and have dramatic cost saving effects.

The report on Holly Street is now to be

circulated widely not only within Hackney but also to other NDFC pathfinder areas.

### The progress made by the CEHI programme

The CEHI team feel that considerable progress has been made over the past five years in terms of analysis, promoting debate and informing policy formation. The concept of 'exported costs' is now widely accepted and some progress has been made in their identification, systematisation and measurement.<sup>6</sup> By drawing attention to the phenomenon, a strong incentive has been given to service providing agencies to work more closely together to minimise not only their own costs but to improve the cost-effectiveness of the local service delivery process as a whole. By helping to engender and develop a more informed debate about these issues the programme has played some part in encouraging a more holistic approach to urban renewal problems. By the emphasis on cost-effectiveness the CEHI philosophy resonates closely with the approach being

brought into renewal processes by the private sector investors the Government is increasingly seeking to involve. CEHI team members are now partners with other EU colleagues in an application to DG XII for funds to research the costs of 'housing exclusion' in a number of European countries.

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# Decent housing for everyone: A challenge for the European Union

*It is a well-established truth that the living conditions of an individual or family play a major role in determining their state of health. All of the relevant research concerning living conditions and human health problems in every part of the world, from the earliest archeological findings to the latest social scientific studies, leads us towards this same conclusion.*



Catherine  
Parmentier

If you live in a spacious well-built home with adequate heating, a constant supply of clean water, good washing and sanitary facilities, and proper facilities for food storage and preparation, then you will have a good chance of living a long, healthy and happy life. However, if your accommodation is overcrowded and affected by damp or infestation, with inadequate or unsanitary toilet, bathroom and kitchen facilities, then you will have a greater chance of

being affected by a wide range of health problems including major diseases such as tuberculosis, as well as depression and mental illness, resulting in a shorter life expectancy. Moreover, if you are homeless and either sleeping rough, squatting or in temporary hostel accommodation, then you will face an even greater risk of being affected by serious health problems.

One can say that decent housing and living conditions are among the most basic needs of each individual or family. But in the 15 countries of the European Union, which represents one of the most prosperous parts of the world, a growing number of citizens and residents are faced with serious obstacles in gaining access to decent housing at a price they can afford. The

*“The provision of adequate housing should be recognised as an essential factor of economic and social cohesion, to be taken into consideration at all levels of political decision-making.”*

European Observatory on Homelessness (created by the European Federation of National Organisations Working with the Homeless – FEANTSA in 1991) has conducted research to assess the situation in each of the 15 Member States. According to the best available data, some 3 million people have no fixed home of their own, while a further 15 million people live in inadequate or overcrowded accommodation. These figures have been accepted and used by both the European Commission and the European Parliament.

FEANTSA brings together more than 50 social sector bodies who are providing a wide range of services to homeless people in all of the 15 Member States and also in the applicant countries. Since 1989, FEANTSA has been a strong advocate for housing issues in general, and most especially the question of ensuring access to decent and affordable housing, to be seriously addressed by policy-makers at all levels: local, regional, national and European.

Last year a group of our most experienced members and researchers came together to address the following question: What could be done at the level of the European Union, in order to promote and facilitate access to decent housing for everyone? The results of this work are published in the FEANTSA Policy Report ‘Europe against exclusion: HOUSING FOR ALL’. The report presents a series of policy proposals which are based on the experiences of our members and on the results of research carried out by the European Observatory on Homelessness.

### **Housing is a human right**

To properly tackle housing exclusion, one must start from the recognition that housing is a basic human right, which every man, woman and child should be entitled to exercise. The revised European Social Charter (1996) sets out clear objectives for the realisation of the right to housing: “With a view to ensuring the effective exercise of the right to housing, the Parties undertake to take measures designed: (1) to promote access to housing of an adequate standard; (2) to prevent and reduce homelessness with a view to its gradual elimination; (3) to make the price of housing accessible to those without adequate resources” (Article 31). While some countries have already signed this text, we would argue that all current and future EU Member States should be required to sign and to ratify the revised European Social Charter.

The European Union currently lacks any effective instruments for the protection of civil and social rights. FEANTSA strongly advocates that there must be an effective guarantee of civil and social rights for each citizen and resident of the European Union, encompassing those rights set out in the European Convention on Human Rights (1950) and in the revised European Social Charter (1996), including the right to housing. As a member of the Platform of European Social NGOs, we are supporting the Campaign for an EU Charter of fundamental civil and social rights which would be incorporated into the EU Treaty and given legal force.

Looking at the responsibilities of public policy-makers, we would argue that the provision of adequate housing should be recognised as an essential factor of economic and social cohesion, to be taken into consideration at all levels of political decision-making. But in most of the EU Member States, public investment in the housing sector has decreased substantially during the past 20 years, resulting in a crucial shortage of homes which are affordable for those on low incomes. Meanwhile, state intervention to tackle homelessness has focused on measures which treat housing shortages as if they were of a temporary nature.

In terms of what action can and should be taken at the level of the European Union, FEANTSA has developed proposals which relate to a wide range of Community policies and areas of responsibility. Here I present a summary of our main arguments:

#### **1. Research and statistics**

Little can be achieved in the longer term without a clear understanding of the causes, nature and extent of homelessness and housing needs across Europe. Therefore, relevant and reliable research is of fundamental importance to policy development. The European Observatory on Homelessness (created by FEANTSA in 1991) comprises a network of national correspondents, based in Research Institutes and Universities in all of the Member States. However, primary research and data collection on homelessness and housing conditions varies widely between different countries, which makes it difficult to make meaningful comparisons, or to evaluate the results and effectiveness of different policy approaches.

In order to obtain a comprehensive and up-to-date overview of housing conditions in the European Union, there is a need for

primary research to be carried out on a regular basis with the same criteria and methodology in all Member States, and in the countries preparing for accession. Coordination, monitoring and analysis of data should be undertaken at European level, to allow for the regular publication of comparable data concerning access to housing, the quality and costs of housing, current and future levels of housing need, including the numbers of homeless people in each Member State. EUROSTAT, which has already created a Task Force on the Homeless, should be given the necessary mandate to compile the relevant data.

## **2. Monitoring and coordination**

According to the Treaties, the tasks of the European Union include the promotion of “a high level ... of social protection”, “the raising of the standard of living and the quality of life”, and “economic and social cohesion”. While the powers of the European institutions are limited according to the principle of subsidiarity, there are a number of Community Policies for which questions of access to housing, and the quality of housing, are of relevance, including:

*Social Policy:* The Social Chapter of the EC Treaty sets out a series of objectives which include “improved living and working conditions”, “proper social protection” and “the combating of exclusion” (Article 136). One cannot provide proper social protection, or effectively combat exclusion, without addressing the issue of access to housing.

*Public Health:* Article 152 of the EC Treaty states that “Community action ... shall be directed towards improving public health ... and obviating sources of danger to human health”. Homelessness, and inadequate and overcrowded accommodation, are damaging to the health of those directly affected, and also present dangers to public health.

*Consumer Protection:* Article 153 of the EC Treaty asserts that “the Community shall contribute to protecting the health, safety and economic interests of consumers”. Everyone who seeks access to accommodation, either in the social sector or on the private market is, in effect, a consumer of housing, including families and individuals on low incomes.

While housing policy as such is not a matter of Community competence, according to the Treaties, FEANTSA is convinced that there is a need to develop European

cooperation in this field, for two main reasons. Firstly, the housing sector in each Member State is affected by European policies in a wide range of areas: including regional, environmental, fiscal and monetary policies. Secondly, the housing sphere has an important contribution to make towards the achievement of common objectives in the fields of social protection, employment creation, regional development, environmental protection and energy conservation.

Within the European Commission, there is no single Directorate-General which could properly address the full range of issues concerning the impact of various European policies on the provision of housing. Therefore, FEANTSA joins the European Parliament in calling for “the permanent monitoring, for example by a Task Force of relevant Directorates-General in the

*“There should be minimum standards for social protection systems in order to ensure that each family or individual who is resident in the European Union can receive an adequate income which is sufficient to pay for permanent access to suitable accommodation.”*

Commission, of the impact of EU policies on the housing sector, to take into account the possible effects on vulnerable and disadvantaged groups and to lead to the development of integrated strategies and coordination of Community resources to achieve maximum effect” (Resolution on the social aspects of housing – PE 260.284 – 29 May 1997).

## **3. “Proper social protection”**

Maintaining “a high level of social protection” is among the primary tasks of the European Union. On average, the EU countries devote 28% of GDP to social protection (the actual levels range from 16% to 35%), but payments allocated specifically to cover housing costs account for less than 5% of this expenditure. FEANTSA would say that systems of social protection in the Member States must be adapted and strengthened so as to promote social inclusion in terms of access to decent housing, as well as access to education, employment, healthcare and other services. There should be minimum standards for social protection systems in order to ensure that each family or individual

who is resident in the European Union can receive an adequate income which is sufficient to pay for permanent access to suitable accommodation.

#### **4. Combating social exclusion**

The Amsterdam Treaty, in force since 1 May 1999, provides a legal base for the EU to support "initiatives aimed at improving knowledge, developing exchanges of information and best practices, promoting innovative approaches and evaluating experiences in order to combat social exclusion". FEANTSA would argue that there is a need to develop and implement a comprehensive European strategy for social inclusion which can promote the spread of effective and integrated policies to improve the living conditions of the most disadvantaged citizens and residents. Such a strategy must be based on the recognition that social exclusion is a multi-dimensional problem, with a range of inter-related causes and effects, such as in terms of social protection, physical and mental health, housing and living conditions.

#### **5. The Economic framework**

Policies and legislation concerning direct and indirect taxation, property transfer and interest rates have a direct impact on the cost of housing and on the dynamism of the housing sector. Monetary Union is having a decisive impact on the cost of borrowing to make investments in housing. Meanwhile, important economic and legislative changes are taking place in the countries preparing for accession. There is a need to establish "housing focal points" within DG II (Economic and financial affairs) and DG XV (Internal market) of the European Commission in order to allow for policies to be monitored for their impact on the housing sector and taking into account possible effects on vulnerable and disadvantaged groups.

#### **6. Housing and employment**

The housing sector has enormous potential as a source of opportunities for creating new jobs in terms of construction, renovation, insulation, plumbing, decorating, electrical installation, etc., as well as in terms of

home-based service jobs (to meet various social and ecological needs). This potential has been recognised by the Informal Council of EU Housing Ministers, at their meeting in October 1998 on the theme: "The employment impact of the construction, renovation and modernisation of housing". In all Member States, the growing levels of demand for the provision of decent accommodation at an affordable price should be seen in positive terms, as an opportunity for sustainable job creation.

#### **7. Urban development**

The European Commission has drawn attention to the growing problems being faced by Europe's towns and cities (in the Communication 'Towards an Urban Agenda in the European Union', 1997). These problems include the increasing numbers of poor households and of homeless people, bad housing conditions, and the "segregation of social groups in neighbourhoods with poor facilities". The Communication concludes that, with no explicit mandate in the Treaties for developing an urban policy, the European Union "should play a complementary role in addressing urban issues as it has responsibility for policies in a number of sectors which have a direct bearing on the development and quality of life in urban areas".

#### **8. The Structural Funds**

To provide the means for pursuing the objective of economic and social cohesion, the European Union has access to four structural funds, including the European Regional Development Fund (ERDF) and the European Social Fund (ESF). FEANTSA agrees with the European Parliament that "the European Union should act as a coordinator and facilitator in the question of housing by granting loans or other measures" (Resolution on the social aspects of housing – PE 260.284 – 29 May 1997). The regulations of the Structural Funds should therefore allow European funding to be made available for innovative housing projects. The ESF should also be used to finance projects of housing construction, modernisation and maintenance, which would increase the provision of decent and affordable accommodation.

By putting forward our proposals, and engaging in dialogue with all the relevant actors – both at European level and in the Member States – we hope to contribute towards building a European Union in which everyone can have access to a decent home.

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*Copies of the FEANTSA Policy Report: Europe against exclusion: HOUSING FOR ALL are available in all 11 official languages of the European Union from:*

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# Disability-Adjusted Life Years:

## An introduction to their objectives, methods and potential

*Gwyn Bevan, Sandra Hollinghurst and Cam Bowie*

*Disability-Adjusted Life Years (DALYs) provide estimates of a population's burden of disease by combining Years of Life Lost (YLLs) through premature mortality with Years Lived with a Disability (YLDs). Murray and Lopez<sup>1</sup> developed this method for the World Bank Development Report in the Global Burden of Disease (GBD) study. This paper outlines DALY methods and the way these were adapted and applied in a project for health authorities in England. It illustrates how our estimates of DALYs are relevant to EU countries in deciding which health care to provide, monitoring the health of populations, and indicating how research funds be spent. The paper concludes with a summary of the potential of DALYs for the EU.*

### The GBD Study

The GBD Study transforms data on morbidity and mortality into DALYs through four sets of weights:

- The number of years lost due to premature mortality was weighted by life expectancy at the age of death. The highest values were used: for Japanese women with a life expectancy of 82.5 years at birth adjusted to allow for lower survival rates of males.
- Future life years (and hence YLLs and YLDs) were discounted (at 3%). This gives future years less weight than current years and is consistent with discounting of costs.
- Life years are valued differently at different ages. A year of young or middle-aged adult life was valued more highly than a year of life lived by young children or the elderly to give greater value to individuals likely to be caring for others.
- YLDs are weighted by disability weights to allow for years of life lost and years lived with a disability to be measured on the same scale. The disability weights used in the GBD Study were derived using a variation of the person-trade-off

(PTO) method. Twenty-two indicator conditions were formally assessed. From these weights measurements for all other diseases and disabilities were obtained.

The disability weights used in DALYs perform a similar function to those used in deriving Quality-Adjusted Life Years (QALYs). As DALYs aim to measure the burden of disease, an individual living with no disability has a weight of zero and a death has a weight of one. (QALYs aim to measure health gained by interventions, and so an individual living with no disability has a weight of one and a death has a weight of zero.)

### The South and West DALY project

We reviewed GBD methods with a view of applying these to health authorities in the South and West of England. The South and West DALY project followed GBD methods, except that we did not weight for age: we used the same life tables, morbidity weights (where possible), and discount rate. The South and West DALY project produced three sets of empirical results for authorities:

- Estimates of DALYs in total and by disease.
- Estimates of expenditure in total and by disease.
- Estimates of 'avoidable' DALYs for heart disease, stroke, cataract, benign prostatic hyperplasia (bph), osteoarthritis, peptic ulcer and depression.

A full account of this work has been published.<sup>2</sup> All the models use Excel spreadsheets that have been designed so that data can be updated and assumptions examined by sensitivity analysis. The models have been supplied to sponsoring authorities on disc and are available for researchers who would like to examine and apply our work.

In this paper we use results of total and 'avoidable' DALYs. For heart disease and stroke our central estimates of 'avoidable' DALYs were based on target reductions in

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*"Similarly, governments can use information on 'avoidable' DALYs to see how the significant variations in the performance of health authorities... change over time."*

mortality specified in the *Health of the Nation*.<sup>3</sup> For the other (chronic) diseases, we estimated 'avoidable' YLDs from estimates of the prevalence of untreated severe cases that could benefit from treatment. This required data on treatment, and progression of diseases, these data were often incomplete and difficult to assemble.<sup>4</sup>

### Deciding which health care to provide

Current patterns of services reflect historical commitments, variations in medical practices, and demands from the articulate and forceful members of populations. Indeed it was precisely because of concerns about these influences on NHS supply that this project was conceived and funded by authorities in the South and West. Figure 1 gives estimates of the 'avoidable' DALYs per 100,000 population for each cause, by health authority in the South and West Region. Figure 1 shows diseases broadly consist of three groups in terms of the magnitude of 'avoidable' DALYs per 100,000:

1. Depression,
2. Peptic ulcers and heart disease, and
3. Stroke, cataract, arthritis of the hip and bph.

Stroke, cataract, arthritis of the hip and bph vary considerably across authorities and these variations are unlikely to reflect deliberate choices by authorities.

The results of Figure 1 suggest how medical practice ought to change. They indicate the consequence of general practitioners treating only half of clinical depression in

populations, and how variations in rates of cataract operations and hip replacements result in variations in the burden of diseases from cataracts and arthritis in different authorities.

Information on 'avoidable' DALYs does not, of course, provide the only information in deciding on treatment. It is also important to consider costs and benefits of interventions that would reduce these potentially avoidable DALYs. Costs of treatment include fixed and variable components, and thus average costs per case will depend on the volume supplied. It therefore follows that in developing a strategy for better use of scarce resources, authorities ought to have estimates of how current volumes might increase to treat those who would benefit from treatment, and hence what future average costs per case might be. The methods that we have developed for estimating 'avoidable' DALYs can derive estimates of these volumes.

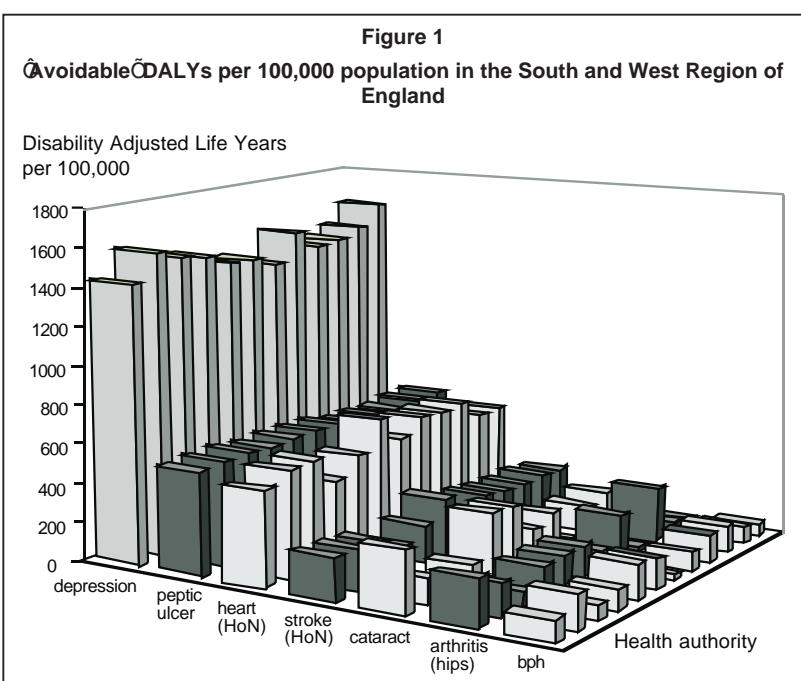
### Monitoring the health of populations

Once health authorities have decided to change the spend to reduce 'avoidable' DALYs, they will want to monitor these changes over time. This is particularly important as medical care responds to demands rather than to needs. Thus monitoring is not only about whether policies are being implemented to treat unmet needs from the past, but also about how changes in care relate to changes in the needs of populations.

One of the objectives of the various EC studies of 'avoidable' deaths across health authorities<sup>5</sup> was that this information was much more relevant for monitoring the performance of health authorities than total mortality. Similarly, governments can use information on 'avoidable' DALYs to see how the significant variations in the performance of health authorities reported in figure 1 change over time.

### Indicating how research funds be spent

Figure 2 ranks diseases in terms of total DALYs in the South and West Region, and also gives 'avoidable' DALYs for each disease. Figure 2 shows that a quite different ordering of diseases emerges using 'avoidable' rather than total DALYs. This is because the 'avoidable' burden for heart disease and stroke is based on *Health of the Nation* (HoN) targets. These apply to those under 75 only and account for 30% of deaths only. In contrast, effective treatment of depression and peptic ulcer is



assumed to be available for all adults. This raises questions about how England compares with other EU countries in mortality from heart disease and stroke. Figure 3 gives estimates of 'avoidable' DALYs using the lowest mortality rate in Europe for each of these diseases. This shows that more than half current DALYs from heart disease could be avoided if the mortality rate for heart disease in the South and West (224 per 100,000) were reduced to the lowest in Europe (France with 46 per 100,000).

The mismatch between total and 'avoidable' DALYs is relevant information for research. For heart disease, for example, this highlights the needs of the over-75s. As the numbers in this age group increase, so also will their needs. Without such information research will be driven by demands of researchers which are likely to follow intellectual challenges of molecular genetics rather than needs of populations that lack effective prevention and treatment.

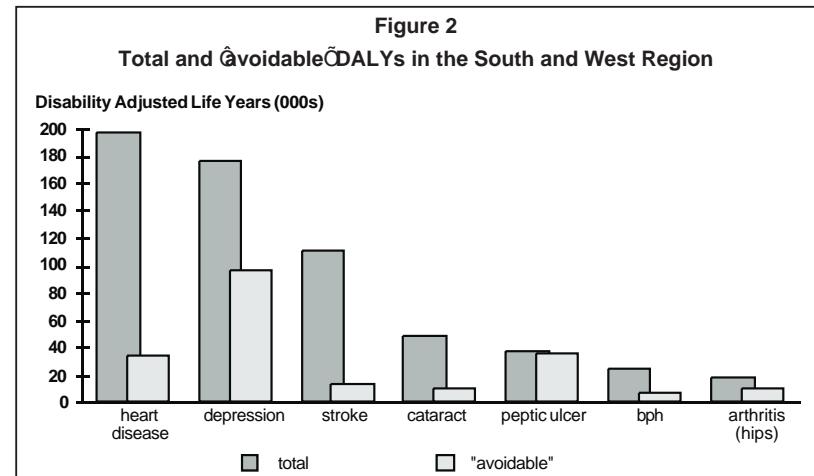
## Conclusions

We have argued that estimates of 'avoidable' DALYs offer useful information:

- in enabling health authorities to review critically the decisions that they currently make on the provision of health care, and
- in monitoring and comparing the performance of health care between and within EU countries.

We have also argued that estimates of total DALYs, when set alongside information on 'avoidable' DALYs, offer useful information in indicating where there are significant burdens of disease that ought to be considered in setting priorities for research.

We appreciate that some economists question the value of information on needs and the burden of disease. They see such information as irrelevant to choices between options for prevention and treatment. But to define relevant information in this way reflects a seriously limited purview of the nature of decision making. It is vital also to consider the processes through which issues are allowed onto the agenda, and the deeper influences on the way people think about these issues. Information on cost/QALY does seek to change radically the way people think about health care by requiring them to consider costs. But this information is designed to evaluate options defined through the interplay between producer interests and demands. Investment decisions in health care and research that solely rely on cost-effectiveness analysis of

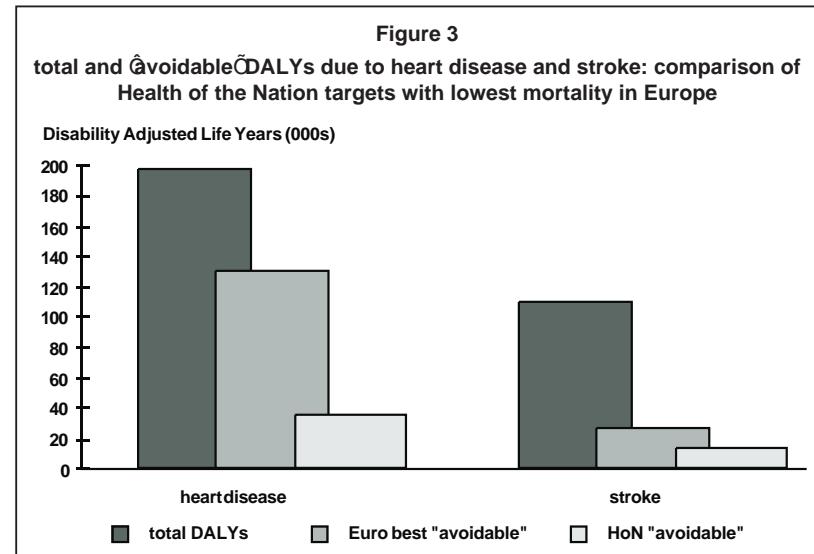


such options will be unbalanced because they ignore the needs of populations. We see it as crucial to redefine this agenda by working out needs that can be met now, and needs that ought to be considered in future research. As we have explained, DALYs offer useful information in helping to redefine the agenda in these ways.

"… estimates of total DALYs, when set alongside information on 'avoidable' DALYs, offer useful information in indicating where there are significant burdens of disease that ought to be considered in setting priorities for research."

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# Measuring the burden of disease: what's the use?

*Measuring the overall burden of disease has a long and unproductive history. It starts from the intuitively appealing notion that if we knew which diseases cause the greatest loss of life and the greatest suffering, we could direct our resources accordingly and make the world a healthier place.*



*Alan Williams*

Unfortunately there is no clear link, either in theory or in practice, between the total burden of disease and our capacity to reduce it. The essential link between them is the effectiveness of any feasible interventions, and this is an entirely different matter which does not require us to know the overall burden of a disease at all. It highlights the crucial difference between conceptualising a problem in terms of totals and averages, and conceptualising a problem in terms of what can be done at the margin.

If we are to reduce the overall burden of disease as much as possible with the resources at our disposal, we need to focus attention on the incremental cost-effectiveness of different policy options, and devote our scarce analytical talent to that difficult task, and not waste it trying to measure things that are irrelevant.

But it might be argued that, even though we do not need to know the overall burden of disease in order to measure the relative effectiveness of different therapeutic interventions, it would nevertheless be useful as a guide to where we might direct research effort so as to create new intervention possibilities. There is some limited truth in this proposition, in the sense that, if we had estimates of the overall burden of each disease, it would be possible to demonstrate that research effort directed at certain diseases, even if cheap and successful, would not make much difference to the health of the population at large.

But the caveat about "cheap and successful" is important. A cheap and successful research programme attacking a disease

which does not impose a major burden in terms of the health of the whole population, may nevertheless do more good for population health than an expensive and unsuccessful research effort directed at some disease which imposes an enormous burden in whole population terms. Again it is the likely cost-effectiveness of the particular research that we must focus on, not the total burden of the particular disease to which the research is directed.

## **Diseases or people?**

But there is a second cause of concern about efforts to measure the burden of disease, which is that it focuses attention on diseases rather than upon people. A possible justification for this disease-based approach is that we collect lots of data routinely about the incidence and prevalence of diseases, and that death certificates routinely ascribe people's deaths to diseases, so there is lots of information to draw upon. But at a common-sense level we know that the reason why many people suffer more than others and die earlier than others is due to poverty or smoking. This is not however what the death certificate says. Death from poverty or smoking is always mediated by some disease which a doctor can identify and write down, and so that becomes the recorded cause of death. Furthermore, many older people have many diseases, but one has to be singled out as the cause of death.

So measuring the burden of disease turns out to be a complex matter, not a routine one, since it requires the unravelling of the separate impact of each disease upon the various people who contract it, and then, abstracting from the individuals themselves, using this synthetic profile for each disease to construct an aggregate measure of the health (or rather ill-health) of the population at large. After which, it has all to be put back together again in some way if you want to estimate the differential disability-adjusted life expectancy (and the

associated 'risk factors') from being rich versus poor, or smokers versus non-smokers, or from any other personal characteristics of individuals.

This interest in the distribution of health within a population (as opposed to the overall burden of disease) may well be motivated by an equity concern about inequalities in health, but in pursuing such a concern it is surely better to take the individual as the primary focal unit for the analysis, not the disease. Instead of working with diseases and then ascribing them to people in order to calculate population health, what should be happening is estimating the health of individuals directly, and then trying work out why some individuals are so much healthier than others. The incidence or prevalence of particular diseases may turn out to be significant causes of these differences, but so may poverty, or smoking, or unemployment, or air pollution. And the estimates of the impact of each of these factors upon the 'burden' of ill-health will come from the independent measurement of that burden (through life expectancy statistics and surveys of health-related quality of life). It will not be built up synthetically from experts' judgements about the supposed contribution of the separate bits and pieces.

But as I explained earlier, measuring the overall burden of ill-health is really not the important thing to be doing. For efficiency purposes the important thing is measuring the cost-effectiveness of possible interventions, and for equity purposes the important thing is measuring the interpersonal distribution of health within the population. But the advocates of burden-of-disease measurement claim that the methods that they have devised for measuring the overall burden could also be used to measure the effectiveness of particular interventions in either of these contexts. With some qualifications that is true, but it then requires us to address the question of whether a method devised for one (rather useless) purpose is the best method to use for a different (extremely useful) one. And that will bring us back once more to the 'diseases versus people' issue.

### The disease-focussed DALY

The most influential of the burden of disease methodologies currently in use is that devised by Murray and Lopez and promulgated by WHO and the World Bank.\* It is quite complex and sophisticated and has many admirable features which make it a distinct advance on what went before it in

this field. But it suffers from some rather severe weaknesses which I will highlight after summarising briefly the main elements in their methodology.

The key concept is the Disability-Adjusted Life Year (or DALY). It is used to aggregate the number of life years lost by sufferers from each disease, and the amount of disability suffered while they are still alive by those with the disease. These two amounts are added together (in a rather complicated way which I will not pursue further here) to give the overall burden of that disease. Disease burdens are thus measured in DALYs lost due to each disease. To understand my concerns about this approach it is necessary to unpick each of these constituent parts a little.

The estimation of life-years lost requires the estimation (or assertion) of what people's life expectancy would otherwise have been. In the original global burden of dis-

*"So treating the individual as the keystone in the construction of the QALY has practical as well as conceptual advantages, in that it enables evidence to be collected that is much more versatile and policy-relevant than anything that panels of experts can generate."*

ease calculations this was assumed to be an idealised length of life of 80 years for men, and 82.5 years for women, no matter what their particular situation might be. But it was quickly conceded that when doing cost-effectiveness studies this should be replaced by the most accurate estimate we have of the actual life expectancy of the individual given their particular circumstances. So immediately the connection is severed between the measured burden of disease and the measured effectiveness of the various means that might be adopted to reduce it, so why did we have to bother with the former in the first place?

The estimation of the appropriate disabili-

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\* First sketched out in the *World Development Report 1993* published for the World Bank by Oxford University Press, and subsequently elaborated on in Murray CJL and Lopez AD *The Global Burden of Disease*, published in 1996 by the Harvard School of Public Health on behalf of the World Health Organisation and the World Bank.

*"Estimating the overall burden of disease is a costly irrelevance."*

ty-adjustment to apply to people still alive with the disease is fraught with a different sort of problem, which is: what is the proper role of experts in this matter? To make the DALY approach work we need to know how each disease affects the health-related quality-of-life of its sufferers. This has two elements, a descriptive one and a valuational one. The descriptive element requires specification of the kind of suffering the disease will generate (e.g. pain, immobility, functional incapacity, anxiety, depression, etc.) and at what level (as the disease progresses). This is a matter properly left to experts, assessing the evidence as best they can. But the valuational element requires each different combination of these attributes to be valued according to the severity of its impact upon people's health-related quality of life.

While ordinary people understand pain and disability concepts, since they lie within their experience, they do not have the same familiarity with the hundreds of disease entities that need to be covered in this vast enterprise. So what happened was that a handful of 'indicator conditions' were rated for their impact on people's health-related quality of life by some panels of experts, and from their deliberations a simple seven point scale was derived, and this was then used by other experts to estimate the impact of all the other diseases (with and without treatment). A precarious enterprise. But are experts in public health the people who know most about individual values? And how could we test their judgements against any kind of systematic evidence? It seems to me that the role of 'experts' is highly suspect in that regard.

### The people-based QALY

Is there a better way? If you stick with diseases as the central concept, probably not. But if you move to people as the central concept, there certainly is, and it existed even before this latest burden of disease enterprise took off a decade ago. The Quality Adjusted Life Year (or QALY) is a concept which predates the DALY and which has similar characteristics. It too combines life expectancy and health-related quality of life within a single unit of measurement. Because it was designed to measure the positive effects of interventions rather than the negative effects of diseases, it is scaled in the opposite direction from

the DALY. The DALY takes healthy as zero and dead as 1, whereas the QALY takes healthy as 1 and dead as zero. This is not an important matter, however, since either scale can readily be converted into the other. What is important is the conceptual starting point, and process which follows from it.

The QALY is typically based on some generic measure of health-related quality-of-life which incorporates those attributes (or dimensions) that are most salient to ordinary people. And then the different combinations of different levels of these dimensions are valued by ordinary people, so that a preference-based scoring system is generated for the generic health measure. Thus when an intervention is being evaluated using that generic measure, QALY gains can be estimated which reflect the valuations of ordinary people, not the valuations of experts. That is why it is very important that all cost-effectiveness studies use one of these preference-based generic measures of health,\* and why it is important to develop them in such a way that local scoring systems can be used when purely local priority-setting is involved.

So treating the individual as the keystone in the construction of the QALY has practical as well as conceptual advantages, in that it enables evidence to be collected that is much more versatile and policy-relevant than anything that panels of experts can generate. It also facilitates accountability by requiring the valuations to be representative of the population that will be affected by the decisions that are to be based upon them.

### Conclusions

In summary my conclusions are threefold:

Firstly: estimating the overall burden of disease is a costly irrelevance.

Secondly: estimating (cost) effectiveness using population-preference-based QALYs is far superior to doing so using expert-based DALYs

Thirdly: it is time to shift scarce analytical resources away from inefficient and useless tasks, and to concentrate them on the useful ones, even if the latter are rather more demanding!

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\* As stressed in Gold MR et al (eds) *Cost Effectiveness in Health and Medicine*. New York: Oxford University Press, 1996 (especially pp 82-134).

# A tool for European Commission priority setting

*Why is a tool that was developed primarily to assess the health status of less developed countries and assist them to make best value of limited health and health care resources of relevance to the EU?*



*Howard Seymour*

The answer is that the needs of politicians and strategic planners are similar wherever they live. All require information on health need in a form that allows priorities to be set and interventions, both public health and in health care, to be compared and costed.

The public health contribution to health policy decisions relies on the ability to assess population health needs. Epidemiologists

have been able to describe incidence and prevalence of disease and produce separate lists of the major causes of premature mortality and disability. What has not been possible is to produce a combined list. The QALY (Quality Adjusted Life Year) has been used to compare the quality of life following specific treatments for specific diseases. But the QALY is not able to undertake the strategic task of assessing the relative merit of interventions for different diseases. The World Bank/ WHO Disability Adjusted Life Year (DALY) is a standardised measurement with just such a potential.

The pros and cons of the Global Burden of Disease (GBD) methodology have already been presented in the articles by Gwyn Bevan and Alan Williams. The two general statements that I would wish to add are that the global burden of disease methodology is not perfect but that it is the best tool around for strategic planners and decision makers. It is easy to use providing as it does a single summary measure of ill health, a fundamental tool for policy makers when considering the relative benefits of different policy options. Its methodology is transparent and open to challenge, it is standardised across the world and there are an increasingly large group of scientists and planners using and refining the approach.

The burden of disease approach is well established in Europe and major studies are underway in the Netherlands, in Spain, in Sweden and in the north-west and southwest of England.

The World Health Organisation is supporting GBD studies as a key part of the pro-

motion of evidence based policy within the health sector world-wide. Also across the world the GBD approach is being used in a number of countries including the USA, Australia, Japan, Mexico and Korea.

The International Burden of Disease Network (IBDN) will bring together those who are undertaking studies with policy makers. Discussion and debate within the network will both assist in the refinement of burden of disease methodology and also ensure that burden of disease study findings are presented in a way which makes them accessible to policy makers to use to create the health services needed to meet the health challenges of the new millennium.

The burden of disease assessment describes the adverse health experience of populations in a single currency, lost years of healthy life. Two fundamental principles underlie this method:

1. that the burden of disease is best expressed by adding up the experience of individuals whose lives are affected by death and disease, rather than just counting or costing health service interventions;
2. that a formal assessment of disease can be achieved by adding up the individual experience of specific conditions rather than assessments of health status which cannot be disaggregated.

The latter is of particular importance for health impact assessments as it allows an analysis of disease experience associated with the known risk factors of specific disease conditions.

The features that GBD offers the EU policy maker are that it:

- provides a single standardised measure of the health status of populations that incorporates premature mortality and the non-fatal consequences of disease;
- measures both death and illness using a single measurement - the disability adjusted life year (DALY). It produces a single number representing the total burden of all premature death and disability for the EU, member state, region or locality, the total number of DALYs lost;
- can be broken down to show the relative contributions of different conditions to the overall burden of disease;
- can show the burden of disease that can be attributed to known risk factors.

European Union public health policy makers need tools that allow them to act where there is clear advantage to acting at the Europe wide level. Member states bear

*"Without overstating the potential of the GBD methodology, the value of the approach is in having a universal indicator to help guide the choice of interventions, make comparisons and develop policy options."*

responsibility for the delivery of improved health and health care to their populations. The added value of the EU is to provide information and other support that assists member states to deliver better health and health care.

Legitimate roles identified for the EU health policy makers, where the GBD methodology will be of assistance, include:

- providing member nations with relevant information on which to base their decisions about health and health care, including information on cost effectiveness of health interventions and systems and the scale and variation of health problems across Europe;
  - providing the citizen of Europe with access to information about health and health care issues with the aim of building citizen's capacity to be fully involved in this important area of social and economic life;
  - tackling health determinants through promoting health and disease prevention;
  - Assessing the impact on health of all the actions of the EU ensuring that a high level of health protection is ensured in the definition and implementation of all Community policies.
- Without overstating the potential of the GBD methodology, the value of the approach is in having a universal indicator to help guide the choice of interventions, make comparisons and develop policy options. There follow some examples of areas of current interest in the EU where such an analysis could be applied:
- to provide, for the first time, a single index to show the relative importance across member states of the premature mortality and the disability caused by ill health. Supporting member state governments to act to promote a better balance in the focus of health policy and in their investment in health services. Such an analysis can also lead policy makers to re-examine the priority given to all programmes;
  - despite the complexity of the methodology, for politicians, it can provide an easily understood and explained backdrop to strategic planning by mapping the biggest causes of burden;
  - to show the components of variations in health status across Europe. It is possible to display the differential burden of death and disability borne by populations across Europe. Work undertaken in the UK in South and West and North-West

NHS Executive Health Regions shows that a very fine grain of picture can be achieved. In the latter case, in work instituted by Neil Goodwin (CEO Manchester Health Authority) and Professor Robert Tinston (Director of the North-West Regional Office of the NHS Executive), a burden of disease picture of the major disease conditions is being analysed down to the 100,000 population level – the new primary care group level of management of the National Health Service. The trend and patterns for any specific conditions such as dementia or diabetes can be shown as a proportion of total burden and analysed by population group, women, children, ethnic group etc.;

- health planners can estimate the benefits, in DALYs, of programmes and intervention and cost these to enhance the value for money of public health and health care investment;
- burden of disease can provide a simple framework to assist governments by comparing the efficiency and performance of their public health and health care policy in comparison to other European countries;
- modelling and monitoring the outcome on population health status of reforms and other major developments in health systems. Including such issues as different approaches to funding health care, the catchment population required by specialist hospitals, the impact of integrated care on communities;
- as a tool in scenario planning. What will be the changes in the health status of the population of Europe, by specific condition, as result of changes in demography or of enlargement?
- as a major component of the health impact assessment and monitoring of all Community policy initiatives. For example, how many DALYs worth of health gain or loss will changes in EU agriculture policy deliver. Did those changes in health status actually occur and at what financial cost?

This article has described the potential benefit and some of the uses to which a GBD analysis could be put in the EU. In conclusion one further benefit is the fact that it already exists. It does not have to be reinvented, it can be taken 'off the peg' and used to address current issues. It does not require the investment, development time and the risk of failure associated with creating a new purpose built tool.

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# Health in the “New” Scotland

*On 6 May 1999 the people of Scotland went to the polls to elect their first Parliament in almost 300 years. The Westminster Parliament will retain legislative control of a number of important areas including the Constitution, Foreign Affairs, Defence, and Social Security, but the Scottish Parliament will have law-making and tax-varying powers and will be able to legislate on a range of issues of immense importance to Scotland and its people, the foremost of which are health and education.*



*Phil Hanlon*



*Susie Stewart*

*“Health in Scotland is currently comparable to the former East Germany.”*

Health did not figure prominently in the political debate that led up to the recent elections. But what could be more important to a devolved Scotland than preventing avoidable death and disease and improving the health and wellbeing of all Scots from every walk of life?

Health will account for about one-third of the Scottish Parliament's total budget and over half when finance to local authorities, which is not under the detailed control of Parliament, is excluded. Health is going to matter to the newly elected Parliament and its members and to electors and their families. The list of health-related concerns that confront the new administration is daunting.

## **Scotland’s health**

Health in Scotland is currently comparable to the former East Germany and the health status of Scots is not improving as rapidly as their counterparts in similar countries. One of the main reasons for this is social and economic deprivation in the large post industrial inner city areas and peripheral housing developments in and around the largest city – Glasgow.

This problem area creates huge inequalities in health within Scotland. Data from the 1991 census, for example, have established that 68% of post code sectors in Glasgow fall into the two most deprived categories compared with only 7% in the relatively affluent capital city of Edinburgh. The consequences of these differences are profound. Male life expectancy for 35 year olds is currently 4.6 years lower in Glasgow than Edinburgh and, in the ten years since the 1981 census, the difference between Glasgow and Edinburgh has worsened by 39%.

Deprivation is central to Scotland’s health

problems. But it is also important to establish the extent to which Scotland’s relatively poor health is the consequence of other additional and distinctive factors – that is, a set of influences that are peculiar to Scotland’s culture or ecology. Is there a ‘Scottish effect’? Analysis of the 1981 census suggested that almost all of the difference between England and Scotland could be explained in terms of deprivation. However, since the mid-1980s, Scotland has shown a striking growth in mortality compared with England. Between 1950 and 1985 death rates in the two nations declined in parallel. Since then, there have been rapid improvements across England as a whole, but a much less marked improvement in Scotland. The largest divergence in the most recent years has been for men aged 45–64 years in Scotland who are now 46% more likely to die than their English counterparts. At present, it is only possible to speculate on why this might be but, clearly, for many in Scotland, the time has come to move from analysis to action.

## **Political analysis of Scotland’s poor health**

When the Conservatives were in power, from 1979–97, they pointed to lifestyles as the key arena for action. They emphasised the need for individuals to take responsibility for their own health and did little to confront the underlying causes of poor health. Historically, the response of the political left has been to emphasise the role of environment and call for improvements in, for example, housing, amenities and benefits. Neither gives the whole picture.

From this old debate a new holistic consensus is emerging that acknowledges a complex interaction among many factors that influence health. This consensus recognises the importance of the physical environment, social environment, genetic inheritance, personal behaviour and lifestyle, the distribution of wealth and health services as major and interactive determinants of health. Health at a population level will improve when all these factors are addressed on a broad front simultaneously. There are no silver bullets or single issue solutions.

*“The health of the Scottish people would be best served by abandoning health policy as a separate entity and embracing holistic government and healthy public policy. This will be neither an easy nor a speedy process but it is one that the Scottish Parliament needs to begin now.”*

### **How will the Parliament react to Scotland’s health problems?**

Although there is this intellectual consensus that supports a socioecological understanding of the determinants of health, it is by no means certain that the new Parliament will be able to operationalise this insight in a way that leads to effective policies and programmes in practice.

The worst case scenario is that the Parliament will descend into a glorified form of parish politics where each MSP champions small scale but locally important health issues, such as ward or hospital closures, from their own constituency or region.

It is more likely that the Parliament will take a more mature and strategic view but, nonetheless, express its concern for health by pursuing health service issues like the number and size of health boards, the balance between primary and secondary care or perceived deficiencies in community care. It is absolutely vital at the outset that two distinct but complementary strands to the Scottish health service are recognised – health care which provides for those who are ill and health improvement which strives to produce better health at a population level.

### **Confronting Scotland’s health problems**

The most interesting development within the parliament will be to observe the degree to which a new body with an exclusive focus on Scotland will be able to confront the nation’s relatively poor health status. The logic that we hope will be accepted by most of the new MSPs has been explained more fully in a recent publication from the Scottish Council Foundation<sup>1</sup> and is as follows:

- Many Scots fail to realise their own desired potential through poverty and disease.
- The challenge will be to ensure that reaching your potential is not the preserve of the affluent but the birthright of all.
- A good health service is vital for Scotland but health services should not dominate the health policy agenda to the exclusion of health improvement.
- Health is not an end in itself but a resource for living.
- Health is multidimensional (physical, mental and social), encompassing negative aspects (disease, diminished func-

tion) and positive aspects (wellbeing, enhanced function). These dimensions can be measured subjectively and objectively.

- Poor health in Scotland arises from the complex interaction of a poor physical environment, adverse social environment, lack of lifeskills, inequalities in wealth and damaging personal behaviour.

These determinants of health are multiple and interactive and consequently healthy policy making must be holistic rather than, as traditionally, departmentalised. A broader understanding of health, for example, could have a radical impact on transport, housing, benefits, education policy and much more. Once this broader understanding of health is accepted, almost all areas of policy are affected because almost all policies contribute to the complex web of interaction from which the health status of the population emerges.

Are we then saying that health policy should drive all other policymaking? Quite the reverse. Our argument is that the health of the Scottish people would be best served by abandoning health policy as a separate entity and embracing holistic government and healthy public policy. This will be neither an easy nor a speedy process but it is one that the Scottish Parliament needs to begin now.

The first stage towards holistic government is that key economic and social aspirations for a new Scottish society are agreed through the democratic process. These outcomes are then worked for by all departments of state and levels of administration and government as joint goals. In this way traditional barriers between government departments and within local authorities will begin to be broken down.

Measurement of the change that contributes to the agreed goals will be essential and budgets should begin to be allocated according to the degree to which departments contribute towards these goals rather than by the “what you got last year plus a little bit more” method.

### **Holistic government – more than just joined-up policymaking**

To embark productively on holistic government, the traditional model of health – with disease as the focus and diagnosis and treatment as the dominant actions – must be replaced by a broader definition of health which includes function and wellbeing as well as disease.

Under the present system, there is overlap, inefficiency and sometimes contradiction in policymaking to improve health across almost every government department. The Treasury, for example, tries to influence health-damaging behaviours through the tax system by increasing taxation on alcohol and tobacco products. The Department of Health aims to influence behaviour through health education programmes, the Department of Transport by taking measures to encourage greater use of public transport or at least car sharing. In short, each constituent part of government may assume a specific responsibility for influencing individual elements in the complex health model but not for the whole.

But, if the determinants of health are multiple and interactive, policymaking must also have these qualities. We need government machinery which is capable of comprehending the whole system, as a system, rather than in its constituent parts – we need true holistic government. The limitations to this in the Scottish situation, where some crucial legislative powers are reserved to the United Kingdom Government, must be recognised but Scotland could take the lead in involving relevant UK departments. There are various other impediments to this new approach of which we will consider two.

### Budgets

The biggest block in government for matching a systems model of health with a systems approach to policy making is the departmental budget system. It is institutionally difficult to shift money from one department to another even if the aim of the system as a whole may be one that all departments support in principle. There are few incentives at present to encourage individual department heads to spend their own budgets in support of results which will be recorded as another department's success – for instance, spending a proportion of the health budget on improving the housing stock, or on better play areas for urban housing estates – even though both would have a positive impact on health.

In addition, there is a political demand for increased spending on the National Health Service, at the expense of spending on healthy public policies in other parts of the system, and an irresistible temptation to spend on tangible inputs (more nurses, an expensive advertising campaign) rather than to invest in development work to improve longer term outcomes (urban allotment schemes, education).

In short, our present model of government is not able to match the subtlety of the model of health we have described. A number of ways to try to break down departmental barriers and to encourage innovative cross-departmental and cross-tier budgeting within and between both central and local government have recently been suggested.<sup>2</sup>

### Information

Apart from the technical machinery within government, the other main constraint against policymakers adopting the health model we have described for the purpose of practical policymaking is a lack of appropriate information. The numbers flowing into government departments, being conditioned by the traditional model, provide little evidence to support either the notion that other policies are at least as effective in promoting health gain as 'health policy', or that money spent in one area can have a positive impact in others.

Departmental budgets, for example, are generally allocated in pursuit of departmental objectives. The performance of the department is then measured against those objectives. That can lead to a situation in which conflicting objectives are pursued side by side: in the United Kingdom, for example, the Department of Social Security gives mothers on income support free tokens for baby milk substitutes while the Department of Health is trying to promote breast feeding, particularly for women on low incomes. It can also lead to perverse incentives in the system. Health is a particularly good example of this in that allocation of funding in the National Health Service is linked to mortality rates: there are few rewards for effective prevention.

We need a better understanding of the multiple and interactive causes of ill health. To reach that point, government needs a different approach to information – to illuminate how health is created or destroyed and to evaluate the effectiveness of its policy interventions. Data gathered in pursuit of the departmental model tend only to measure quantities and trends. These data answer the questions how many or how much ('number fetishism'). Equally important is the question why? That requires qualitative and, sometimes, longitudinal data, tracking the same individuals and families over time, recording their changing attitudes to health and the relative importance it assumes in their lives.

Thus government is not the only actor with an influence on the health model, and probably not even the most important and

*“...funding in the National Health Service is linked to mortality rates: there are few rewards for effective prevention”*

*"There is an appetite in Scotland for 'a new kind of politics'. Adopting holistic policymaking as an innovative approach to Scotland's health problems would be a good way to start."*

there is an imperative on modern government to harness other actors and forces to its goals in order to achieve success.

An acceptance of ignorance is also necessary. The model is complex and interactive: none of us can predict with confidence how it will react to intervention, still less how the myriad interventions of government in many policy areas simultaneously will affect results, particularly in the long term. There needs to be a culture in government which sees all policy as a continuing experiment, observed through appropriate mechanisms for monitoring which lead to adjustments to policy as necessary. It is a technique that is already built into the microchips which control even the simplest of machinery today, based on a discipline known as 'fuzzy logic'.<sup>3</sup>

To begin to translate the health model into the policymaking process we need a machinery of government which is:

*Holistic:* incorporating incentives for cross-departmental and cross-tier working and

for cooperation with non-governmental actors;

*Challenging:* in its analysis of the system, in searching for answers to the question 'why?', and in seeking innovation at every turn;

*Smart:* always seeking to improve understanding, willing to experiment, to learn, to anticipate and to prevent;

*Informed:* gathering sophisticated data, measuring indicators for the system as a whole, constantly monitoring and evaluating the effects of policy interventions;

*Participative:* so that those whom policy is intended to benefit are also included in its design, implementation and evaluation

Anything new, like the Scottish Parliament, is a blank canvas onto which many will want to paint their vision or aspirations. Many within Scotland see improved health as a national priority but the approach the Parliament will take to confront the problem has yet to emerge from analysis and debate. The danger of falling back on familiar but narrow disease focused policies is real. However, there is an appetite in Scotland for 'a new kind of politics'. Adopting holistic policymaking as an innovative approach to Scotland's health problems would be a good way to start.

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## Health system development in the new millennium: issues and priorities

*The dawning of the new millennium will undoubtedly raise new challenges for the development of European health systems. While the exact nature of these challenges*

*may be difficult to predict, there is no denying the importance of anticipating priority areas for development if the future well being of European societies is to be safeguarded within effective and efficient health care systems.*



Miriam M. Wiley

Notwithstanding the difficulties of predicting specific developments with accuracy, it is reasonable to expect that a growing

European community will bring ever-increasing expectations to bear on the level, range and scope of health services required. If health systems are to meet these challenges successfully, planning must be informed by past experience and based on modern developments in health care, both nationally and internationally.

While individual commentators may vary in the prioritisation of issues considered likely to influence health system developments in the coming decades, there are probably a number of core areas of interest which would be generally recognised. As a

starting point, it is suggested that a consideration of the issues likely to influence the transition of European health systems into the 21st century may be focused on such areas as the structure, financing and management of health care systems and changing sectoral demands.

Since the 1970s, the structure and organisation of national health care systems have increasingly been subject to review and reassessment. While there is no European country currently which would claim to have found the 'best' blueprint for health service provision and delivery, substantial though varied progress has been made over this period. The quest for the most effective organisational framework, together with the most efficient approach to resourcing health care systems is, however, likely to continue in the short to medium term. As consumer expectations regarding the level of health service provision continue to increase, the challenge of matching expectations with the available resources becomes particularly acute.

Pressure for future expansion in the range of available services may be expected to be accompanied by additional requirements for improvements in the quality of these services. The emergence of a quality culture within the health service will, in turn, be associated with increasing demands for quality management and risk management in pursuit of operational strategies for quality. In addition, quality of life assessment continues to pose substantial challenges, both technically and methodologically. Improvements in these techniques will be essential if advances are to be made in the estimation and enhancement of health gain. As with any other era, advancements will be expected in medical technology. Such developments must, however, be increasingly accompanied by comprehensive clinical and economic evaluation if system-wide adoption is to be considered feasible.

The epidemiological and demographic context for national systems will have important implications for developments for particular population groups and service areas. In addition to the continued development of health promotion strategies and the exploration of the epidemiology of disease, the incidence and prevalence of infectious diseases, in particular, will have important implications for the priorities determined for disease prevention and treatment programmes. The demographic context in which these developments are likely to occur is important. A young, expanding

population will have different priorities relative to an ageing population. While the member states currently within the European community are mostly at the ageing end of the spectrum, with the prospect of enlargement it is likely that this demographic profile may change at the European level. Regardless of changes in the size of the EU, care of the elderly and the treatment of the diseases of older people, particularly dementia, will pose serious challenges for future health system development. At the other end of the spectrum, the achievement of good reproductive health, safe birthing practices and advances in neo-natal care will need to be addressed.

The achievement of health and social gain is now considered an essential objective for health systems nationally and internationally. If these objectives are to be achieved, it will be necessary to ensure that the appropriate structures and information systems are put in place so that health system managers can access essential management tools and information as required and that the necessary leadership skills are developed among clinical staff to facilitate participation in management at various levels. As the health care environment continues to take shape in a multi-disciplinary and multi-sectoral context, efforts must increasingly be focused on integrating both hospital and community doctors, nurses and all relevant health personnel into the care process.

*The one point of certainty for any attempt to predict the future is that there will be change. When the focus is health care, we can be assured that the pace of change will be rapid and far reaching. The challenges posed by the process and achievement of enlargement of the EU would be expected to underscore the importance of ensuring that such change is positive and can be supported by the health system framework. The anticipation and management of change will undoubtedly be most productive when all parties to the process are well informed about the consequences of development. Setting the agenda for health care system development in the transition to the new millennium would seem to be an important first step in this process.*

*"The one point of certainty for any attempt to predict the future is that there will be change."*

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*Many of these issues are addressed in a recently published book on the Irish health system titled *The Irish Health System in the 21st Century* by Austin L. Leahy and Miriam M. Wiley (eds), published by Oak Tree Press, Dublin, 1998, ISBN 1-86076-103-8.*

# Health Technology Assessment

Dear Sir,

In his otherwise uncontroversial article on health technology assessment (HTA) in Europe in the Spring 1999 issue of *eurohealth*, Franco Sassi comes to some remarkable conclusions, one of which is that HTA agencies should be "...committed EXCLUSIVELY (our emphasis) to setting priorities for HTA, monitoring the quality of assessments, and establishing links with potential users." Our letter is to disassociate ourselves from this conclusion, since the reader may believe that our preceding article is one of the factors leading to this conclusion, with which we strongly disagree. We wish to assure your readers and our colleagues and friends that we certainly do not support the conclusion.

It seems to us that Sassi does not understand the role of HTA in Europe and the rest of the world. HTA developed in fact because existing knowledge was not effectively used in policy making. Synthesis of such knowledge is the key method of HTA in most countries. Such synthesis leads to conclusions (and sometimes recommendations) relevant to policy. Sassi gives no basis for his recommendation that member states of the European Union cease such activities.

In fact, as Sassi himself acknowledged, "...most HTA research, and almost all primary research programmes, were undertaken by academic or independent institutions." Why then does he call for a change in this direction in his last paragraph? It is true that some countries, notably the United Kingdom and the Netherlands, rely on primary research as an important method of HTA, and that some agencies have research budgets to commission research related to their assessment activities. But where does he find the evidence that undertaking research is "far more effective and efficient" in the private sector? We find it disturbing that such a statement can be made without even a reference.

HTA has established itself as a bridge between the scientific and policy communities. Most academics know little about policy making. HTA is a form of

policy analysis and must be carried out mainly by those close to policy makers. We cannot see any argument to support Sassi's conclusion that HTA agencies should not carry out assessments, whether based on primary research or on systematic review and synthesis.

All countries are different, and European countries are no exception. The Eur-Assess project was careful to note the diversity of HTA activities in Europe. Any European effort aimed in the direction of coordination must also deal with diversity and not try to force one model of HTA on member states. In our European network, we have a good basis for recognising and using the experience and expertise that has developed in all European countries.

*H. David Banta & Wija J. Oortwijn  
TNO Prevention and Health  
Leiden, The Netherlands*

Dear Sir,

We were very surprised by Banta's comments and should like to take this opportunity to respond, in the spirit of academic debate and respect for the opinions of others. Banta and Oortwijn (B&O) say we do not understand the "role of HTA". However, we are certain that they have not grasped the meaning of our comment, which is much more straightforward than the role of HTA itself. The conclusions of our article are not about the past and present (the "role of HTA"), but only about what HTA might or should be in the future.

As we are sure other *eurohealth* readers understood, the conclusion that public (governmental) agencies and programmes should focus in the future on setting priorities, monitoring quality of evaluations, dissemination and implementation, surely does not represent a change in direction from the past when "most technology assessment activities were undertaken by academic or independent institutions". In our article we referenced our survey in which non-parliamentary and non-governmental HTA programmes were classified into a group including private (a small minority in Europe), academic (a large majority) and other indepen-

dent organisations. Compared to this group, public (parliamentary and governmental) programmes played a minimal role in primary and secondary research. With few remarkable exceptions, public programmes have been able to assess a limited number of technologies, often using partial approaches (for instance, efficiency and equity concerns have rarely been addressed).

B&O's arguments ignore the dramatic changes that have taken place recently in connection with the development of the Cochrane Collaboration. The synthesis of existing evidence is now a science in its own right, involving the use of resource-intensive methods. Generally speaking, public HTA programmes are unlikely to play a more significant role in the synthesis of existing evidence than they did in primary research.

There are important examples of the role we envisage for HTA programmes, such as the NHS Research and Development programme in the UK. This is mainly concerned with setting priorities and monitoring the quality of evaluations funded by the programme, but undertaken externally mainly by academic and independent centres.<sup>1</sup> Similarly, the Agency for Health Care Policy and Research in the USA is predominantly engaged in selecting areas for commissioning research and developing methods for translating evidence into practice.<sup>2</sup>

We could not agree more that it would be inappropriate to force one model on very different programmes. Indeed, Banta himself experienced fierce opposition to his idea of developing a standardised assessment methodology as part of Eur-Assess. Such experience should highlight the fact that the issue of what type of research (if any) should be directly undertaken by HTA programmes is full of controversy.

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\* \* \* STOP PRESS \* \* \*

3rd June 1999

## PRODI ANNOUNCES NEW COMMISSION DG FOR HEALTH

The new European Commission President, Professor Prodi, announced at the European Council on 3rd June 1999 that as part of his structural reforms of the European Commission, health and consumer protection issues will be brought together in a single portfolio under a one Directorate-General (DG).

Health is currently spread across a number of separate DGs and, in particular, the division of responsibilities between DGV (Public Health) and DGXIV (Consumer Health) has been unclear.

Mr Prodi also announced that the list of future Commissioners needs to be finalised before the middle of July.

Eurohealth will continue to monitor these developments closely and report on them in future editions.

## Commission Communication to continue the fight against drugs

A Communication to the Council and European Parliament on an EU Action Plan to combat drugs (2000–2004) was adopted by the Commission at the end of April. It is the successor to the current Action Plan (1995–1999), and follows up on the conclusions of the Vienna and Cardiff Councils which requested that the EU develop new plans for a replacement once the current plan expires. The new programme, which takes the individual responsibility of each Member State to combat drugs within its own territory as its underlying premise, reflects the aims of the three United Nations conventions on drugs.

The Communication identifies five general aims for the Commission under the new strategy against drugs: to ensure that comparable and reliable data on the EU drugs situation is available; to continue with a policy which regards demand and supply reduction as mutually reinforcing; to promote international cooperation; to ensure that prevention policies receive the highest priority in political and resource terms; and to make sure that the fight against drugs remains a priority for the Community. It is based on the need for increased cooperation between Member States and continues and expands on the three prima-

ry objectives of the 1995–1999 plan. Specifically, in addition to prioritising demand reduction, supply reduction and international cooperation, the new programme emphasises the need to:

- Combat synthetic drugs: the EU is the world largest producer of amphetamines and ecstasy, as is witnessed by their increased use by young people in Europe.
- Decrease urban delinquency: there is an increasing number of juveniles involving themselves with criminal groups in the sale of illicit drugs.
- Prepare for EU enlargement: with the pre-accession countries expected to become members of certain EU agencies such as the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in Lisbon, other EU programmes in the justice and home affairs field should be made open to candidate countries (recalling that drugs and drug-related matters fall within this area of the Community remit).
- Develop new methodological tools: there is a pressing need for reliable, systematic evaluation of actions undertaken to combat drugs at EU-level.

## European Commission- World Health Organization Conference on Mental Health

**A meeting jointly sponsored by the European Commission and the World Health Organization (WHO) entitled 'Balancing Mental Health Promotion and Mental Health Care' was held in Brussels on April 22nd–24th.**

Attended by Ministers of Health from the EU Member States, along with those of Iceland, Norway, Switzerland, Turkey, and several from the Central and East European states, the meeting was intended to increase awareness of mental health and its impact on society. Among the issues covered were: promotion, care service planning and delivery, along with mental health in the workplace and models of good practice.

Delegates were told that mental health problems rank as one of the major contributors to the global burden of disease and disability, accounting for five of the leading ten causes of disability. Against the considerable improvements in physical health in most countries, mental health has not improved this century, with some countries in fact recording higher levels than before. The increased prevalence of such diseases are in part due to complex responses to serious or chronic diseases, and are the side-effects of war, trauma, and difficult socioeconomic conditions such as unemployment, poverty and discrimination. The burden of disease caused by mental disorders is expected to continue rising with the increased longevity of European populations; as people live longer, they attain ages which carry higher rates of mental disease. In highlighting these factors and issues, the conference sought to explain that in many countries current levels of care service are insufficient to handle these problems, and that there is a distinct need for mental health promotion policies in Europe.

## COMMISSIONER FLYNN ADDRESSES FOURTH CONFERENCE ON VACCINOLOGY

**On 18th March 1999, Social Affairs Commissioner Padraig Flynn spoke about future priorities for public health in Europe during a speech to the Fourth Conference on Vaccinology.**

At the Conference, held in Brighton, UK, the Commissioner sought to explain the Community's health policies as they relate to the future of vaccines and the spread of communicable diseases. He pointed to the European vaccines industry as the global leader (supplying two-thirds of the vaccines used by UNICEF), and said that it was a Community priority to maintain this competitive edge. Expressing his concern over the spread of communicable diseases, Mr Flynn cited the success of vaccinations in controlling such childhood diseases as polio, whooping cough, diphtheria and measles, and referred to the role played by vaccines in curbing morbidity and mortality from influenza and Hepatitis B.

Despite such achievements, one-third of all deaths are the result of infectious disease. This is due to the emergence of new diseases in recent years, including AIDS, Ebola and Legionnaires' disease. And while the rates of such diseases are highest in the developing world, Commissioner Flynn listed migration, increased travel, and climatic change as elements encouraging the spread of pathogens to the developed world. He pointed to the spread of

parasites and viruses, zoonotic diseases such as TSE, and the increasing resistance of certain bacteria to modern antibiotics as posing health threats to European citizens.

Elaborating on the need to ensure the safety of European populations, Mr Flynn outlined the Commission's work towards establishing an EU network for tracking communicable diseases. He expressed his dissatisfaction with the fact that the network will not wield the control mechanisms requested in his original proposal. He stressed the need for political support from national governments and surveillance bodies to ensure that the early warning and response capacity of the new network can work.

Remarking that "unless you have been on the planet Mars for the last few days, you will be aware that the Community and its institutions are currently undergoing a major crisis", Mr Flynn said that the Commission's perceived lack of success in carrying out its duties had in part led to this crisis. Thus, he referred to the need for greater resources and increased exposure to be given to the network so that it can accomplish its goals. He also made a case for more

research to be undertaken in the field, and pointed to the fact that the 'control of infectious' diseases is one of the Community's six key action areas under the 5th Framework research programme.

### Adoption of public health programmes on rare diseases and pollution-related illnesses

**On April 23rd 1999, the long-awaited Community public health programmes on rare diseases and pollution-related illnesses were finally adopted.**

This follows extensive discussions between the Council and European Parliament, and a positive outcome to the conciliation committee meeting on February 2nd. Agreement on the programmes was described as a 'step in the right direction' by Social Affairs Commissioner Padraig Flynn, who went on to say that the Commission would begin work within the context of the two agendas immediately.

Nevertheless, the Commissioner also expressed his regret that agreement had been so long in coming, and said that he was sad that the length, scope, and funding of the pollution-related diseases programme had all been decreased from the original Commission proposal.

Specifically, he cited the exclusion of training initiatives, information campaigns, and assistance for self-help groups in the fight against respiratory conditions from the final programme as particularly disappointing. He did, however, declare his hope that the agreement and adoption of the two programmes would serve to reflect continued Community interest in the wider field of disease prevention.

### MEETING OF THE HIGH LEVEL COMMITTEE ON HEALTH

**At the end of April, the High Level Committee on Health met in Freiburg under the German Presidency of the EU to discuss current and future EU-level development in public health.**

On the agenda were questions relating to health policy and future enlargement of the Community; the costs and cost-effectiveness of pharmaceuticals in Europe; cross-border care and the internal market; and the promotion of cooperation with international organisations. In this vein, the Committee voted to establish working groups to address matters relating to health services and health telematics,

pharmaceuticals and public health, and cross-border care and the internal market. The three working groups will be expected to submit their findings in reports to the Commission in October 1999 during the Finnish Presidency of the EU.

A further decision taken at the meeting was the scheduling of a workshop in June 1999 on the topic of 'Best practice in health care'.

## SCIENTISTS RECOMMEND REDUCING USE OF ANTIMICROBIALS

**The European Scientific Steering Committee (SSC) has expressed great concern about increasing health threats due to antimicrobial resistance and recommends immediately reducing the inappropriate use of antimicrobials.**

The core strategy of reducing antimicrobial use should apply equally across each of the areas of human medicine, veterinary medicine, animal production and plant protection. This is the recommendation of the 16 independent senior European scientists in an opinion on antimicrobial resistance adopted unanimously on Friday 28 May.

Micro-organisms are increasingly becoming resistant to existing antimicrobials, including antibiotics. Of further concern is the fact that no truly novel antibacterials have been introduced in the last decade, leading to increasing difficulties in the treatment of infectious diseases such as pneumonia, tuberculosis or salmonellosis. Governments and all users of antimicrobials should urgently address these problems. The current absence of clear causal links between antimicrobials usage and the development of resistance should not be taken as an excuse for avoiding urgent action.

Actions should be taken on an EU-wide and preferably a global basis,

recommend the scientists. As more than 50% of antimicrobials in Europe are used in human medicine, doctors have a key role to play in the fight against antimicrobial resistance by reducing the unnecessary use of these agents. The experts also ask for tighter controls on the sale, supply and distribution of antimicrobials, the development of 'best practice' guidelines for the use of specific agents to treat human or animal diseases and of programmes for the education of healthcare professionals, farmers, food producers, industries and consumers to make them aware of the problem and to encourage disease-preventing methods. An EU-wide monitoring system for collecting comparable data, monitoring consumption as well as a surveillance system should be set up. The development of effective alternatives to antimicrobials should be encouraged.

Regarding the use of antimicrobials as growth promoters in animal production, the scientists propose to phase out and ultimately abolish those classes which are or may be used in human or veterinary medi-

cine. The phasing-out should be carefully planned and accompanied by changes in animal husbandry practices as well as organised health control and disease prevention methods including vaccination and eradication of specific diseases in order to maintain animal health and welfare.

According to the SSC, there is presently no evidence that antibiotic resistance marker genes have been transmitted from genetically modified plants to micro-organisms. Nevertheless, the scientists recommend removing marker genes from plant cells before commercialisation whenever feasible. The use of marker genes which might confer resistance against clinically important antibiotics should be avoided in future GMO-plant development.

The report provides the Commission with a scientific basis for a comprehensive response to the emerging and wide-ranging problem of antimicrobial resistance. It will soon be available on the Internet at the following address: [http://europa.eu.int/comm/dg24/health/sc/ssc/outcome\\_en.html](http://europa.eu.int/comm/dg24/health/sc/ssc/outcome_en.html)

## NEWS IN BRIEF

RELEASED on 22nd March 1999, a new report from the European Agency for Safety and Health at Work in Bilbao, assesses in detail the positive role to be played by economic instruments in improving occupational safety and health.

*For more information contact Alun Jones, European Agency for Safety and Health at Work, Bilbao, Spain; Tel.+39 94 479 4377; <http://www.eusha.es>.*

A NEW Opinion of the European Parliament's Committee on Economic and Monetary Affairs and Industrial Policy on the Communication from the Commission on the Single Market in Pharmaceuticals was released on 21st April 1999. The Opinion was drafted jointly

with the Committee on the Environment, Public Health and Consumer Protection, and is available on the Commission's DGIII website for pharmaceuticals and cosmetics; <http://dg3.eudra.org/>

ON 29TH APRIL 1999 the Economic and Social Committee (ECOSOC) adopted, by 50 votes to 3 (eight abstentions), an Opinion on the amended proposal for a Community action programme on violence against children, young persons and women (DAPHNE). The Committee approved of the amendment generally, but expressed reservations that the amended legal base of the programme could downgrade the prevention of violence to a public health problem. In voting its

approval, the Committee emphasised that violence, maltreatment and sexual abuse represented fundamental abuses of human rights.

THE Council adopted a second amendment of Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens in the workplace on 29th April 1999. It gives Member States four years to transpose the new legislation which, amongst other things: extends the Directive to cover mutagenic substances; sets an exposure limit for hardwood dust; and requests that the Commission revise value limits on vinyl chloride monomer within two years of adopting the relevant Directive (78/610/EEC).