Learning to live with Health Economics

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Chapter IV
Economics of management and the change process

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FORECASTING
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4. Economics of management and the change process

4.1 Introduction

Chapter 4 of the learning materials is concerned with change, a pervasive feature of health systems in Europe and the societies in which they are embedded, and how the change process can be managed. Change is endemic at all levels of European health systems, and some commentators argue that the rate of change is accelerating. Change and how to manage it is relevant to all stakeholders in the health and health care systems. It also affects their relationships with other sectors, disciplines and stakeholders.

The discussion of the change process and its management is organized in three sections, which include a total of six modules. Section 4.2 includes a module by Professor John Lavis of McMaster University in Canada providing an introduction to concepts for health policy analysis, and two further modules on health management and administration.

Health policy analysis is the study of why groups respond to some health problems or issues and not others, why they develop some health policies and not others, and why they implement some health policies and not others. Identifying patterns in agenda-setting and the development and implementation of health policy, as well as understanding the reasons for those patterns, are important skills for those in the health field. Module 4.2.1 supports the development of these skills, which are important for all the potential users of the learning materials, particularly those in senior policy-making or policy-influencing positions (in health and related areas). It also emphasizes that, while analytical constructs can be a valuable aid for understanding and empowerment, the world is a messy place where the implementation of change generally involves bargaining, negotiation and compromise.

Module 4.2.1 considers health policy at three levels: legislative, administrative and clinical (where a practice guideline can be thought of as a health policy for clinicians). For example, at the legislative level three factors are cited to help explain action or inaction in policy development: interests (who wins and who loses), institutions (the rules for decision-making), and ideas (both values and research). The module concludes that policies are more likely to be developed when the benefits are concentrated among more influential groups and when the costs are diffused across less influential groups; when decision-making structures concentrate influence in a small number of individuals at the same level of policy-making; when policies are less visible (especially to those who will have costs imposed on them); and when both values and empirically tested "facts" support the policy.

The two further modules in Section 4.2 are concerned with the administration and management of change. Module 4.2.2, by Keith Barnard and Professor Chris Selby Smith looks at how public health is managed politically (by government or organized society rather than in the narrower party political sense), noting that the ultimate responsibility for the overall performance of a country's health system must always lie with government. The module emphasizes that HEALTH21, the health for all policy framework approved by the WHO Regional Committee for Europe in 1998, is intended to stimulate and guide countries and communities, enabling them to develop strategies that address the determinants of health and result in: socially responsible and sustainable health development; greater equity in health; higher levels of health throughout the individual's life; a reduced burden of sickness and injury through the unlocking of new resources for multisectoral action; and high quality cost–effective health care. The underlying ethic is that of equity. The module also discusses the valuable contribution which can be made by economics and economists to the achievement of the objectives of HEALTH21, and key success factors for an effective approach to the political management of health policy and changes in health practice. The essentials are articulated clearly: the shared view; the political will to cooperate; the support of participating interests; appropriate mechanisms and structures for identifying and implementing options; and a climate of creativity. The module concludes that: "While it may not be easy, while it may take time, it can be done. However, it often is not done; and the task tends to be more difficult in a declining economy than in an expanding one."

Module 4.2.3, by Professor Chris Selby Smith and John Wyn Owen, is concerned with health administration and management at a more devolved but no less important level. The module notes that all managers are affected by the environment in which they work, that the environments in which health care managers operate have some special features, and that, in many European countries, significant changes are taking place in that environment. The authors argue that managers contribute to the provision of health care and the achievement of health gain i.e. adding years to life and quality life to years. Managing for health involves deciding what needs to be done and ensuring that it gets done, through people.

Managers are concerned with both processes and outcomes, where outcomes include quantity and quality. Since managers take decisions in order to achieve results, it is crucial that the objectives to be achieved are clearly defined, however difficult it may be to achieve them completely and irrespective of whether tactical adjustments are required from time to time (they will be). Good managers provide a support service, which enables a wide range of resources (wider than in many other industries) to be brought together in an efficient, effective, economic and equitable manner. The result is enhanced achievement of the health objectives of their organizations. People are a particularly important resource in health care; over time, good management expands the capacity of people, whether providers or users, to achieve outcomes and make informed choices.

Outstanding managers, the authors argue, are characterized by their ways of thinking, presenting and behaving. While they are aware of the complexities of the managerial environment they are not paralysed by analysis. They are oriented to action and to taking the best decisions which are possible in the prevailing circumstances. The manager's role necessarily involves balancing a range of risks, deciding on the course of action which appears to be most appropriate in the light of the available information, and ensuring that it is pursued in a business-like fashion. "The only manager who never makes a mistake is the one who never takes a decision, so that risk management is inherent in the role."

The managerial role is demonstrated in practice. How the manager acts tends to be more powerful than what he or she says. Much of the manager's influence occurs through setting the climate, in

leadership rather than mere administration. Managers also need to be aware of the dynamic elements of the managerial task and of the intersectoral contributions to health outcomes, and that he or she has responsibilities to the wider health care system and society as well as to the particular institution.

Section 4.3 contains one module written by Professor Björn Lindgren from the University of Lund, Sweden and Professor Michael Drummond from the University of York, United Kingdom, with contributions from Eva Bondar in Hungary. Module 4.3.1 is concerned with the development and diffusion of health technology where costs (capital and recurrent) and benefits can be substantial. It emphasizes that technologies for health, which are the mechanisms through which resources are combined to produce health improvements for the individual and for the overall population, are not confined to the clinical care sector but comprise all health promotion, disease prevention, diagnosis, treatment, rehabilitation and care activities. New health technologies are developed by publicly or privately funded research and development, but they are not developed haphazardly. They are induced by the incentives which are provided for developing specific kinds of technology. The incentives may be created by government regulations or by the financial incentives of the market. The authors stress that considerable inefficiencies can occur in how health technologies are produced and how they are used. The payment mechanisms for health professionals and institutions are among the factors which can either inhibit or encourage the development and diffusion of health technologies, while both regulation and financial incentives can be used to encourage a more rational process of diffusion and use. Economic thinking, economic models and economic evaluation can help decision-makers decide whether to use various health technologies, when and to what extent, and subject to what indications or other conditions. In general, new health technologies are diffused gradually, technologies which have entered the health care system are not easily removed, and many older health technologies have never been subject to careful economic evaluation of their costs and benefits.

Section 4.4 includes two modules. Module 4.4.1, prepared by Chris Buttanshaw (United Kingdom), is concerned with primary health care. He emphasizes that primary health care, the broad concept underpinning HEALTH21, covers both a way of organizing health care and a set of beliefs about the best way of improving health. It includes care directed at both individuals and communities; its interventions are often diffuse and difficult to evaluate with the empirical quantitative methods which are frequently used in health economics; and its resources are often provided through informal care, by individuals, families or communities. Primary health care has much to offer in terms of cost-effective interventions, but there are many factors that can prevent these services having an appropriate priority. There can also be differences between the viewpoints of professionals, individual patients and society in general.

The module reiterates the message that, in many countries of the WHO European Region, changing demography and social patterns pose special challenges to primary care, especially in terms of long-term care and care for older people. The module also stresses that lack of evidence is not necessarily evidence of lack of effectiveness. The difficulties in obtaining hard evidence, such as that from randomized controlled trials, are greater in some parts of the health system than in others. The author points to a danger that, with developing evidence-based initiatives, resources may be allocated to areas where harder evidence is available, which may not necessarily be the areas where the health needs are greatest.

Module 4.4.2, by Dr Manfred Wildner and the late Dr Oliver Sangha (Munich, Germany), is concerned with citizen participation, patients' rights and ethical frameworks. It makes a valuable contribution to the learning materials, since these topics are often inadequately considered in many health economics textbooks and traditional economic theories based on individual preferences do not

adequately describe the full set of conditions influencing demand in health care markets. In fact, knowledge of theoretical frameworks of ethics and rights, as well as the possible strategies for their implementation, is of great importance for health economists as they can regulate or otherwise influence the market and the behaviour of participants on both the supply side and the demand side. Furthermore, public participation, patients' rights and consumers' rights are widely expected to play an increasingly important role in medical practice as well as in other health care markets in the future. The module is highly relevant for all four of the groups of potential users of the learning materials, with the understanding that ethical choices can be painful. A health service which seeks to retain the confidence of its patients, its political constituency among the general public, and its funders (whether public or private) cannot afford to ignore the important issues which are raised in this module.

4.2 The process, administration and management of change

4.2.1 Policy analysis, bargaining and negotiation

John N. Lavis[1]

Key messages

- Why are some health problems or issues on the agenda to be deliberated (and not others)? Why are some health policies developed to achieve particular objectives using particular policy tools (and not others)? Why are some health policies acted upon by people in the field (and not others)? Identifying patterns in agenda-setting and the development and implementation of health policy, as well as understanding the reasons for these patterns, are important skills.
- Health policy can be considered at three levels: clinical, administrative and legislative. Health policy analysis is the study of why groups respond to some health problems or issues and not others, why groups develop some health policies and not others, and why groups implement some health policies and not others. Each of these topics can be explored at each level of the audience.
- Health care providers work at the intersection of educational, economic, administrative, community and personal environments, and the concordance of a practice guideline (which can be thought of as a health policy for clinicians) with these environmental influences will determine whether it is implemented. Practice guidelines are more likely to be implemented when large amounts of high-quality information from a range of sources support the action or inaction suggested by the practice guideline, when financial incentives reward it, when regulations make such action or inaction possible, when public pressure is either non-existent or supports the action or inaction suggested by the guideline, and when personal experience makes the health care provider comfortable with the action or inaction suggested by the practice guideline.
- Three factors are typically cited to explain action or inaction in policy development at the legislative level: interests (who wins and who loses), institutions (the rules for decision-making), and ideas (both values and research). Policies are more likely to be developed when the benefits are concentrated among more influential groups (and the costs across less influential groups), when decision-making structures concentrate influence at the same level of policy-making and when policies are less visible (especially to those who will have costs imposed on them), and when both values and empirically tested "facts" support the policy.

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[1] This module was prepared by Professor John Lavis (e-mail: lavisj@mcmaster.ca), Centre for Health Economics and Policy Analysis, McMaster University, Canada.

- These insights can be used to assess the feasibility of change and to establish a strategy for bringing about change if it appears feasible. For example, certain people may have a particular policy that they would like to see developed. The first step involves a stakeholder analysis to determine who wins and loses, and what this means for the proposal's political feasibility. The second step is to determine the rules for decision-making and whether values and empirically tested "facts" support the policy. The final step uses the knowledge from the first and second steps to establish political strategies for improving the chances that the policy will be adopted. These strategies can include bargaining, strengthening the position of supporters and weakening the position of opponents, and mobilizing disorganized supporters and deterring organized opponents.

Tutors' notes

This module introduces a very different set of skills from the modules that precede it. As outlined in Module 3.2.1 on the relationship between the health for all (HFA) strategy and health economics, the frameworks and tools from health economics can help in understanding the HFA targets and how to implement them. The frameworks and tools from health policy analysis expand the discussion even further and provide an understanding of the context in which these targets may be discussed, converted into policy and acted upon. While it is not an exercise for this module, participants could be challenged to answer the following questions.

1. What conditions would make it more likely for the idea of "health for all" to be put on the agenda of legislators in participants' countries?
2. What conditions would make it more likely that HFA policies (with targets and indicators) are developed by their countries?
3. What conditions would make it more likely that HFA policies (with targets and indicators) are implemented by their countries?

One important condition is met by encouraging policy-makers, civil servants and other government technical staff, health care managers and health care professionals to learn about health economics' frameworks and tools. This module seeks to stimulate thinking about the other conditions.

The first exercise is aimed at the level of *appreciation*. The first half of the exercise would provide the most opportunities for learning if at least some members of the group were either health care managers or health care professionals (e.g. doctors and nurses). The second half of the exercise would provide the most opportunities for learning if at least some members of the group were either policy-makers (e.g. elected officials) or civil servants and other government technical staff. These subgroups would have valuable experiences on which the tutor could draw to illustrate points for participants who are unfamiliar with practice guidelines or legislative policy.

The second exercise is aimed at the level of (critical) *appraisal*. It can be used with the following groups:

- policy-makers (e.g. elected officials)
- civil servants and other government technical staff
- health care managers
- health care professionals (e.g. doctors and nurses).

The first two subgroups would be a helpful resource to the tutor in working through the exercise because this is a type of analysis with which they are very familiar.

Introduction

For those working in the health field, there can often appear to be no particular reason as to why some health problems or issues are on the agenda for discussion and not others, why some health policies (and not others) are developed to achieve particular objectives using particular policy tools or why some health policies are acted upon (and not others). Identifying patterns in agenda-setting and the development and implementation of health policy, as well as understanding the reasons for these patterns, are important skills for those in the health field. This module supports the development of these skills by encouraging participants to explore these patterns in the context of their own countries. The objective is to provide participants with several analytical tools for health policy analysis, rather than to discuss the advantages and disadvantages of particular health policies.

The module begins with a framework for understanding the range of topics that health policy analysis can address. Two examples of health policy analysis are provided, one at the level of a health care service (caesarean sections) and one at the level of the health care system (user fees for health care services), followed by an exercise for participants which builds on these examples. The module then introduces tools for understanding patterns in two of the topic areas: the implementation of clinical policy and the development of legislative policy. The enumeration of factors is not meant to be exhaustive; participants are expected to add to and modify them. The module concludes with a second exercise in which participants are asked to select two cases of policy development and, in view of their awareness of possible explanatory factors, to offer explanations for why these policies rather than others were introduced.

Health policy analysis

Health policy analysis is the study of why groups respond to some health problems or issues and not others, why groups develop some health policies and not others, and why groups implement some health policies and not others. In other words, health policy analysis is the study of **agenda-setting**, health policy **development** and health policy **implementation**. What health policy is not also warrants attention. Health policy analysis does not include the study of how best to advance particular interests (i.e. political strategy) or what interests to advance (i.e. political advocacy).

Health policy can be considered at three levels: clinical, administrative and legislative. The **clinical level** includes health care providers who deliver services to patients. These providers often play a role in deciding which health problems or issues warrant the development of clinical practice guidelines (e.g. treatment of dyspepsia, treatment of HIV disease, or use of caesarean sections) and how these guidelines will be developed (e.g. by using clinical evidence regarding effectiveness, analytical evidence about decisions regarding the cost–effectiveness of alternative courses of action, or econometric evidence of budgetary impact). Moreover, these providers are the people called upon to implement clinical practice guidelines. The **administrative level** includes the range of administrators working in health-related facilities or programmes. These administrators often play a role in deciding which health problems or issues warrant the development of administrative policy and which administrative policies will be developed. They may be called upon to implement their policies or may work with health care providers or other administrators to implement their policies. The administrative level also includes private firms whose managers can make decisions about how the employees should be treated or what products and services should be produced, in part on the basis of the health consequences of their decisions. The **legislative level** includes the politicians and senior

bureaucrats charged with the authority to develop legislative acts or regulations that can affect health. These politicians and bureaucrats ultimately decide which health problems or issues warrant the development of public policy, which legislative policies will be developed, and under which legislative policies resources will be allocated to facilitate or monitor implementation. It is recognized that there are a number of issues, especially in safety and risk management, where the population manifests political will and influences agendas directly.

Note that this categorization differs slightly from the categorization of decision-makers introduced by Professor Stoddart in Module 2.3.2. His categories can be collapsed into individual service providers (corresponding to the clinical group), programme managers and regional or community authorities (which, with the addition of the administrators in hospitals and other health facilities, corresponds to the administrative group), and elected politicians and senior officials of government ministries (corresponding to the legislative group).

Table 1 provides a conceptual framework for this discussion. It outlines three distinct topics that health policy analysis might be used to explore – agenda-setting, policy development and policy implementation – and the three levels (clinical, administrative and legislative) at which these topics can be considered. These examples and those in the text below provide brief illustrations of the two most frequently studied topics from Table 1: the implementation of clinical practice guidelines and the development of legislative policy.

While agenda-setting is not further discussed in this module, interested participants can obtain a rigorous introduction to this field by consulting Kingdon *(1)*.

Table 1. Examples of topics addressed by health policy analysis

Steps in the policy-making process	Levels of policy-making		
	Clinical	Administrative	Legislative
Agenda-setting	Why are particular practice guidelines developed?	Why do needs of a particular group become an issue?	Why does privatization of health care become an issue?
Development	Why do practice guidelines for the same condition differ?	Why do some managers of primary care centres focus on young children and others on the elderly?	Why do some governments privatize health care and others not?
Implementation	Why are some practice guidelines implemented?	Why do some programmes targeted at particular groups succeed?	Why do privatization initiatives sometimes succeed?

Health policy is not just health care policy. As foreshadowed by Professor Stoddart in Module 2.2.1 and addressed by him explicitly in Module 2.2.2, health policy may have health as an objective or as a consequence. As examples of the former, consider policies related to the remuneration of health care providers or policies related to income support for low-income pregnant women to allow them to afford better nutrition and make eating choices that are healthier for their babies. As examples of the latter, consider tax or transfer policies to reduce the financial burden on low-income parents with small children or more generally public policies on taxes and income security. As Professor Stoddart points out in Module 2.3.1, while "the health care system is a critical component of health policy, and in most countries receives the largest share of resources directed to health as well as the largest share of media coverage about health issues", it is not the only component of health policy.

Some examples of health policy

As a first example of a health policy, consider a **practice guideline**. Such a guideline can be considered a case of explicit clinical policy. In Module 3.4.2, Professor Stoddart introduced the idea of practice guidelines in the narrow context of the requirements for clinical employees set out by some international for-profit hospital chains. In Module 5.4.1, Professor Leidl will introduce two clinical areas in which health economics could inform the development of practice guidelines: the recently "rediscovered" drug treatments to eradicate *Helicobacter pylori (hp)*, thought to be one of the causes of dyspepsia, peptic ulcer and gastric cancer, and the newly discovered combination drug treatments for HIV disease. Decision analysis could inform whether eradication treatment should generally be offered to all dyspeptic patients found *hp*-positive, irrespective of whether there is evidence of further disease, and econometric analysis could inform whether to fund combination treatments involving protease inhibitors given its implications for public budgets.

Consider now the case of a practice guideline for caesarean sections, the implementation of which has been extensively studied by Jonathan Lomas and colleagues *(2)*. This guideline generally recommended a reduction in the use of caesarean sections and specifically recommended that women who have had a caesarean section previously should be given a trial of labour. One year after the release of this guideline, 94% of obstetricians were aware of the guidelines, 67% of their responses to knowledge questions were correct, and 85% of them agreed with the guideline (they may not have known what was in the guideline but they agreed with it!). According to obstetricians' own reports, the caesarean section rate among women who had previously had caesarean sections had dropped from 72.1% to 61.1%. However, according to more objective records, the caesarean section rate in these women had only dropped from 94.5% to 91.0%.

Disappointed with these results, a team of researchers at McMaster University conducted an experiment to determine how best to improve the implementation of this practice guideline. They randomly allocated obstetricians to receive: (i) no intervention (the control group), (ii) an audit of their practices with regard to caesarean section and the feedback of these results to them, or (iii) the opportunity to interact with an opinion leader. For the latter, an opinion leader in each community was selected and educated about the key messages from the guideline. The opinion leaders then passed on these messages to their obstetrical colleagues in routine encounters, both formally (at medical rounds) or informally (even on the golf course!). The caesarean section rate dropped by 4.7% in the control group, 6.7% in the audit and feedback group, and 11.9% in the opinion leader group. Something (or many things) that the opinion leaders did seemed to have made a difference.

As a second example of a health policy, consider a **legislative act or a regulation** that would remove a ban on user fees so that health care providers could charge patients for services either instead of or in addition to the fees that they already received through public or private programmes. Such a policy regarding user fees can be thought of as a specific case of health care financing policy. In Module 3.3.1, Professor Stoddart introduced user fees as one legislative area in which health economics could inform the development of public policy. The income–expenditure identity which he described could be used to highlight the effects of increasing direct charges to users on utilization of services and the incomes of health care providers.

Several factors have made it unlikely that a ban on user fees would be removed in a jurisdiction such as Canada. First, as the income–expenditure identity suggests, there would be losers as well as winners. The losers would include the sick and the poor (who are often one and the same); these individuals would be likely reduce their use of needed services and feel the impact, as a proportion of their income, to a greater degree. The winners would include the healthy and the wealthy, as well as health care providers whose incomes would rise if a ban were lifted. The losers would tend to outnumber the winners. Second, the decision-making structure for health policy in Canada and the visibility of decision-making on this issue make lifting a ban particularly difficult. With a constitution and a legislative act that gives the federal government the authority to develop health care financing policy, even though the provincial governments administer the health care system, the federal government can reap the electoral benefits of banning user fees while not having to deal with public concerns regarding perceived funding shortfalls. Moreover, health care financing is a highly visible policy domain in its perceptibility (voters can usually identify that a policy has or could have an effect on them) and in its traceability (voters can usually link policies to individual politicians who they can reward or punish). Third, user fees have not been shown to achieve one of their principal objectives: to reduce selectively the inappropriate use of health care services. Faced with user fees, individuals stop seeking health care services for both the right and the wrong reasons. This empirical finding makes it difficult to argue that no one would be hurt by the introduction of user fees.

Exercise 1

Before going further in the module, describe why you think practice guidelines sometimes are and sometimes are not implemented. Identify as many distinct factors as possible that might help or hinder the implementation of a particular practice guideline. Use the following questions as a guide for systematic discussion.

- In what specific ways can the amount and type of information available to health care providers influence their uptake of a practice guideline?
- In what specific ways can the incentives that health care providers face influence their uptake of a practice guideline?
- In what specific ways can the regulations that govern the practice of health care providers (at the national, local or facility level) influence their uptake of a practice guideline?
- In what specific ways can the public influence their uptake of a practice guideline?
- In what specific ways can the personal views of health care providers influence their uptake of a practice guideline?

You should feel free to add other factors which you feel are important. You are also requested to illustrate your answers to the above questions with examples, observations and statistics from your own countries.

Now consider legislative policy. Describe why you think some legislative policies are developed and not others. Identify as many distinct factors as possible that might help or hinder the development of a particular legislative policy. Use the following questions as a guide for systematic discussion.

- What specific groups can win and lose with a legislative policy related to the health field, and in what specific ways can these groups influence policy?
- What decision-making structures exist for legislative policy related to the health field, and in what specific ways can these structures and interactions between them influence policy?
- In what specific ways can values influence policy? In what specific ways can research influence policy?

Again, you should feel free to add other factors which you feel are important and should illustrate your answers to the above questions with examples, observations and statistics from your own countries.

A tool for understanding the implementation of clinical policy

While some attention in recent years has focused on which health problems or issues warrant the development of clinical practice guidelines (e.g. caesarean sections instead of the treatment of dyspepsia or HIV disease) and on how the process by which guidelines are developed may influence their content (e.g. who sits on the guideline development panel, what types of information they use, and what rules are used when consensus cannot be reached), most attention has focused on the implementation of clinical practice guidelines. As the study of the caesarean section guideline suggests, practice guidelines are often not implemented by health care providers – they fail to receive guidelines, read them or act on them.

By studying patterns in the implementation of practice guidelines, we can begin to understand why some practice guidelines are implemented and others not. Building on his study of the implementation of the caesarean section guideline, Lomas has pointed out the fundamental limitation of a simple dissemination strategy for a guideline: it fails to acknowledge the range of environments in which health care providers work. A guideline represents only one component of a provider's educational environment. Providers also obtain information from journal articles, textbooks, continuing medical education sessions and colleagues. Moreover, the **educational environment** represents only one environment of many. Health care providers also face the following:

- an **economic environment** which, for example, might include incentives such as higher fees for a surgical procedure such as a caesarean section than for a trial of labour;
- an **administrative environment** which, for example, might penalize health care providers less severely for errors of commission (doing something unnecessarily) than for errors of omission (failing to do something);
- a **community environment** which, for example, might put public pressure on health care providers to take a particularly aggressive approach to management when a pregnant woman and her baby are involved;
- a **personal environment** which, for example, might include a bad experience with trials of labour.

Picture a health care provider who has to present the pros and cons of a caesarean section to a woman in labour and her husband. While the clinical practice guideline might suggest a trial of labour, other aspects of the provider's educational, economic, administrative, community or personal environments might suggest a caesarean section. In an ideal world, all of these pressures would point in the same direction – and in ideal worlds, practice guidelines are probably fully implemented by

every health care provider. In the real world, efforts are made to reorient as many of these environments as possible so that they support the implementation of practice guidelines. Interventions by opinion leaders probably work in part because these individuals can help to make sense of guidelines in the light of these environments. The same holds true for academic "detailers", the "public" equivalent of pharmaceutical detailers.[2]

The questions in the first half of Exercise 1 and the environments described above, taken together, provide a framework for considering why some clinical practice guidelines are implemented and others are not. Practice guidelines are more likely to be implemented when large amounts of high-quality information from a range of sources support the action or inaction suggested by the practice guideline, when financial incentives reward the action or inaction suggested by the guideline, when regulations make possible the action or inaction suggested by the guideline, when public pressure is either non-existent or supports the action or inaction suggested by the guideline, and when personal experience make the health care provider comfortable with the action or inaction suggested by the practice guideline.

A tool for understanding the development of legislative policy

While some attention in recent years has focused on which health problems or issues warrant the development of legislative policy (e.g. choosing to develop health care financing policy rather than a policy for the remuneration of health care providers) and on the implementation of legislative policy, most attention has focused on why some policies are developed and others are not. As the discussion of user fees suggests, legislative policy in some domains may rarely be changed, while in others it may be changed quite regularly and in predictable ways.

By studying patterns in the development of legislative policy, we can begin to understand why some policies are developed and others are not. Three factors are typically cited to explain action or inaction: interests, institutions and ideas. Consider **interests** first. Because any policy will provide benefits and impose costs (i.e. some will win and others lose), many voters and interest groups will have a reason to ensure that their interests are taken into account in policy-making. However, because some policies provide concentrated benefits or impose concentrated costs, voters and interest groups with more to gain or lose have more reason to seek to influence the policy-making process than those with less to gain or lose. Next consider **institutions**, which includes both formal decision-making structures and past policies. These institutions determine the rules within which ideas and interests develop and policies are made. Some policies may be more likely to be developed in jurisdictions with particular features (e.g. federalism with shared authority for health care) or with particular policies already in place (e.g. a ban on user fees for health care services). Finally, consider **ideas**, which includes values (i.e. views about how the world should work) and empirically testable or tested hypotheses about how the world actually works. Some policies may be more consistent with some values and empirical "facts" than others, making these policies more likely to be developed.

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[2] Academic "detailing" refers to university-based educational outreach (see, for example, Soumerai, S.B. & Avorn, J. Principles of educational outreach ("academic detailing") to improve clinical decision making. Journal of the American Medical Association, **263**(4): 549–556 (1990). The term comes from the pharmaceutical sector: drug representatives who meet one-on-one with physicians are called detailers. Whereas pharmaceutical company detailers act in the interests of their firm, academic "detailers", by passing on accepted scientific knowledge, act in the public interest.

Now let's return to the issue of user fees for health care services. First, as outlined by Professor Stoddart in Modules 3.3.1 and 3.4.2, the losers from removing a ban on such fees include the sick and the poor. The winners include the healthy and the wealthy, as well as those people who derive their incomes from the provision of health care goods and services, and from the management and overhead components of the health care system. The latter include the employees, shareholders, lawyers and accountants of private insurance firms, pharmaceutical firms, medical equipment suppliers, and for-profit managed care firms. Second, to take the example mentioned previously, the division of authority between the federal and provincial governments in Canada and the visibility of health care financing policy-makers makes lifting a ban particularly difficult. Third, user fees have not been shown to reduce selectively the inappropriate use of health care services, so that the policy cannot be argued to have no effect on the sick.

Health policy analysis, like any field, has its pet explanations at any one time. Interest-based accounts dominated explanations in the 1970s. Institution- and idea-based accounts dominate today. Nevertheless, all three factors warrant consideration to explain why some policies are developed and others are not. Often the answer lies in the interaction between all three factors.

The questions in the second half of Exercise 1 and the three factors described above, taken together, provide a framework for considering why some policies are developed and others are not. Policies are more likely to be developed when the benefits are concentrated among more influential groups and when the costs are diffused across less influential groups, when decision-making structures concentrate influence in a small number of individuals at the same level of policy-making and when policies are less visible (especially to those who will have costs imposed on them), and when both values and empirically tested "facts" support the policy. Health economics can provide many of these "facts".

Exercise 2

Using today's local newspaper (which could be the same one you used in the exercise for Module 2.2.2), select one major news story concerning a policy developed by government with health as a primary objective. Analyse who wins and who loses (and who might have won or lost under other possible alternatives, including the alternative of the status quo), what are the rules of the game for developing policy in this domain, what are the (explicit or implicit) values of the policy-makers, and whether and how they used research evidence to inform their decision.

Repeat this exercise for a government policy or decision which has health as a consequence but not as a primary objective.

Conclusion: from understanding to action

For people seeking to achieve the health for all targets, these insights can be used to assess the feasibility of change and to establish a strategy for bringing about change if it appears feasible. For example, they may have a particular clinical practice guideline that they would like to see implemented. The first step would involve an analysis of the educational environment within which the target clinicians function. The second step would be to use this knowledge to establish implementation strategies for improving the chances that the practice guideline will be adopted. Sometimes these strategies might include modifying financial incentives (i.e. the economic environment); at other times they might involve changing a hospital policy (i.e. the administrative environment).

More likely, given the focus of the health for all targets, motivated individuals or groups will have a particular policy that they would like to see developed. The insights from this module, as well as those from another resource devoted to this issue *(3)*, may prove helpful here. The first step would involve a stakeholder analysis to determine who would win and who would lose and what this would mean for the political feasibility of the proposal. Stakeholders in the health sector can often be grouped according to whether they are providers (e.g. hospitals and physicians), consumers (e.g. disease-specific patient groups), economic groups (e.g. business associations), ideological groups (e.g. political parties) or health development groups (e.g. voluntary aid groups). The power of each of these groups should be assessed, both in terms of the tangible sources of their power (money, organization, people, votes and skills) and the more intangible sources (information, access to the media, legitimacy). In addition, their positions and commitment to these positions should be assessed.

The second step would be to determine the rules for decision-making and whether values and empirically tested "facts" support the policy. For example, some decision-making structures lend themselves more easily than others to penetration by stakeholders. A structure in which policies are developed within policy subsectors often makes it easier for stakeholders to get a seat at the policy-making table. Many decision-making points involving many different decision-makers can make it easier for a single stakeholder group to veto a policy. Some policies may also be less visible than others and thus less likely to attract the attention of groups other than the main stakeholders.

The final step would be to use the knowledge from the first and second steps to establish political strategies for improving the chances that the policy will be adopted. The first such strategy is bargaining. Bargaining can include promises (I'll give you something in exchange for your help), trades (I'll do something for you on another issue if you help me on this issue), threats (if you don't do this, I won't work with you again) and deals (I'll do this if you do that). The second strategy involves strengthening the position of supporters (e.g. by giving them money) and weakening the position of opponents (e.g. by distracting them with another issue). The third strategy involves mobilizing unorganized supporters and deterring organized opponents. Policy development is a complex game. It pays to know who you are playing with, the rules of the game, and what kind of support you can build on the basis of shared values or "facts".

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4.2.2 Political management of public health

Keith Barnard and Chris Selby Smith[3]

Key messages

- **Public health** definitions typically reflect one of two perceptions. The first, narrowly focused, conception refers to a range of technical services, such as environmental health and communicable disease control. The second conception is broader. It covers the organized efforts of society to protect and promote the health of the population, to prevent and control disease, to mitigate the effects of disability and handicap, and to ensure the wellbeing and care of those with chronic health problems and the terminally sick. Public health in this second sense equates with the values, operating principles and objectives of WHO's health for all (HFA) strategy.
- **Primary health care**, as elaborated in the Declaration of Alma-Ata (http://www.euro.who.int/AboutWHO/Policy/20010825_2), provides a set of principles to be adapted by each society to pursue the goal of health for all. Primary health care identifies actors to be involved and ways of mobilizing resources to ensure that essential tasks are undertaken to achieve the highest attainable level of health. The underpinning ethic is that of equity (in the sense of fairness).
- **Public health management** involves formulating and implementing action plans that:
  - address the health problems of a given community, as identified by epidemiological and other assessments of need;
  - mobilize, deploy and use resources efficiently to achieve given ends which meet political, social and cultural expectations;
  - monitor the impact of services and make appropriate adjustments;
  - scan the operating environment for early warning signs of developments that could affect what needs to be done and how it is done;
  - are based on maintaining close contact with all operating partners, community groups and opinion leaders; and
  - are supported by a clear strategy of public advocacy, public information and public education to promote informed choice.

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- Public health management makes prudent use of economic concepts and reasoning (and of economists as advisers). It recognizes where they are helpful, but is also aware of the limits of their frame of reference and the assumptions they make to live within it, and the questions to which they cannot provide usable answers.

Tutors' notes

This module is concerned with the political management (by government or organized society rather than in the narrower party political sense) of public health, where public health relates to the organized efforts of society to protect and promote the health of the population. It equates with the values, operating principles and objectives of WHO's health for all strategy, adopted by WHO in the Declaration of Alma-Ata in 1978 *(1)*, later endorsed by the World Health Assembly and reaffirmed in the Ljubljana Charter on Reforming Health Care in 1996 *(2)*, the World Health Declaration *adopted by the world health community at the 51st World Health Assembly in May 1998 (3)* and the two WHO publications setting out HEALTH21, the health for all policy framework adopted by the WHO Regional Committee for Europe in 1998 *(3,4)*.[4]

Primary health care is the means by which the goal of health for all is to be pursued. This remains the foundation of WHO policy, so that this module has close links to others throughout the learning materials. The essence of primary health care is putting into practice at the local level a coherent, rational and broad-ranging health policy to promote and protect, maintain and restore the health of all people in a community. Its underlying ethic of equity implies preferential consideration for the disadvantaged and the vulnerable.

The module is organized in four parts.

1. The first part outlines the scope of health for all.
2. The second part is concerned with the particular contribution of economics to HFA and primary health care. Exercise 1 discusses the contribution which the economic way of thinking (and economists) can make. It considers the contribution from an overall perspective and from the specific viewpoints of four major stakeholders in the health care systems of WHO's Member States.
3. The third part focuses on how the HFA framework can be used to improve outcomes, including the tension between imagination or vision and realism, noting that it is practice rather than rhetoric that determines how the health agenda is set and acted upon. Exercise 2 asks participants to consider the extent to which the HFA framework assists decision-makers to address the political and ethical challenges involved in socioeconomic policy-making for health by reference to a topical example in their own countries.
4. The fourth part discusses certain factors which can improve the chances of success, since the overall purpose of the political management of public health is to identify the innovations to be adopted, and then to secure the commitment of all those interests whose involvement is necessary to achieving them. Exercise 3 invites participants to reflect on the key health, political, economic, social and other factors for success in handling the political management of public health.

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[4] The earlier of these: Health21 – an introduction to the health for all policy framework for the WHO European Region (4), sets out the essence of health policy in an HFA context. The later – *HEALTH21: the health for all policy framework for the WHO European Region (5)* – provides the evidence and rationalefor specific policy proposals and is in effect a planners' manual.

The module is primarily for the purposes of *appreciation* and *appraisal* rather than *analysis*. It can be used by each of the four groups of users for whom the learning materials have been developed. For example, policy-makers at national, regional or local levels (both political, and administrative and managerial policy-makers) can use the module in developing, implementing and evaluating their strategies, while managers, practitioners and other concerned groups can understand more fully what is required, how needs are being met and where their influence can be most effectively applied.

The scope of health for all

The intention behind WHO's health for all concept is to encompass within one policy framework long-term objectives relating to:

- healthy living by a population educated in health problems and the appropriate responses;
- a healthy environment providing shelter, food, water and sanitation, with good economic opportunities and freedom from the fear of violence; and
- an accessible, rational and comprehensive system of preventive treatment, care and rehabilitation services.

HEALTH21 advocates specific proposals for preventing and controlling disease and injury to reduce their incidence, prevalence and impact. It identifies multisectoral strategies to ensure that physical, social and other environments are more health-promoting, to enable people to adopt healthy patterns of living, and to provide health services that are efficiently run, responsive to people's needs and produce health gains through improved outcomes. It proposes strengthening the knowledge base, mobilizing partners for health improvement, and managing the process of policy development and implementation in an efficient but sensitive way.

The aim is to stimulate and support countries and communities, enabling them to develop strategies that address the determinants of health and result in:

- socially responsible and sustainable health development;
- greater equity in health;
- higher levels of health throughout people's lives;
- a reduced burden of sickness and injury through the unlocking of new resources for multisectoral action; and
- high-quality cost-effective health care.

WHO's health for all strategy was originally adopted by the World Health Assembly to give effect to its resolution WHA30.43 in 1977, which committed Member States, at least morally, to action. They undertook to pursue as a social policy goal the attainment of a level of health by all their peoples that would enable them to lead socially and economically productive lives. This commitment was reaffirmed by the World Health Assembly in resolution WHA51.7 of 16 May 1998 and by the WHO Regional Committee for Europe in 1998 in resolution EUR/RC48/R5 on the Health for all Policy Framework for the European Region for the 21st Century.

The underpinning ethic, made clear in the original HFA resolution, is that of equity. Good health is a right to be enjoyed by all (irrespective of the argument that a high level of population health produces benefits in terms of social and economic development). This means that action taken and the allocation of resources require that preferential consideration be given to those whose needs are greatest and whose health could be improved the most.

In the terms of the Declaration of Alma-Ata *(1)*, and later endorsed by the World Health Assembly, primary health care is the means by which the goal of health for all is to be pursued. This remains the foundation of WHO policy. The essence of primary health care, as promulgated in the Declaration of Alma-Ata, is putting into practice at the local level a coherent, rational and broad-ranging health policy to promote and protect, maintain and restore the health of all people in a community. The task is to sustain people's capacity for independent living, their integrity and self-respect, and to seek to empower people individually and collectively to promote their own health and to make rational use of health care services.

The values underpinning the policy are:

- health as a human right and people's responsibility to use the health potential they have;
- equity in health and solidarity in action; and
- participation of people and groups in decision-making and implementation and their accountability for action.

The proper objective of health care must be to provide services equitably to those in need of them. This is irrespective of the pattern of ownership of institutions or how services are funded. At the same time, society and its policy-makers should avoid placing an unreasonable burden on physicians by expecting them to treat every problem presented to them even when the causes are not biomedical. Rather, society and its policy-makers, in WHO's view, must ensure that actions focus on the underlying factors, the lifestyle and environmental determinants of the health of communities, and not just the presenting problem.

Central to the HFA concept of health policy is the emphasis on the determinants of health and the importance to economic and social development of a population enjoying good health, defined as the capacity to lead socially and economically productive lives. This does not, of course, make the minister of health and the health sector responsible for everything. However, they need to recognize that they have a crucial advocacy role. It is their responsibility to make the argument for health in the political sphere, including to other ministers and decision-makers in all sectors, whenever and wherever it is needed. To undertake this advocacy role successfully they need negotiating and diplomatic skills so that they can devise appropriate strategies jointly with actors in the different sectors. It is also their responsibility to ensure that health policies rooted in HFA, not just for health care but for the broad field of health protection and promotion, are developed, adopted and implemented at all levels.

The primary health care strategy and its effective implementation require technical expertise of different kinds and knowledge of people's circumstances and living conditions. It shows equal concern for the sick and the currently well. The ethic of equity implies preferential consideration for the disadvantaged and vulnerable. Primary health care is teamwork and collaboration, such as general medical practitioners working with community nurses and others. Each of the participants and groups has their own particular skills and responsibilities. In some tasks they cooperate with professionals from other sectors.

Primary health care workers offer prompt, professionally sound treatment locally for conditions that do not require more specialized attention, such as those involving the use of hospital-based technology. They also need an effective referral system that gives their patients access to more specialist services when needed. They function as agents of their patients in relation to the rest of the health care system. When that role is properly discharged, it should lead to a more rational use of all specialist care and indeed of all resources.

The health for all policy also included Europe-wide targets and indicators by which progress is measured periodically and in relation to which remedial action can be taken if required *(5,6)*. However it is done there is a need for continuous monitoring and regular evaluation of the actions which are taken to achieve health for all (and of relevant developments in the external operating environment). Mechanisms need to be provided for the periodic review of policies and practices, so that appropriate changes can be made when required.

Although governments differ in the arrangements they make for the provision of health and social care, the propositions in the 1978 Declaration of Alma-Ata *(1)* were formally accepted by WHO Member States in the World Health Assembly. They were reaffirmed in the 1996 Ljubljana Charter *(2)*.

This immediately raises the issue, how can HFA really mean care for all (and not just for some)? Perhaps there can never be certainty, but it is only even possible if the following two conditions are satisfied, and any health care reform should be judged against them.

1. First, are services financed according to the fundamental principle of equitable collective funding, so that users' contributions, whether by taxation, insurance premiums or direct payments, are determined in relation to their ability to pay? However it has been generated, the aggregate level of funds available must be sufficient to make reasonable provision to meet the essential care needs of the population. The same principle applies in the allocation of resources in other respects, such as to geographical areas and health care providers.
2. Secondly, are services organized and managed with the purpose of achieving the highest possible equity of access to and quality of care and treatment, according to need, not ability to pay? This should apply, for example, across geographical areas and socioeconomic status. However, equity does not mean equality, literally the same for all, but fairness. Attention is also paid to efficiency, effectiveness, responsiveness and quality of care. The intention is to make the best use of resources in order to achieve the best attainable outcome from health care interventions. This includes reduced disability, better quality of life and user satisfaction, and wider considerations such as seeking to restore a capacity for independent living and enabling citizens to play a full part in society.

The twin criteria of equity and efficiency were discussed in more detail earlier in the learning materials. When applied in practice they require decision-makers to clarify their sense of priorities. In particular, this means stopping what is reasonably judged to be unnecessary and (in terms of results) ineffective activities. It is to focus on what is in tune with the values and expectations of the community and, recognizing what is affordable, to make a defensible use of the available resources.

In the *World health report 2000 (7)*, stewardship is ranked above the other three functions of a health system (service delivery, input production and financing) "… for one outstanding reason; the ultimate responsibility for the overall performance of a country's health system must always lie with government. Stewardship not only influences the other functions, it makes possible the attainment of each health system goal: improving health, responding to the legitimate expectations of the population, and fairness of contribution. The government must ensure that stewardship percolates through all levels of the health system in order to maximize that attainment". Stewardship is "the very essence of good government" *(7)*.

Chapter 6 of the *World health report 2000* examines certain aspects of how the public interest is protected.

- What is wrong with stewardship today? The report concludes that "stewardship has major shortcomings everywhere" (p.120).

- What vision for the future should be encouraged and pursued? How should the rules or incentives be set? How can compliance be encouraged?
- How is information to be developed, collected and disseminated? How is intelligence to be exercised and knowledge shared?
- Who should do what in relation particularly to strategies, roles and resources?
- What are the key challenges, how can improvements be made and, in a world of limited resources, what are the critical messages to facilitate better functioning health systems?

The contribution of economics

Robbins' definition of economics was "the science which studies human behaviour as a relationship between ends and scarce means which have alternative uses" *(8)*, while Oskar Lange saw it as "the social laws governing the production and distribution of the material means of satisfying human needs" *(9)*. These definitions remind us that economic concepts and reasoning are a thread running through HEALTH21 *(3)* and the thinking that lies behind it.

HEALTH21 is a reasoned presentation of possibilities (whether they are called ends, wants or needs) which, taken together and if satisfied in full, would result in everyone achieving their highest attainable level of health, i.e. WHO's constitutional objective. While the document is intended to be technically realistic, its purpose is more about clarifying proposals for action in the WHO European Region than addressing constraints on action such as limited financial and material resources ("scarce means").

The task of the policy-maker, the administrator implementing policy and the health practitioners exercising their professional skills, is to pursue HEALTH21 objectives as far as these are practicable. At the same time they will be faced with constraints in their particular situations. Among the other resources available to them, they will look to economists for advice. They will be aware that economists cannot and should not make decisions for them. The choice of ends, and of means having different consequences, are policy decisions, and as such are the business of politics and of wider decision-making processes in society. Economists in their professional role are (or should be) neutral between alternative political choices.

Economists are in the business of asking particular sorts of question and providing particular sorts of information. The questions are relevant to issues that policy-makers, administrators and practitioners must confront in coming to a decision. The information from economists can assist them in addressing those decisions. Economists look particularly at alternative ways in which ends can be achieved, the implications of those ends, and the consequences of choosing different means.

Prudent policy-makers, administrators and practitioners will also be aware when an economist is involved as a stakeholder (for example, as a citizen or local resident) in the choices that are to be made. This will make it harder for the economist to be neutral. Policy-makers, administrators and practitioners know that economists, unlike scientific advisers, will not have the benefit of any controlled experiments to support or corroborate the advice they give; that many aspects of what they advise on may not be susceptible to measurement; and that their models (however sophisticated and comprehensive) are dependent on assumptions and estimates.

In fact, of course, a wide range of social sciences are concerned with the study and understanding of human behaviour, the decisions and actions people take. Perceptive decision-makers who make use of their results will be aware that the different social science disciplines sometimes work in parallel,

sometimes in competition and sometimes in collaboration. Perceptive social scientists have concluded that their impact on decision-makers is enhanced when they address issues together, making complementary contributions to an improved understanding of causes and consequences.

It has been noted that "different social and behavioural sciences are in the main distinguished not by the events they study, but by the kind of relation between events that they seek to establish. Events themselves are neutral to the different disciplines" *(10)*. The implication is that "disciplinary frontiers (as artificial barriers between subjects) should be vibrant channels of communication, not iron curtains of mutual unintelligibility and mistrust; [the] narrow minded approach misconstrues the complementary aim and interests of these cognate subjects" *(11)*.

This should be an issue of great urgency for all social scientists with an interest in health since, as a general rule, significant groups of potential users of their work are not interested in the territorial disputes of social science theory. These groups include: politicians as health policy-makers; the permanent civil servants who are advising on and executing policy; the managers responsible for the operation of health care and other health related institutions and agencies; and individual health care practitioners and users. In their different roles these groups are concerned with the pragmatic handling of difficulties, responding to pressures and exploiting opportunities to achieve desired change. The more the advice of social scientists is based on abstract theory (and therefore suggestive of the world not as it is, but as they think it ought to be) and the less it is rooted in observed experience of actual behaviour, the less likely is it that the decision-makers will take notice, unless this advice coincides with their own existing values-based perceptions.

It is worth noting that, while social scientists, including economists, are seeking to offer rigorously generated *information*, as additions to knowledge, decision-makers contemplating choices in their particular operating environment are often interested in *intelligence.* This is the distillation of stories and statistics, hard (verifiable) and soft (unconfirmed but plausible) evidence from multiple sources in different forms or formats, which provides a usable picture of what is wrong or what change is possible and how changes could be achieved. It is as well that both decision-makers and scientists recognize the difference and understand each other's mindsets. The underlying assumption, nevertheless, is that the more extensive knowledge becomes through the analytical frameworks and research findings provided by economics and other social sciences, the more likely will it be that institutions can be reformed and policies reoriented with "good enough" assessments of the probable consequences of any changes that are proposed. But this is a hope rather than a guarantee.

Despite the limitations, there will be many issues on which economists' contributions will be found helpful, although economists have often found it necessary to develop their concepts to apply them satisfactorily to the health field. Included in these concepts would be:

- public goods in the health field;
- the notion of consumer sovereignty applied to health care, including the feasibility and limits of user choice;
- the effects of dissemination to and use of information by users of health services, clients receiving health advice, and consumers purchasing health products;
- monopoly, such as public ownership of institutions, professions as monopoly providers, and national health insurance agencies as monopsonists;
- laissez-faire and collectivism as appropriate economic systems for the health field;
- the concept of "utility" applied to the health field;
- pricing in health care;

- the principle of substitution; and
- returns to scale and the division of labour.

Seven key HFA concepts and issues for the economist are identified. First, the importance of **values** (what is held to be good) and **principles** (what needs to happen or be in place to ensure that the values are given practical effect). There is a crucial coherence in HFA values and principles. For example, an inefficient intervention is an unethical and inequitable measure, because it uses resources that could have been deployed equitably and effectively there or elsewhere.

Secondly, there is an issue about making the concept of **responsibility** operational. This includes clarifying what is properly an individual responsibility, avoiding simplistic assumptions about what decisions individuals can or will make for themselves and what requires collective action. In addition, there are matters concerning how the conditions can be created to enable individuals to take decisions and actions that could enhance their health, in particular how to develop the **co-production** concept.

Thirdly, economics can assist stakeholders and decision-makers in the health care system to clarify the nature of **outputs** and **outcomes**. This includes distinguishing between those that are directly health-related and those that have another beneficial effect; between those that are visible and those that are invisible or intangible; between those that are intended and unintended; and between positive and negative outputs and outcomes. These distinctions often have substantial implications for the action to be taken by stakeholders.

Fourthly, economics can assist decision-makers to understand the nature of **costs** (whether or not these can be usefully given a monetary value), in particular the costs of any change (e.g. of introducing new technology or new working arrangements in health care institutions) and of inappropriate health care reform. Economists also tend to raise the issue of distribution – who gains and who loses from particular arrangements or proposed changes?

Fifthly, economists emphasize the crucial importance of **knowledge**, including for informed choice and for advocacy. It can be valuable to appreciate that actors in different sectors may have different logics which they bring to bear, including in assessing situations facing the health sector.

Sixthly, since economists are concerned with choice, they tend to understand the nature of the **pressures** on **decision-makers** and the costs and benefits to them of making or not making (postponing or avoiding) a decision. In some situations, such as when there is gross inefficiency in the use of resources, it may be possible to make big efficiency improvements and thus achieve given outputs with fewer resources (or a greater output with the same resources) without sacrificing other desired outputs or outcomes. In other situations, however, economists are likely to stress that more of one (desirable) outcome can only be achieved by accepting less of another.

Finally, it is important to see the economic dimension in the context of the **bigger picture**. There are particular contributions from the insights and methods of economics to the pursuit of the goal of health for all. However, the skills and insights from other disciplines, such as epidemiology, operational research, political science and sociology, are also valuable and often complementary.

A study of the principal objectives of HEALTH21 and its underpinning values and principles confirms the significant contribution that health economics can make. When economists are sensitive to the environment of decision-making and action they tend to find policy-makers, administrators and practitioners receptive to the contribution of health economics thinking and to the application of its methods in the development of policies and strategies and in the planning and management of services. Interestingly, the broad way of thinking adopted by economists can be as valuable as the technical

minutiae, e.g. the costs compared to the benefits of alternative uses of scarce resources; decision-making at the margin; the implications of varying preferences, including for risk and uncertainty; and the distributional issues relating to who gains and who loses from adopting particular courses of action.

Exercise 1

Discuss the contribution which the economic way of thinking (and economists) can make to:

(i) the clarification of HFA objectives

(ii) the means which may be used to achieve them

(iii) the assessment of the extent to which they are achieved.

Consider the contribution of economics from the viewpoint of four stakeholders in the health care system:

(i) national or regional policy-makers and planners

(ii) managers of health care facilities and services

(iii) health care professionals, such as doctors, nurses, pharmacists or dentists

(iv) the users of health care services.

Using the health for all framework

> The health of the people is really the foundation upon which all their happiness and all their powers as a state depend.
>
> *Benjamin Disraeli*[5]

A distinction has been drawn between economic policy designed to create wealth and social policy designed to create harmony, or at least to create greater social cohesion. The political reality is that, in the hierarchy of values that steers government and ministerial careers and reputations, it is the portfolios of internal and external security and the management of the economy that enjoy primacy. Health and other aspects of social policy are clearly subordinate. In consequence, one underlying concern of the HFA movement has been to secure greater political visibility and awareness for HFA objectives, and recognition by governments (not just health ministries) of their importance for social and economic development. These have been seen as preconditions for effective implementation of HFA.

If Disraeli's view of health and the state is endorsed, should there be agreement with Beveridge that collective, responsible social action is preferable to economic individualism in the pursuit of human wellbeing?

> We should regard want, squalor, disease and ignorance as common enemies of all of us not as enemies with which each individual may seek a separate peace, escaping himself to personal prosperity while leaving his fellows in their clutches. That is the meaning of social conscience – that one should refuse to make a separate peace with social evil. *(12)*

[5] Speech, 23 July 1877. In domestic politics the British Conservative Prime Minister Benjamin Disraeli was associated with social and political reform, including the 1875 Public Health Act.

Health sector policy-makers addressing the political and ethical challenges in socioeconomic policy-making have the HFA framework with which to start. HFA has its critics; but it is in fact a carefully built structure which uses public health traditions, epidemiological evidence, technological trends and forecasts, moral appeal and political optimism. Effectively and persuasively presented, HFA can have considerable operational appeal. It can be a catalyst for increased collaboration between the health service and other social service agencies, private sector enterprises, various voluntary organizations and community groups, and the media. Such collaboration also implies joint information efforts for planning and monitoring purposes about the population to be served and their needs, and about present policies and provision of services and their effects. It should also be possible to show what can be done with little or no extra expenditure if there is good coordination and people are motivated.

The policy goes well beyond the health sector agenda perceived by the medical profession – or often by politicians and the general public. Yet it has survived. This is, or at least may be, partly because while it is kept in the most general terms no Member State wishes to be in opposition. As the product of an intergovernmental international organization, formally endorsed by its constituent Member States, HFA must be projected as politically neutral or universal. On balance however, the HFA strategy is collectivist, not least by its open espousal of equity as a fundamental objective and prerequisite for health. And, while the strategy must be adapted to a country's or a community's circumstances if it is to be properly implemented, too selective an adoption of its component parts will destroy the overall coherence of the strategy.

It is important to be aware of the interdependence of the different levels of policy-making. If the principle of **subsidiarity** is applied, decisions will be taken at the most appropriate level for the object of each decision. Generally speaking, the nature of the action, the actors involved, and the way decisions are arrived at will vary according to a country's constitution, practice, circumstances and traditions. Subsidiarity implies that, to the greatest extent possible, detailed policy-making and action are a local matter, although often operating within a framework that has been determined or influenced at other levels. This includes several dimensions, such as the physical environment, housing, communications and transport, work and economic activity, medical services, social history and tradition, lifestyles, culture and education, and other people-oriented activities and processes, creativity and tolerance.

Against this background the HFA agenda can be fashioned by identifying, analysing and responding to collective needs. The decisions taken will have short-term effects and possible long-term consequences. Both need to be weighed before decisions are taken. They can broadly be classified as the:

- **musts –** such as services and measures to ensure a safe environment, which minimizes unacceptable hazards to public health;
- **choices –** creating alternatives, such as healthy homes that people live in by personal preference; and
- **challenges –** developing appropriate policy responses to acknowledged social problems with health consequences: for example, how can an alienated group in the population be integrated into the community, or how can the social and psychological consequences of unemployment be mitigated?

There are certain realities to contend with in many countries: a culture of sectoral isolationism; the relative lack of power and status of health ministries, and the political disadvantage of health development being perceived as a limited concept which is unable to command sustained political and

governmental attention. There may be an indifference among political or bureaucratic decision-makers towards scientific knowledge as the basis for making better decisions – they may prefer other rationales.

The approaches to these realities can be arrived at by working through a series of propositions for HFA policy formulation. These point to key success factors, which are discussed in the next part of the module. Although derived from an analysis of direct experiences, they are in the form of an ideal type and are not a blueprint simply to be endorsed and implemented. They are intended to help trigger discussion of practical strategies in particular local circumstances. They stimulate the search for alternative approaches when the conditions for success are not immediately met.

In developing an effective approach to the political management of health policy, the health policy-maker is faced with four basic questions. What can be controlled? What can be changed? What can be influenced and how? What can be negotiated (or credit built up for later use)? In identifying the range of appropriate feasible actions (e.g. legislation, regulation, financial, education and research), the agency(ies) to be made responsible should also be identified, having first been assessed for their capacity to take action in the given situation.

Policy-making and planning are a tension between imagination and realism. Although plans must be tempered by feasibility and the availability of resources, the initial starting point is generally the generation of ideas. Starting with realism tends to mean that no vision results. This is an important point, because within many countries the pressures for delay and compromise are incessant. Nor is there any sense of shared vision in most instances.

For example, is a primary health care strategy:

- the sum of measures designed to assist the achievement of three common interpretations of health (longevity, healthy behaviour and physical fitness; *or* the absence or cure of disease and access to medical care; *or* social equilibrium, contentment and satisfying relationships?); *or*
- the operational coordination of health with other services, such as education and the environment?; *or*
- the functional integration through a referral system of first contact care with increasingly specialized institutional medical services?

It is the way these questions are answered **in practice**, rather than the rhetoric of policy documents, that determines how the health agenda is set and acted upon. Policy advisers and planners need to be sensitive to trends and concerns being generated both outside and within the health sector. In all events, the probability of opposition emphasizes the need to have in place a variety of tools for change that involve both public and private actors.

Maintaining the momentum for HFA is often a question of preparing defences against opposition. Arguments may be formulated on various bases. For example, the viability of the policy may be questioned at a **political** level, such as when particular vested interests (ranging from the manufacturers and distributors of products deemed to be harmful to health to the hospital with a high reputation which is threatened with a budget cut) seek to influence political decision-makers. Other arguments may be formulated at the **institutional** or **professional** level. For example, those in authority may be reluctant to encourage (or participate in) a controversy that could spark change – smooth-running organizations prefer to carry on as they are. Opponents may assert that there is no place or need for proactive or interventionist policy-making; the future is best left to the dynamics of the relationships between interests, or to the market; and in any event are not HFA objectives based on assumptions of doubtful scientific validity? In short, it will be alleged that it is all politically unrealistic and economically

unfeasible. A third set of objections may emerge at the **sociocultural** level. For example, objectors to HFA may maintain that nobody is really interested in health policy reform if they feel healthy and are satisfied with the available services. And if they are not, they will be concerned with quite specific worries. These could be based on perceptions of shortcomings in the operation of the health care system; or falling clinical standards; or anxiety prompted by the emergence of old-style public health problems, such as food safety linked to a serious loss of trust (e.g. Bovine spongiform encephalopathy, or mad cow disease, in the United Kingdom). Some objectors may even claim that HFA is a veiled form of "victim blaming", since in emphasizing individuals' responsibility for their own lifestyles and thus state of health, they are made the focal point for change.

It tends to be easier to advocate (and, if necessary, defend) HFA-based objectives if they have emerged from an open debate among all groups with an interest (stakeholders). The active dissemination of information and promotion of public debate are essential tools in creating from below more political visibility for health-related policy issues, and strengthening the political will to treat health seriously as a public concern. It tends to be easier to counter opposition if there is a properly thought through rationale for a comprehensive and integrated approach which emphasizes connections and linkages between seemingly separate issues. For example, a cost-effective approach is the use of multiple coordinated strategies to address the shared causes of the major noncommunicable diseases, which together account for most morbidity, disability and mortality in industrialized societies *(13)*. Of course, it may sometimes be politically expedient to present and explore certain issues separately, in order to win support for particular measures in public debate. However, that is a separate matter from keeping one's own comprehensive frame of reference (i.e. systems thinking) as a policy developer, implementer and manager. If opposition is not at root a reflection of a perceived threat to specific interests, it may be possible to engage with the objectors, especially if it can be convincingly argued that their suspicion and opposition to HFA is based on a misconception or a misreading of the evidence.

Exercise 2

To what extent does the health for all framework assist decision-makers to address the political and ethical challenges involved in socioeconomic policy-making for health in your country? Consider this issue in relation to:

(i) a specific recent health policy or practice change (or proposal), preferably a controversial and substantial one;

(ii) the different levels of decision-makers outlined in Exercise 1.

Key success factors

An effective approach to the political management of health policy and changes in health practice requires careful attention to three matters.

First, it benefits from a multi-level, intersectoral process with specific agencies designated as responsible for securing initiation and implementation. The range of possible types of action (e.g. legislation, regulation, financial, education and research) together with the specific agency(ies) that would be responsible, either solely or in cooperation with others, should be identified and assessed for appropriateness to the particular circumstances which are anticipated.

Secondly, an effective approach requires sustained political commitment, which means taking action when required. Major change generally takes a considerable period of time to accomplish. If

the key participants waver in their political commitment during the process (or it is thought that they might), the task of reform is more difficult and the defined objectives may not be achieved.

Thirdly, there needs to be targeted dissemination of information on health, health problems and risk assessments, and on possible counter measures, with an assessment of their likely impact.

The conditions for effective policy development include the following.

- The availability of strong evidence about the size of the problem, its main features and the need for action that would be affordable and broadly acceptable in that environment.
- The responsibility for protecting and promoting health (and where appropriate the need for joint, including intersectoral, action) is acknowledged by actors outside the health sector at ministerial, managerial and operational levels. This is especially important where the proposed action requires intersectoral cooperation, involves major expenditure or is contentious among powerful groups.
- The priorities, programmes, resource allocations and operating methods of the sectors involved can be reconciled or harmonized. This may not always be possible, but when it can be achieved it tends to make policy development more effective (and speedy), and effective implementation on a sustainable basis significantly more likely.

A policy proposal is much less likely to be adopted as the preferred option if it is perceived as a "zero sum game" by any of the interests involved. The number of policy initiatives being developed in detail at any one time should also be limited so as to increase their impact. This helps to ensure that the focus of the relevant interests and participants is not dissipated among competing demands and their capacities overloaded. It is desirable that there be a reasonable probability of early visible and positive results from the initiative, so that a success can be demonstrated publicly and politically. The stock of goodwill is limited, and key stakeholders are unlikely to be willing to gamble it on risky innovations, especially if they are not central to their perceived interests.

The options in HFA policy formulation can be organized in descending order of preference:

- first, identifying to other sectors the mutual benefit in cooperation to achieve health development;
- second, identifying a range of possible exchanges of favours with other sectors to induce them to cooperate;
- third, arguing to other sectors that there is an overriding national, regional or public interest to be served in adopting health criteria in their policy formation;
- finally, deferring attempts to engage with other sectors until the health policy-maker is in a stronger political position.

In all circumstances, it is important to avoid a posture that would appear as health "imperialism" or an attempt to colonize other sectors.

In summary, the approach means three things: (i) to identify the courses of action required, who are the interested parties to be involved and what consequences will follow; (ii) to seek political commitments, build networks and encourage grass-roots activities and support; and (iii) to negotiate action planning on specific issues with proper preparation and consultation and to build in agreed monitoring and evaluation procedures. This enables developments to be assessed promptly, remedial action taken when required and a virtuous cycle of consultative learning encouraged.

If it is effectively and persuasively presented, HFA can have a substantial operational appeal. It can be a catalyst for increased collaboration between the health service and other organizations and groups, including the media. The valuable role that can be played by voluntary organizations and

individual volunteers is sometimes overlooked. Such collaboration also implies joint information efforts for planning and monitoring purposes. Of course, different emphases may be effective with different groups. For example, some politicians may become more interested if the emphasis is on cross-national comparisons, particularly if these are given prominence by the mass media, while others may be persuaded by a bandwagon effect. Some interest groups may be persuaded by information about how their counterparts are being involved in other Member States and the desirable results that are being achieved. Sometimes a clear exposition of the available information may, of itself, begin to shape the tasks and persuade the responsible agencies, which means distilling evidence from all relevant fields to strengthen the empirical support for proposals. The arguments can be geared to reasoning with interest groups, but without resulting in contradictions between the statements which are made to different groups.

Against this background the role of (local) health sector policy-makers and planners has several aspects. Three are emphasized here. The first relates to the analysis of local circumstances, highlighting those concerns which are of interest to the local population, and persuading other levels of government or agencies (in both the public and private sectors) whose involvement or cooperation is required. The second aspect relates to spreading enthusiasm to other agencies, educating others (including health care professionals) by whatever means seem appropriate, lobbying for HFA concepts to be introduced into training programmes and using collaborative health systems research to enhance the credibility of HFA thinking. The third aspect relates to the use of even small successes to demonstrate the relevance of HFA. Prompt dissemination results in sharing successes and failures with others and facilitates learning, remedial action (where necessary) and improved health outcomes.

There is no one method for these tasks. Each "entry point" must be tailored to the circumstances. The political, administrative and cultural framework is the determining factor. HFA must be demonstrated as being relevant to real concerns. Certain responsibilities, however, remain constant.

- The distinction between policy (the content of a desired and intended action or set of actions) and politics (the process of debate and negotiation by which decisions on proposed actions are reached and implemented) must be clarified and maintained.
- The focus of interest for which a policy is to be prepared (e.g. the intended beneficiary population or the intention of any proposed action or intervention) must be clarified and a framework for analysis of the policy constraints and for judging what is politically and administratively feasible (as well as desirable) must be developed.
- Different approaches to priority determination must be recognized and the appropriate approach to apply in particular circumstances selected. A distinction is made between five types of criteria. The first involves **health** criteria, such as the reduction of mortality and disability using the most effective available technology. The second involves **ethical** criteria, such as minimizing preventable mortality, morbidity and disability, for example where an effective technology is available (within or outside the health sector) but is not yet in use. There are also **resource** criteria, such as cost or staffing implications; **political** criteria, such as pressure on decision-makers to act; and **social** criteria, such as the importance of an issue in the community (e.g. substance abuse). The chosen criteria generate, as a prelude to the selection of a strategy, a set of questions concerning what action is to be taken, by whom, where and in order to achieve what objectives.

The overall purpose of the political management of public health is to identify the innovations to be adopted, and then to secure the commitment of all those interests whose involvement is necessary to achieve them. This means trying to build up a shared view of the desired future, a shared ideology, and to identify mutual benefit wherever possible. This requires organization – structures, processes

and procedures for consultation and negotiation, for networking with and between various participating interests, and for building coalitions of critical support to initiate strategies, implement action on projects and sustain the resulting programmes.

Taking effective action requires the identification of all the required resources and where they are available. These resources might include money, human resources (both paid staff and volunteers), materials and buildings, and also less tangible factors such as enthusiasm and access to information. Judgements have to be made about how best to harness and use these resources, including how to combine them. The analysis, building of support and development of strategy must be followed by implementation through coordinated action in the appropriate practical steps. At this critical stage the realities need to be looked at very closely, including the strength of the evidence for the HFA proposals being pursued. How far will they convince those who oppose or doubt the proposal? Will the countervailing forces engineer a compromise solution? If so, is it better to push on, modify the current proposal or delay it for a more propitious occasion?

Successful actions have outputs. These could take various forms. For example, there may be **political** outputs, involving elements such as evidence of broad participation in debate and decision-making, of constructive conflict of ideas, or of political and other mechanisms to release people's creativity. Secondly, there could be **activity** outputs, such as an increase in activity for an unchanged level of resource input or a sustained level of activity for a reduced level of resource inputs. Thirdly, there could be **health** outputs or outcomes, such as measurable or observable improvements in health status or reductions in health inequity. These outputs need to be monitored, where necessary sustained and if possible increased.

The essentials for the successful political management of public health can be seen clearly: the shared view, the political will to cooperate, the support of participating interests, appropriate mechanisms and structures for identifying and implementing options, and a climate of creativity. While it may not be easy, while it may take time, it can be done. However, it often is not done; and the task tends to be more difficult in a declining economy than in an expanding one.

Exercise 3

What do you consider to be the key factors for success in handling the political management of public health? Consider this issue:

(i) in relation to a specific recent health policy or practice (or proposal), preferably one which is substantial in its implications and controversial; and

(ii) in terms of who gains and who loses from the change – would the political management of the public health issue have benefited from a different distribution of the gains and losses between the various participants?

Would the key factors and how they could best be handled be similar in a declining economy compared to a growing one? If not, how would they differ?

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4.2.3 Health administration and management

Chris Selby Smith and John Wyn Owen[6]

Key messages

- Health management matters and it can make a difference. Managers in health care contribute to the provision of health care and the achievement of health gain, i.e. adding years to life and quality life to years.
- Managing for health involves deciding what needs to be done and ensuring that it gets done, through people.
- Managers are concerned with both processes and outcomes, where outcomes include quantity and quality.
- Good managers provide a support service, which enables resources to be brought together in an efficient, effective, economic and equitable manner. The result is enhanced achievement of the health objectives of their organizations.
- People are a particularly important resource in health care; over time, good management enhances the capacity of people, whether providers or users, to contribute to achieving outcomes and to making informed choices.
- Outstanding managers are characterized by their ways of thinking, presenting and behaving. They are aware of the importance of risk management, and they enable value to be added throughout the organization.

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Tutors' notes

This module has been written as a guide for those in various managerial positions. It will also be of interest to those in policy development and advisers, as it provides insight into key aspects of successfully implementing change and more effectively managing resources. The module should enable the tutor to promote the importance of clear vision and values, learning from experience, encouraging practitioners to be responsive and influential towards internal and external changes, involving staff in decision-making and encouraging a culture of continuous improvement and development.

Although the module is, at first sight, most relevant to managers and health professionals among the four main groups of potential users of these learning materials, particularly in relation to *analysis*, it is useful for all four groups of users in terms of *appreciation* and *appraisal*. It is highly relevant for very senior political and bureaucratic decision-makers and the members of various concerned public groups, not least because of the influence they have, directly and indirectly, on the environments in which managers operate and the incentives (and sanctions) which apply to them. In addition it may be helpful to them in terms of analysis of their own working styles and approaches, their strengths and weaknesses, and the implications both in health and health care and in the many other arenas in which they may be operating (e.g. politicians, senior bureaucrats in non-health agencies, journalists, trade union officials, and prominent citizens who contribute to nongovernmental, religious, charitable and voluntary organizations as well as sit on a hospital board).

The three exercises are designed to highlight some important aspects of the module. Exercise 1 focuses on the key factors in the internal and external environments in which managers operate, how managers react to them and how they can influence them in the immediate situation and over the longer term. Exercise 2 focuses on the respective responsibilities and areas of authority and accountability of managers in particular situations; how they do (or could) relate to each other; and the consequences (for processes and outcomes) which arise when the three elements are not closely related. Exercise 3 focuses on the objectives of managerial action at both the macro and the micro levels, how they can be achieved (including the determination of priorities), and how managerial achievements can be measured.

The exercises can be used in various ways. For example, they could be used in a written presentation, in oral discussion or debate. Role-play could be useful for some audiences. Specific or hypothetical examples could be used.

The managerial environment

All managers are affected by the environment in which they work, and health care managers are no exception. Thus, legislators, policy-makers, planners (and wider political, economic and social factors) influence the incentives, both positive and negative, which managers face in performing their functions. The environmental factors can be divided into those within the organization, termed internal environment factors, and those operating from outside the organization, termed external environment factors. Examples of internal factors include the local workers, such as doctors, nurses, other professionals and ancillary or support staff; organizational processes, such as working arrangements or internal budgeting processes; and established practices and expectations. Examples of external factors for an individual health care institution include the national ministry of health or regional health authority, the organized medical profession, the general community, suppliers and trade unions. All the

environmental factors can be relevant, in greater or lesser degree, to the decisions made by health care managers. In some cases they constrain managerial action; in others they can provide opportunities.

The environment in which health care managers operate has some special features. For example, outcomes can be difficult to quantify and aggregate, in contrast to the clearer bottom line of many private sector organizations. This is partly because in most European countries public provision is important. When nongovernmental provision occurs it is often non-profit, religious or charitable in orientation rather than privately-owned and profit-focused, and the providers have particular relationships of trust and responsibility to patients. In many cases users of health care services are vulnerable groups or individuals, who are often particularly vulnerable when interacting with the health care system (e.g. they are sick, homeless, stressed or relatively ill informed compared to providers).

Health care managers operate in an environment with significant:

- political elements, for example media interest in low birth weight infants
- bureaucratic elements, such as high levels of public funding and provision
- professional elements, which are especially significant among doctors, and
- community elements, such as local relationships and expectations.

Since the health sector is large and varied there are significant differences in the managerial environments facing particular health care managers, for example, the public or private sectors, or managers of care for the elderly compared to those in university hospitals or general practice. In general, the health care sector tends to be a demanding environment for managers.

Furthermore, in many European countries significant changes are taking place in the environment within which health care managers are operating. These changes vary between jurisdictions, as does the speed with which they are occurring. Examples include:

- the relative weight attaching to the preferences of the users of health services compared to the preferences of providers;
- the balance between public and private provision (and financing) of health care;
- the balance between prevention, cure, rehabilitation and care;
- the relative priority attaching to quality and quantity;
- increasing recognition of the importance of intersectoral aspects of managing for health;
- the extent to which managerial decision-making is devolved, democratized and influenced by evidence.

Exercise 1

Identify the key environmental factors affecting your managerial decisions. Distinguish between the internal and external environmental factors. To what extent are you able to influence them: in the short run and in the longer term?

The levels and stages of managerial decision-making

Managing for health requires decision-making at various levels. First, at the level of national policy-making, managers seek to establish appropriate parameters for decision-making by practitioners to manage intersectoral relations and to obtain sufficient resources. In federal systems the relationships

between national and regional or provincial authorities are important; in unitary states these relationships occur but may be less visible. Political and bureaucratic considerations are both involved, since policy and politics are not separate from management and administration, but interrelated with them. Policy-making can have distinct stages: identification of problems and setting an agenda; formulation of a policy; adoption of the policy; implementation of the policy; monitoring of the budget and policy evaluation. In practice, these stages are often less separate and linear, e.g. implementation problems may result in a change of policy.

Secondly, there is managerial decision-making at the level of individual health care institutions, such as a university teaching hospital, a nursing home chain or a private health care organization. Managerial decision-making at this level can have parallels with management in other organizations, taking account of the specific features of the health care environment. The culture of health care managers at this level tends to differ significantly from the culture of the civil service. In decentralized health care systems or where command and control systems permit some local discretion, managers typically are required to develop and implement appropriate policies rather than merely adopt central directives. Managerial decision-making involves consideration of both top-down and bottom-up approaches.

Thirdly, there is professional decision-making, such as that by doctors, nurses, pharmacists, dentists, therapists or other health care professionals. The relationship between providers and patients in health care implies that decisions made by both users and providers affect health care processes and outcomes.

In Module 4.2.1. on policy analysis, bargaining and negotiation, John Lavis identified three levels of health policy which he termed the clinical, administrative and legislative levels. Managerial decision-making as discussed here refers primarily to decision-making at the administrative level, and at the clinical level when health care providers are making administrative decisions.

The health care manager is frequently faced with developing decisions and initiating action which take account of various disciplinary approaches. The accountant's view may not correspond with that of the economist, the medical practitioner's with that of the ethicist. The perspective of the professional provider may not equate to those of either the funder or the patient. The manager is charged with reaching a fair and reasonable decision, taking account of relevant factors and perspectives, and acting accordingly. Managers are not only charged with making decisions themselves, but with creating climates and providing incentives which encourage appropriate decision-making by others, primarily in their own organizations but also in the wider health care system.

Responsibility, authority and accountability are not always closely related to each other for an individual manager. Where this is the case the three elements should be brought into a closer relationship with each other. No one should be able to avoid blame for those matters for which they are in fact responsible: for example, where a surgeon who takes inadequate care kills a patient who would have recovered to live a satisfactory life if they had been treated competently. On the other hand, no one should be required to accept blame for matters which are beyond their control.

Exercise 2

In your managerial environment:

1. Are responsibilities (what you are expected to do), authority (what you have the power to do) and accountability (what you are expected to have done) closely related or not?

2. If responsibility, authority and accountability are not closely related for individual managers in your environment:
   (i) To what extent does this result from factors internal or external to the organization?
   (ii) What consequences are there for health care processes and outcomes?
   (iii) In what ways could responsibility, authority and accountability be brought into a closer relationship with each other?

Objectives

Managers take decisions to achieve results. It is crucial that the objectives to be achieved are clearly defined, however difficult they may be to achieve completely and irrespective of whether tactical adjustments are required from time to time. Countries vary in the balance of objectives they seek to achieve. For example, the United States is more tolerant of inequality in health care outcomes than the United Kingdom, while private provision is more highly regarded in some European countries than in others where social solidarity has greater societal acceptance. Managers who are taking decisions at the level of individual health care institutions also vary in their balance of objectives: for example, prevention through screening, cure through surgery or care through long-term community support of patients and their families. But managers always need to be clear about the objectives they are seeking, otherwise there is no chance of achieving them. It needs to be recognized, of course, that health outcomes are derived from more than solely the health care sector or the administrative responsibilities of the health ministry. They can be significantly affected by factors such as improved road engineering, seat belt legislation or random breath-testing of drivers for alcohol; or whether a person is in employment, and average levels of income and their distribution; or housing and superannuation.

Each health service and manager can benefit from thinking carefully about what they are trying to achieve and the alternatives available for doing so. A quality health service has three hallmarks. First, a commitment to health gain, whereby years are added to life and quality life is added to years. Second, there is a commitment to people and a conscious attempt to provide people-centred services. This applies both to those who work in the health sector and to those for whom the services are provided. Third, there is a commitment to the effective use of resources, including financial resources, human resources and the intellectual resources of the health workforce. The four "E's" of efficiency, effectiveness, economy and equity provide a guide for managers to think about their objectives in the immediate future and in the longer term. The objectives of health care managers include both outcomes and processes, such as the dignity and respect with which patients and their families are treated. However, it is difficult to measure the extent to which such changes occur, and the extent to which managerial decision-making contributes to them.

While economists are accustomed to thinking of maximizing outcomes, subject to given constraints, managers often find that their task is to give satisfaction. They bargain, negotiate and compromise where it is unavoidable. At worst, decision-making is delayed, tough decisions are avoided and responsibilities are blurred. At best, managers achieve the most beneficial result they can at the time, often in a number of different dimensions simultaneously. They adjust when they have to the realities of the moment, but are ready to achieve further gains when the opportunity arises in the future. The process is continuous, so that what is gained today can be lost tomorrow. There can be difficulty in satisfactorily conceptualizing the objectives of the organization compared to the varying objectives of groups and individuals within it: for example, see Lindblom on "still muddling, not yet

through" *(1)*. An important managerial objective is to create conditions where one set of improvements facilitates others in a cumulative process. Systems can be significant, but people, incentives and motivations tend to be particularly important.

Combining resources

Few health outputs can be achieved through the use of one input alone. In the typical situation a variety of resources have to be combined, organized or managed. For example, a medical practitioner, a secretary/receptionist, facilities, equipment and information may be combined to produce a general practitioner service; while a range of medical specialties, such as surgery, anaesthetics and diagnostic services, plus nursing and administrative staff, a specialized theatre, equipment, consumables and information contribute to the carrying out of a successful surgical operation. Managers at all levels of decision-making combine and organize resources to ensure that efficiency, economy, effectiveness and equity are achieved. Sometimes managers are able to use the resources of others to achieve their own purposes: Keeling calls this diplomacy *(2)*. This applies to health care outcomes and the processes by which they are attained. Managers are responsible for organizing the production function of health care, i.e. the processes by which inputs produce valued outputs.

Management in the health care sector can involve the combination and organization of a wide range of resources.

- In terms of expenditure, labour tends to be the largest single input: two thirds to three quarters of total health care expenditure in many advanced countries. Indeed, this may be an underestimate, given the substantial contribution often provided by contributed service (from family members, religious orders and voluntary or charitable contributions). Labour is critical for the processes of health care as well as its outcomes. The labour inputs are very varied. They can include doctors, nurses and other health professionals; administrative, clerical and support services, such as engineering and maintenance, catering, cleaning and security services; and paraprofessional services, such as those provided by ambulance workers, paramedics and laboratory technicians.
- Other important resources include finance, information and the technology of health care. Managers also need to be aware of the legal framework and the administrative structures within which they operate, because these both constrain action and provide opportunities.
- Since the relevant relationships are dynamic, health care managers need an openness to developing perspectives and new knowledge as well as basic skills, training and experience in management. Theory, practice and their integration are all important, while continuing learning is essential in a field of practice characterized by rapid change.

Those who are managing for health primarily work through people. In the short term they need to be aware of what resources are available and how best to use them to achieve objectives. But in the longer term good managers seek to expand the resources that are available through demonstrating achievement, investing in institutional and infrastructure resources, and arguing strongly in the fora where resource allocation is determined.

Investments can involve additional or improved resources, such as labour, buildings, equipment or information, from which an enhanced flow of services can be derived. It may also be possible for managers to get more outputs from existing resources, including through:

- an organizational culture that encourages learning and increased productivity;

- incentives that link personal rewards and recognition to their contribution to organizational goals; and
- transparent decision-making which more closely relates responsibility, authority and accountability.

It is surprising how much, even in large organizations, the personal qualities, vision and drive of senior managers can influence the health care outcomes that are achieved; and how competent and motivated teams in well managed environments can achieve results that are beyond even the ablest and most dedicated individuals.

Managers at all levels of decision-making also have a responsibility to acknowledge limits. Workers have lives beyond work, and sometimes the human resources are inadequate to achieve the desired results, however competent, committed and well managed they are. It is a managerial responsibility to ensure that health workers are not held accountable for failing to achieve impossible targets, while ensuring that resources are so managed that the absolute maximum of health care outcomes which are possible are achieved.

Many OECD[7] countries are examining the financing and organization of their health care systems. Wales is presented here as a case study where significant progress was made within a strategic framework aimed to raise the level of health of the population to among the best in Europe. This strategic framework focused on health gain, people, and a resource-effective health service informed by a focused research and development framework.

Case study: experience from Wales

Aligning health agendas and improving the operational performance of health systems is an increasing priority in a number of countries. There are at present limited examples which can serve as case studies of integrating public health and health services management, but the Strategic Intent and Direction in Wales was "a pioneering response to the WHO Strategy for Health for All by 2000 and therefore lacked models to follow …" *(3)*. The National Audit Office report considered "The initiative had had a more substantial effect on the way in which the NHS in Wales plans service developments." *(3)*

Reforms to the British health system in the 1990s fundamentally changed the management and organizational landscape. Although the guiding principles for the National Health Service (NHS) are common to all parts of the United Kingdom, considerable autonomy is given to the Service in England, Scotland, Wales and Northern Ireland. Recent changes in the United Kingdom constitution establishing a Scottish Parliament and Assemblies in Wales and Northern Ireland have consolidated this trend – politicizing what was previously administrative space *(4)*. Wales developed a health strategy of its own, as did Scotland and Northern Ireland. The Strategic Intent has proved to be robust and, although it was introduced by the Conservative administration, was re-emphasized as a policy by the following Labour administration in Wales *(5)*.

Although they differed in detail, the strategies adopted by England, Scotland, Wales and Northern Ireland had important similarities. First, they emphasized the need to tackle the major public health challenges, including cardiovascular diseases and the cancers, as well as give a higher priority to health promotion and sickness prevention. They all highlighted the need for intersectoral action and the development of healthy alliances, including with key players in both the private and public sectors,

[7] Organisation for Economic Co-operation and Development.

whether in education, industry, transport, the environment or housing. Partnership with higher education was seen as one of the main agents for change and prosperity. Intersectoral collaboration was facilitated by the Welsh Office, of which NHS Wales is part – a one-stop-shop in government policy. The portfolio ranges from agriculture, industry and employment, through roads and transport, housing and the environment, education and the arts as well as health and personal social services. It was tailor-made for promoting the broader health agenda. Second, the four strategies reflected the conviction that citizens should be placed at centre stage in health planning and service delivery. Finally, there was a determination to secure better value for money from the substantial resources invested in health care systems. This was particularly important in Wales, which, with a population of some 3 million and about 70 000 people engaged in the health service, has the second lowest GDP per head in the United Kingdom.

Three aspects of the Welsh experience are emphasized. Firstly, a striking feature of the Welsh approach was its emphasis on looking for best practice wherever that might be found, and learning lessons for the development and implementation of policy. For example, Wales is one of the so-called "motor" regions of Europe, where the motor industry represents a key part of the economy, and Wales was a founder member of the WHO Regions for Health network. The Welsh strategy also sought to learn systematically from its experiences about how to improve future performance.

Secondly, the Welsh approach incorporated a strategic management approach. This meant being clear about who did what, by when, and then evaluating performance remorselessly. There are four key factors to the success of this approach: defining the purpose of the service; sharing the vision and securing ownership; translating policy into effective management and clinical action; and monitoring progress carefully. The Welsh vision was for the NHS, working in partnership, to take the people of Wales into the twenty-first century with a level of health on course to compare with the best in Europe. The idea was introduced, a novel one at the time, that improving health is one of the goals a health care system should strive for.

This initiative covered ten areas where health could be improved (recently updated), which together accounted for 80% of total health service expenditure in Wales. Three strands ran through each of the ten health gain areas:

- health gain, focusing on improving health by shifting resources to make treatment effective;
- making services more responsive to people's needs and preferences by considering the total effect of services on people's lives rather than the narrower clinical perspective; and
- effective use of resources by providing an appropriate balance between prevention, promotion, diagnosis, assessment, treatment, care and rehabilitation.

Thirdly, although the Welsh Office had a key role to play in offering leadership, the real action took place locally. These were the health plans which proposed specific management actions to achieve the milestones set in the local strategies. Frameworks were to be developed in collaboration with managers, professionals and staff across the system. Pursuing a leadership role while at the same time promoting further devolution of responsibility proved to be a difficult balance to strike. The Welsh strategy recognized the need to engage more fully than in the past the people involved in the management and delivery of services in setting and achieving Welsh health goals. It proved to be essential that local plans for health were understood and accepted by those involved, if they were to be effectively delivered and health gains achieved. The Welsh approach was not without its difficulties *(6)*. There were overspending and problems with the financing of health services in some counties. Progress was slow

in implementing the Hine Report for cancer services *(7)*. There were tensions between policy and management in the Welsh Office, cultural differences between the civil service and the NHS, and differences as to how best to treat mental illness – whether to consider it a social care issue or a health matter. But overall it was a period of development and a way of taking public health and the health services forward. This was a period when the concept of health gain became the currency of the World Bank, and the model not only influenced developments in Australia and New Zealand but also served as a case study which informed in due course the development of the Ljubljana Charter *(8)*.

Exercise 3

(a) Identify what objectives the health care manager is trying to achieve, at the macro level, and what strategies might assist in achieving them.

(b) At the micro level, what factors would you consider:

· in determining managerial actions to achieve a specific objective; and

· in determining priorities between alternative health care outcomes?

(c) How would you know if you had achieved your objectives?

Ways of thinking

Outstanding managers, at all levels of decision-making, are characterized by their ways of thinking, presenting problems and behaving. Firstly, while they are aware of the complexities of the managerial environment they are not paralysed by analysis. They are oriented to action and to taking the best decisions possible in the prevailing circumstances. They are clear about their objectives but willing to be flexible about how to achieve them. As circumstances alter their tactics may change too. While they take decisions in the present, their orientation is to the achievement of medium- or longer-term objectives. They recognize that their major effect on outcomes is likely to be mediated through other people; and they seek to create the conditions in which others are able and willing to give of their best. They appreciate that producing health care outcomes is a complex business; that many individuals, disciplines, occupations and perspectives can contribute something; and that the manager is the conductor who enables the orchestra to deliver on its full potential.

Secondly, the manager's role necessarily involves balancing a range of risks; deciding on the course of action that appears to be most appropriate in the light of the available information; and ensuring that it is pursued in a businesslike fashion. Thus, presenting alternatives, encouraging others (and when necessary disciplining them) and sustaining action once decisions have been taken are all essential elements of the managerial role. For effective outcomes to be achieved, the manager needs the support of the contributing resources, just as they need the manager's support if they are to contribute fully. Furthermore, all managers make mistakes. Some decisions prove to be incorrect, while other decisions are not taken that should have been. This is inevitable. The only manager who never makes a mistake is the one who never takes a decision, so that risk management is inherent in the role. It is often argued that the managerial role has become more difficult as a result of, for example, increasing change, declining direct authority and multiple accountabilities. What some see as a problem others perceive as an opportunity.

Thirdly, the managerial role is demonstrated in practice. How the manager acts tends to be more powerful than what the manager says. Much of the manager's influence occurs through creating the

climate, in leadership rather than mere administration. A manager who is not apparently open to new ideas or alternative suggestions for improving health care outcomes is not likely to elicit the full contribution potentially available from colleagues. Improving health care processes and outcomes often rests on an open and collaborative search, a willingness to consider new evidence or alternative approaches. For example, a managerial orientation towards providers rather than patients is likely to be reflected quickly in organizational operations and priorities. Managers need to be aware of the dynamic elements of their task and of the intersectoral contributions to health outcomes, and that they have responsibilities to the wider health care system and society as well as to their own institutions. As WHO has argued, "It is very clear that health does not arise from actions pursued solely by the health sector: rather it is a manifestation of all public policies and how they individually or in interaction with each other, promote or damage health" *(9)*. While networking can develop two-way flows of information, skills and attitudes which improve decision-making, it is increasingly being recognized how much knowledge is already tacit and embodied in individuals.

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4.3 Updating inputs

4.3.1 Development and diffusion of health technology

Michael F Drummond and Björn Lindgren, with contributions from Eva Bondar[8]

Key messages

- Technologies for health are the mechanisms through which scarce resources are combined to produce health improvements for the individual and for the population.
- Health technologies are not confined to the clinical patient care sector but comprise all health promotion, disease prevention, diagnosis, treatment, rehabilitation and care activities.
- New health technologies are developed through publicly funded research at universities and research institutes. There is also privately funded research and development (R&D), for instance, in the pharmaceutical industry.
- New health technologies are not developed haphazardly but they are induced by the incentives for developing specific kinds of technology created by government regulation and the financial incentives of the market.
- Considerable inefficiencies can occur in how technologies are produced (through R&D) and the ways in which they are used, for example on inappropriate patients, in the wrong settings or by untrained professionals.
- New health technologies are diffused gradually, and adoption generally follows an S-shape pattern.
- Different factors either inhibit or encourage the development and diffusion of health technologies. These include the payment mechanisms for health professionals and institutions.
- Both direct regulation and financial incentives can be used to encourage a more rational diffusion and use of health technologies. Regulation can be linked with economic evaluation.
- A number of factors influence the cost–effectiveness of a health technology in a given setting.
- Economic models can be used to help decision-makers interpret evidence on a given technology for their own setting.

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Tutors' notes

A wide range of groups within the health system would benefit from understanding more about the development and diffusion of health technology.

This module may be of particular interest to those involved in designing direct regulation and financial incentives to encourage a more rational diffusion and use of health technologies, including:

- health (and health care) policy-makers
- pharmaceutical industry policy-makers
- civil servants and other governmental technical staff
- public health officers
- health service managers.

The module contains boxes illustrating the issues presented in the text, several questions for discussion within a country-specific context and an exercise designed to help health care decision-makers wishing to interpret data on the cost–effectiveness of health technologies for their own setting. The exercise builds on material given in Module 5.3.1 (on economic evaluation) and Module 5.4.1 (on modelling).

Introduction

Health improvement is the primary objective of the health sector *(1)*. Technologies for health are the mechanisms through which scarce resources are combined to produce improvements in health. Health technologies are not confined to the clinical patient care sector but comprise all health promotion, disease prevention, diagnosis, treatment, rehabilitation and care activities. For example, a surgeon's time and skills are combined with those of anaesthetists, nurses and operating assistants, plus operating theatre equipment, in order to produce an appendectomy, which under certain circumstances may be a necessary procedure to maintain health; or physical exercise, low-fat food and abstinence from smoking can reduce the risk of developing coronary heart disease and stroke and may, hence, extend life expectancy and quality.

In the short run, existing health technologies determine the maximum possible contribution to population health, given the available resources spent on health. There is ample evidence of inefficiency, however. Inefficiency mean that this potential is not fully realized – resources are wasted and the quality of the health sector is too poor in terms of health improvements achieved. The health of the population could be increased in the short run by increasing the efficiency of the health sector (Module 3.2.2). In the long run, more resources spent on health may yield (marginal) contributions to people's health. There are obvious limits, however, to that approach. Sooner or later, improvements in health will diminish when further resources are added. The only way to increase substantially the possibilities for a long and healthy life is through new knowledge about how scarce resources can be combined in order to produce improvements in health, i.e. through the development and diffusion of new health technologies.

Quality development in the health sector in terms of improving the health of the population can be achieved by reducing inefficiencies in the use of existing health technologies, by increasing resources spent on health, and by developing new health technologies *(1)*. Given the critical role played by health technologies in producing population health, it is important that health policy-makers, managers and professionals understand their development and diffusion. Otherwise, there can be considerable

inefficiency in how new technologies are produced, through research and development, and the ways in which they are used. This module deals with the following two linked themes:

(i) *The economics of research and development*
Research and development are essential features of the development of new health technologies. What are their potential inefficiencies? What influences do different approaches to the reimbursement and pricing for health technologies have on R&D? How can those undertaking R&D be given incentives to improve efficiency? How should priorities for R&D be set?

(ii) *The economics of transfer and diffusion*
New health technologies are diffused at different rates in countries. They are adapted and changed, and are spread to other settings and to other groups of patients. What factors encourage the use of particular technologies? What factors inhibit the use of particular technologies? How do health technologies spread from one setting or application to another? What is the influence of different payment systems on health professionals and institutions such as hospitals? How can key actors in health care systems be given incentives to use health technology appropriately? How can decision-makers adapt or interpret economic evidence on a given technology for their own settings? What is the role of economic evidence in designing regulation? (This last issue is explored in Module 5.3.1 on Economic evaluation.)

The economics of research and development (R&D)

Health technologies comprise all health promotion, disease prevention, diagnosis, treatment, rehabilitation and care activities which may contribute to the health of the population. New knowledge about how health can be promoted through changing individual behaviour may be at least as important as new procedures in clinical patient care in the development of quality in the health sector. In clinical patient care, technologies are not confined to conspicuous items such as electromagnetic resonance technology or other expensive equipment but include "all drugs, devices, procedures, and systems of organization" *(2)*. Some technologies are to a large extent embodied in physical items such as drugs and devices, whereas other technologies, such as systems of organization or surgical procedures, represent knowledge only available in people's brains and skills.

Since the end of the Second World War there has been a rapid change in the technologies available for health. Almost all diagnostic and treatment methods that are used in clinical patient care today were unknown 50, or even 40, years ago. Among prescription drugs, for instance, about 10% of the 200 largest-selling drugs are new each year; and only 25% of the 200 top-selling drugs remain in that group 15 years later. The revolution in the processing of information through the development of new computer hardware and software facilities has included health care. New ways of organizing health care have been introduced in recent years. In addition, there is substantial new knowledge about the effects of healthy lifestyles and about how to modify environments so that people will make healthier choices.

New health technologies are developed through publicly-funded research at universities and research institutes. There is also privately-funded R&D, for instance in the pharmaceutical industry, which produce new health technologies. The incentives may differ between private- and publicly-funded organizations regarding the extent and direction of research and development of new health technologies, but for all agents involved in the development of new health technologies the expected utilization of the new technology is vital. For a private, commercial pharmaceutical company, this is self-evident, but research fellows at universities may also want to see their scientific discoveries

developed and used in practice. Few people are interested in developing technologies that no one will use.

Thus, new technologies are not developed haphazardly but are induced by the incentives that are available to develop specific kinds of technology. The expected return determines the development. Returns may be both pecuniary and, for people such as university researchers, non-pecuniary (fame, high positions, etc.).

Thus, some major characteristics are the same for the research and development of all health technologies, even though there may also be differences. The economics of R&D in the pharmaceutical industry are fairly well documented. Furthermore, the pharmaceutical industry works in a market environment in which the behaviour of both firms and the industry as a whole is governed by financial incentives – the prospect of market revenue to cover the costs of developing the drug, in addition to the costs of producing it. Therefore, we will use pharmaceutical R&D as an example to explore the characteristics of the R&D process and to discuss the factors determining the extent and direction of R&S of new health technologies. The role of academic research is emphasized in Box 1.

Box 1. The role of academic research

Academic research plays an essential role in the development of new health technologies. Publicly- or privately-funded university research is often a prerequisite for applied R&D in, for instance, pharmaceutical companies. So, to a large extent, basic research at universities and applied R&D in pharmaceuticals are complementary. It has been shown, however, that there is also some substitution: when basic academic research in a specific area of therapeutics is increased, there is increased private investment both in the same category of R&D and even more in other categories.

Since incentives differ, the financial incentives being decisive in private business, the direction of research is also different. The resources allocated to research into the less prevalent and more severe diseases tend to be greater from public funds than from private industry. This kind of research, however, may not lead to applied R&D, because the financial incentives for industry do not exist (see, for instance, the example discussed in Box 2).

Universities (and university hospitals associated with medical education and research) also play an important role for the location and success of private industry. Most production of new scientific knowledge is concentrated in a few regions within a few countries. If knowledge only flowed through published papers, geographic location would be unimportant. The importance of informal personal contacts appears, however, to be crucial. Thus, universities and academic research not only provide industry with highly qualified labour but also with R&D externalities in the form of symposia, conferences, seminars and education.

Sources: Jaffe *(3),* Ward & Dranove *(4)*.

R&D of pharmaceuticals

The development of a new pharmaceutical product takes time and money. After a potential market has been identified, the pharmaceutical company is involved in the search for new chemical substances. Often thousands of substances are tested before one single substance proves to be potentially useful; this substance is then further improved and superior substances produced as candidate drugs. Various pharmacological tests (e.g. regarding the toxicity of the substances) are carried out using both animals and non-animal cell models.

When the substance fulfils certain criteria, tests are carried out on human volunteers. This does not start, however, until the company has filed an application to the appropriate regulatory body (in the United States this is the Food and Drug Administration, FDA) and received approval for doing clinical tests. The time from application to approval may take 5–9 years. Clinical studies start with rather small, randomized control trials including only healthy individuals (say 50–100). When the relations between dosage, effects and tolerance have been analysed, large-scale trials on say, 500–5000 patients are performed. Different dosages are compared with placebo and conventional therapy. The evidence on efficacy and adverse reactions, interaction with other drugs, etc., including during long-term treatment, is documented.

Once the safety and efficacy of a drug have been established, an application is filed with the appropriate regulatory body in order to register the new pharmaceutical product. After approval, a process which may take 1–3 years, the company can finally market its new pharmaceutical product. According to estimates, it takes on average 12 years and US $360 million to discover and develop a new pharmaceutical product before it is introduced on to the market. This is essentially the cost of producing new knowledge about how scarce health care resources can be used. If competitors were able to use this new knowledge without paying in order to produce their own pills, these "free riders" could easily set prices on their products far below what would be necessary for the inventing company in order to recoup its R&D costs. Obviously, there would be too little R&D in private pharmaceutical companies if the market was not regulated. The main measure used here by governments is guaranteeing a temporary monopoly through patent legislation. (Patents actually have a rather long history: the first patent law seems to have been adopted by the Republic of Venice as early as in 1474.) The inventor's property rights on pharmaceutical products, processes and uses are protected for 20 years under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights. There does not (yet) exist a Europe-wide patent, but after a single application the patentee receives a bundle of national patents. The patent-holder can either make sole use of the discovery or license others to use the invention at an agreed royalty rate.

In order to protect its commercial interests from competitors, a pharmaceutical company normally applies for patents as early as possible during the development process. This means that a new pharmaceutical product will have less than 20 years (maybe only 10 years) left of patent protection when it finally reaches the market. The expected revenue during the remaining period of the patent time is vital for the company's decisions to develop and market the new pharmaceutical product. Society uses patents as an incentive to the inventor to develop appropriate technology *and* to make it available and accessible at reasonable cost.

The impact of regulation

Expected revenue depends both on expected prices and expected volumes sold in the pharmaceutical market, both of which are influenced by government regulation. Prices are more or less regulated in all European countries, especially if pharmaceuticals are to be reimbursed by (social) insurance. Reimbursement may also be a prerequisite for large volumes; estimated price elasticities are very low for prescribed drugs, for which patients only pay a minor share. Volumes are also affected by the size of the target group of patients and the medical decision behaviour of physicians. The size of the target group of patients can be influenced by decisions taken by regulatory bodies. Commercial marketing as well as recommendations by therapeutic drug committees may influence physicians' behaviour. The way physicians prescribe drugs may also be affected by direct financial incentives, created by how doctors are paid under the system.

Thus, there are several ways for governments to affect the behaviour of pharmaceutical companies by influencing either the cost of developing new drugs or the expected revenue when the new drug has entered the market. The regulation of the pharmaceutical market in particular and health care systems in general creates the environment in which a company makes strategic decisions. For instance, in some countries, governments require or request economic evaluations to show "reasonable" cost–effectiveness or cost–utility ratios for a new drug to be reimbursed. If the cost (price) of the new drug is too high in relation to its effects in terms of health consequences, then it will not be reimbursed. Thus pharmaceutical companies have an incentive to make their own economic evaluations of potential new drugs as early as possible in the R&D process. It would be of no use to a company to develop a new wonder drug if it could not recoup its R&D costs.

However, from the start there is great uncertainty over the characteristics of a product, and hence over future returns. Nevertheless, a company may still want to make at least rough calculations of the potential cost–effectiveness of its new drug as part of deciding whether or not to continue the process. At several other points, the company will make decisions whether to continue, contract or expand. Even though such decisions naturally depend on potential therapeutic benefits, and the expected frequency and severity of adverse reactions, they also depend on estimated future revenues and hence on the estimated results of economic evaluations. As more information is produced during the development process, the economic evaluations become more and more reliable as a tool for decision-making within the company.

Can an optimal level and direction of R&D in health technologies be achieved?

Obviously, the development of health technologies is influenced by government regulation. Thus, at least in principle, regulators would be able to create incentives for innovators to develop an optimal level and direction of R&D in health technologies in a societal perspective. Since R&D in health technologies takes time and money, it is an investment with expected benefits in the future after many years of costs only. The resources used for R&D in health technologies could be used for immediate purposes or for other kinds of investment. The optimal level and direction of R&D in health technologies from a societal point of view is achieved when there is no better way of using scarce resources, taking into account both present and future demands of a population.

In principle, no new health technology for which the willingness to pay is not great enough should be developed. By the same token, all new health technologies for which the willingness to pay is great enough should be developed. Willingness to pay represents other present and future consumption opportunities foregone by using resources for R&D in health technologies. To what extent do present health care systems create incentives for the optimal development of health technologies?

Technologies for health are developed for the world market, and hence for the leading markets in the world, notably the United States market, with other characteristics in terms of demography, incomes, preferences, etc. than, for instance, small countries such as Belgium and Sweden. Even though the regulation of health insurance in all countries may matter, the United States health care system has probably the greatest impact on R&D in health technologies.

Box 2. Too little R&D on vaccines?

The lack of incentives due to market failures is a reason why socially valuable health technologies may not be developed. Vaccines, for instance, have proved to be effective against several infectious diseases – the success of the smallpox vaccination programme, which has led to the eradication of the disease, is perhaps the best example of the potential of vaccines. There are fears now, however, that there is too little R&D today in order to produce new vaccines, especially against communicable diseases which are common in poor countries.

R&D on vaccines is a global public good. Efforts in one country to develop a new and more effective vaccine against tuberculosis will benefit many other countries too. Once a vaccine has been developed and R&D have been sunk into it, however, governments may be tempted to use their powers as regulators and major purchasers not to compensate the developer for his expenditure on R&D but only for the manufacturing costs. Thus potential developers will not invest in R&D without credible commitments that they will be paid, but on the other hand no single small country has an incentive to pay.

Traditionally, governments have financed both the basic research on vaccines and the later stages of development through grants to researchers, hence paying in advance of the development of the vaccine. The growth of the biotech industry and the increased availability of risk capital, however, has made it possible for researchers to get investors to finance R&D as long as a big enough market can be expected. So for the later, more applied stages of the development of a new vaccine, commitments in advance to pay (only) if a vaccine is actually developed have important advantages. It gives the researchers, pharmaceutical companies and investors strong incentives to focus on projects which have reasonable chances to yield a viable vaccine.

Mr James Wolfensohn, President of the World Bank, has made a proposal along these lines. He has suggested that the Bank should create a US $1 billion vaccine purchase fund to help poor countries purchase specified vaccines if and when they are developed. The proposal has several advantages in comparison with alternative ways of rewarding the developers of vaccines. Extending patents on other pharmaceuticals would place the entire burden of financing R&D on vaccines on the people who need these other pharmaceuticals. Increasing the prices of already existing vaccines may not create sufficient incentives for new research.

Source: Kremer *(5)*. Major progress has now been made by establishing the Global Fund to Fight AIDS, Tuberculosis and Malaria, and creating the Global Alliance for Vaccines and Immunization.

As emphasized above, there will be too little technological progress in a completely unregulated market. Such worries are solved, at least in principle, by granting patents. It has been suggested, however, that the regulation and design of health insurance may induce the development of new technologies for which unsubsidized consumers would not be willing to pay, hence creating a welfare loss to society. This would be the case if all other regulatory measures were designed in order to induce the optimal investment in new technology in an unsubsidized market. If, for instance, patent protection falls short of being optimal in that sense, there is not necessarily any welfare loss from a too rapid rate of innovation induced by insurance.

Some new technologies increase the expected health care cost for a specific patient, while others decrease it. The biologist Lewis Thomas *(6)* distinguishes three levels of health technology: (i) "non-technology" means that the disease is poorly understood; it involves reassuring and nursing patients with very little hope of recovery, for example the treatment of patients with intractable cancer; (ii) "half-way technology" adjusts to disease and postpones death, for example organ transplantations and the surgical treatment of cancer; (iii) "high technology" comes as a result of a genuine understanding of disease mechanisms, for example vaccines and antibiotics for bacterial infections. Generally, half-way technologies are more expensive than non-technologies and high technologies.

As explained in Module 5.3.1, the aim is cost-effective technology. Although the therapeutic value of new technology is becoming an important policy issue, policy-makers are still predominantly concerned with cost and expenditure. It seems to be common wisdom among health economists that most new technologies have increased rather than decreased expenditure. Thus, there seem to have been relatively more development of half-way technologies than high technologies. The reasons may be found in the cost-reimbursement insurance systems used until recently in the major world markets for health technologies, notably in the United States. In such systems there is little or no incentive for health care providers to avoid costly technologies that are only marginally effective, since the costs are paid retrospectively by insurance. This may have created a non-optimal development of health technologies from a societal perspective, both from the narrower American perspective and from a broader global perspective. In systems with prospective-pricing and cost–effectiveness evaluations, there should be incentives to bypass the development of half-way technologies. Thus, the regulation and design of health insurance will have influence not only the amount of R&D activities but also the direction and type of innovation which will be developed.

The economics of transfer and diffusion

New health technologies continue to be developed and adapted once the are introduced into the health care system. For example, a new surgical procedure may first be used by highly skilled surgeons working in tertiary referral centres. After a while it may be more widely used as more surgeons hear about it.

The spread, or transfer, of health technologies raises two efficiency concerns. First, as the technology spreads it may be used on a wider patient population. An assessment would need to be made, through economic evaluation (see Module 5.3.1), whether a broader range of indications for use could be justified on the grounds of cost–effectiveness.

Second, as a technology spreads it will be applied in different settings, where the availability of facilities and the skills of professionals and systems of organizing health care are different. It is therefore not clear whether the cost–effectiveness of the technology **as applied in the new setting** is the same as in the original one. Also, issues related to technology transfer may differ by type of technology. For example, the training requirements associated with acquiring a new surgical technology may be different from those needed to prescribe a new drug.

This part of the module deals with the second of these two efficiency concerns, which is particularly important in an international context. Namely, is a given technology, when transferred to a new setting, as cost-effective as in its original setting?

Factors affecting the cost–effectiveness of health technologies

Basic demography and epidemiology of disease
Countries differ in respect of the age structure of their populations and the incidence of various diseases. In some cases this will affect the cost–effectiveness of health care technologies and programmes,

Box 3. Cost–effectiveness of new health technologies

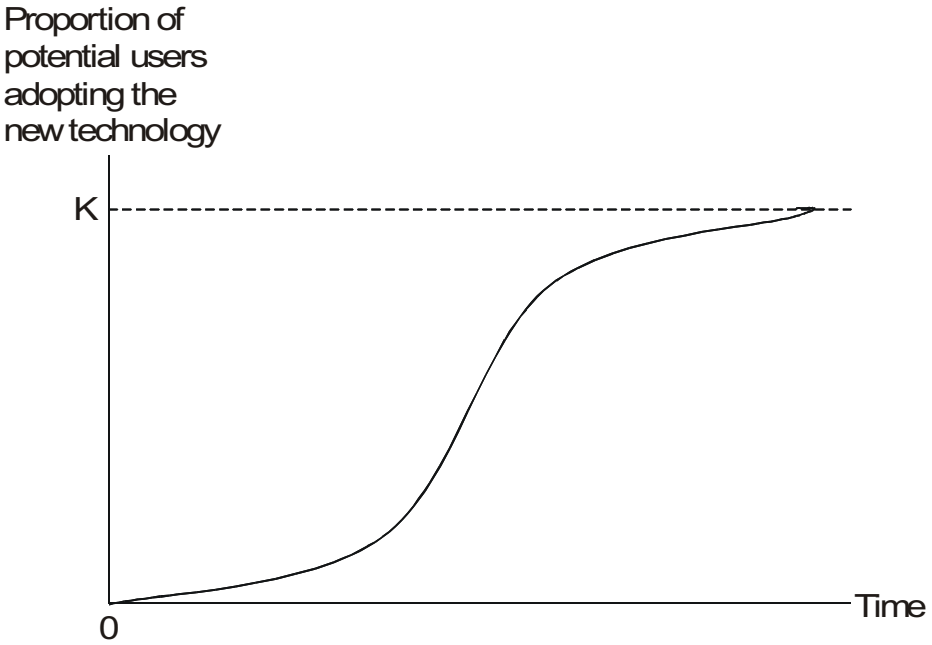
A new health technology is never automatically and simultaneously adopted by all who could use it or benefit from its use. Diffusion takes time and generally follows an S-shaped pattern (Fig. 1). The vertical axis measures the percentage of potential providers who have adopted the technology, while the horizontal axis measures the passage of time. Thus, adoption normally begins slowly but quickens. At some point, the percentage continues to increase but at a decreasing rate. The share of providers asymptotically approaches 100% by the passage of time.

Why do some providers adopt a new technology more or less immediately it is available, while others wait? One explanation is that it is seldom totally obvious whether early adoption or waiting is the best strategy, since the costs and benefits of using a new technology in practice could never be known with complete certainty in advance. Thus, while waiting means that individuals cannot benefit from the new technology (which represents a welfare loss to them), early adoption can be risky in that some serious adverse effect (undetected in clinical trials) may occur. So, there are two types of error that a provider can make: to introduce a new technology too early or too late. The degree of risk aversion may thus be one explanatory factor.

Other factors determining the rate of adoption may be whether or not the new technology (i) requires a greater investment, (ii) has an impact on the organizational setting, (iii) requires a change in the skills of the provider's staff, or (iv) implies a shift of expenditure from the public budget to the patient's pocket or from the private to the public sector.

Not all new health technologies follow exactly the same S-shaped pattern. Some technologies are diffused more quickly than others. Often the diffusion process is interrupted before all the potential adopters are reached. Still newer technologies may be introduced that will compete with the recently introduced one. Thus, an increase in the percentage of adopters will sooner or later be followed by a decline. Some technologies will survive, however, while others will leave the market completely.

Fig. 1. The diffusion of a new health technology



particularly those delivered on a population basis. For example, immunization or screening programmes and for the treatment of disease are likely to be more cost-effective in populations where the incidence of the disease in question is high. Differences in age structures between countries are likely to lead to different levels of incidence in various countries and hence the size of the overall economic burden. The cost–effectiveness of treatment is also likely to vary by patients' characteristics, including age, lifestyle and medical history. Therefore, when discussing the cost–effectiveness of health care treatments and programmes, it is important to specify the patient population to which any statements apply.

Availability of health care resources and variations in clinical practice

Countries differ in respect of the range of treatments and health care facilities available to their populations. In the case of treatment for ulcer, the availability of surgery could vary from place to place. In some countries with national health care systems, such as Sweden and the United Kingdom, there is rationing with waiting lists for hospital admission. The availability of important diagnostic facilities, such as endoscopy, could also vary from one location to another. In turn, the availability of resources may affect the way medicine is practised. For example, if there are long waiting times for endoscopy, a clinician may try a therapeutic dose of a drug for a patient experiencing ulcer-type pain without waiting to confirm the diagnosis. Another difference between countries, more directly related to drug therapy, is the range of licensed products and availability of generics.

Although clinical practice is partly constrained by the available alternatives, it is known that practice varies among clinicians in the same geographical area facing essentially the same range of treatment options *(7)*. To the extent that clinical practice varies systematically between countries, this is likely to affect the relative cost–effectiveness of health technologies.

Box 4. The diffusion of health technologies to older age groups

Once developed, new health technologies will be diffused. They can be spread across countries, to new health care settings and to new patient groups. Thus, the application of a new technology may initially be implicitly (or explicitly) restricted to individuals within a specific age span, which may gradually be extended to older (and/or younger) patients.

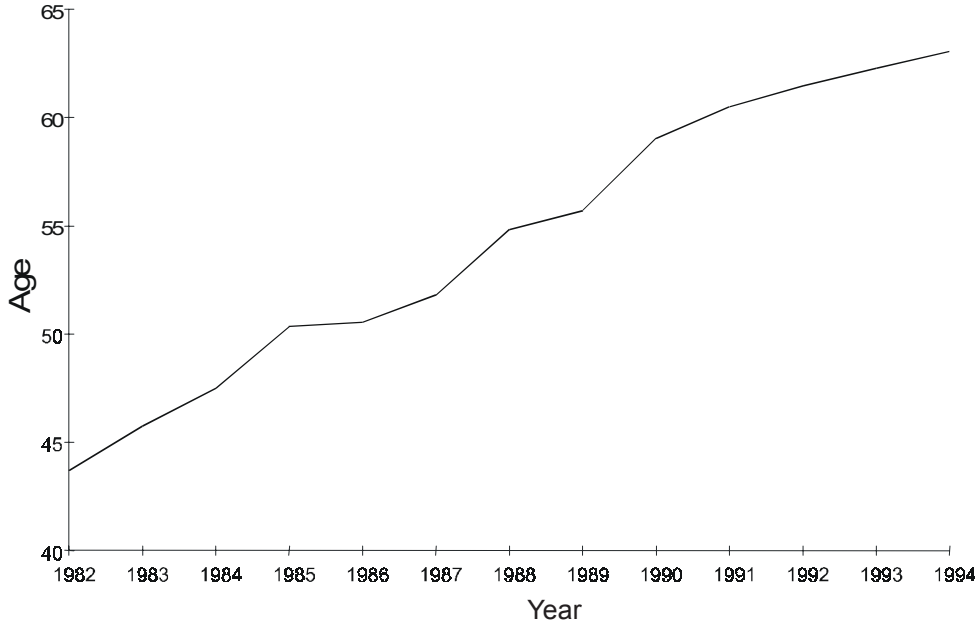
The rationale for restricting the access to new health technologies is often resource constraints in combination with limited or uncertain health gains to individuals above or below a particular age. One explanation why access to new health technologies is usually extended to older (and younger) patients is the fact that health care resources have increased over time. Another is the gradual improvement of technologies that increase the expected health gains from treatment. Diffusion across ages of an existing technology can have a substantial impact on per capita health care expenditure among the oldest people.

Uraemia is a disease which may affect only a small proportion of the population but still represents a significant share of health care costs. The two preferred treatments are kidney transplantation and/or dialysis. Dialysis is the process of removing blood from a patient, purifying and returning it to the patient's bloodstream. Even though the technology of kidney transplantation is fully known, the availability of this alternative is strictly constrained by the supply of organ donors; in some countries there is a waiting time of 2–3 years and greater use of dialysis than is desirable.

In Sweden, for instance, dialysis became common in the early 1960s and the first kidney transplantation was performed in 1964. Fig. 2 shows clearly how the use of dialysis was diffused among older age groups in Sweden between 1982 and 1994 (together with an increase in the total number of new patients taking up dialysis each year). The age structure for kidney transplantations, however, was more or less constant during the same time-period. Here, diffusion was obviously prohibited by the limited access to organ transplants; the total number of transplantations per year were roughly the same.

Source: Nystedt *(8)*.

Fig. 2. Mean age of new patients on dialysis in Sweden, 1982–1994



Incentives to health care professionals and institutions

In some health care systems the level of remuneration of health care professionals and institutions is largely independent of the level of service delivered. For example, hospitals are given a global budget and physicians are paid by salary. In other systems physicians are paid by fee per item of service and hospitals are reimbursed by the number of cases in each category treated.

It has often been suggested that physicians operating under a fee-for-service system are more likely to generate extra demand for their services, whereas those paid by salary or capitation are more likely to deter demand. This may affect the number of visits to a physician by and diagnostic tests carried out for a patient suffering from (say) ulcer-type pain.

In the case of hospital treatment for ulcer, the method of reimbursement could affect which services are delivered on an outpatient basis and the length of stay for inpatients. A hospital being paid a fixed amount for treating a given case has more incentives to free the bed for the next patient than a hospital being funded through a global budget.

Relative prices or costs

It is well known that absolute price levels vary between countries. However, from the point of view of cost–effectiveness assessments, the critical issue is whether the *relative* prices of health care resources differ. Most obviously, if the relative prices of the main drugs for a given condition differ between countries, then their relative cost–effectiveness will differ.

Perhaps less obvious is the fact that the relative cost–effectiveness of drugs will differ if the relative prices of *other* health care resources differs between countries. For example, a drug with greater efficacy, a better side-effect profile, or a more convenient route of administration, will appear to be better value for money in a country where the costs of investigations, hospitalizations, surgery and visits to the physician are relatively higher, since consumption of these items is likely to be reduced. For example, Hull et al. *(9)* found that the relative price of venography (a diagnostic test for deep-vein thrombosis – DVT) differed between the United States and Canada. This affected the relative

cost–effectiveness of alternative diagnostic strategies for DVT in the two countries and would also affect the estimates of the value for money of drugs to prevent DVT.

Ways of adapting economic evaluation results

An analyst seeking to adapt the results of economic evaluation from one setting to another could be faced with one of three situations. First, only clinical data may have been collected in the clinical trials and there might be a need to produce economic evaluations for more than one country or setting. The only option in this case would be to undertake a modelling study, where the clinical data are combined with cost (and possibly quality of life) data from a number of sources (e.g. routinely available statistics or free-standing cost studies).

Second, economic data (e.g. quantities of resource use) may have been collected alongside a clinical trial undertaken in one country, but economic evaluations be required for other settings. In this situation a modelling study using only the clinical data could be undertaken, as above. Alternatively, the resource use data could be adapted in some way in order to make them relevant to another setting.

Third, economic data may have been collected alongside a multinational clinical trial and economic evaluations be required for all the countries enrolling patients in the trial. Here the analyst has a number of options for using the resource use data. Either they can be pooled, as is common for the clinical data, and priced separately for each country. Alternatively, the resource use data for patients from each country could be analysed separately and then priced for each country as above. In this case the analysts would also have the option of calculating cost–effectiveness ratios for each country using the pooled clinical results or the individual results for each country.

Questions for discussion

1. Identify three examples each of (a) non-technologies, (b) half-way technologies and (c) high technologies among the health technologies available in your country.
2. Name five health technologies that have been introduced in recent years in your country. Where were they developed?
3. Name five health technologies that have disappeared during the last few years and that are no longer in use.
4. Explain why these changes have taken place. Have they been appropriate? To what extent have they been the results of deliberate decisions, including economic evaluations of new versus old technologies?
5. Is there a lack of "high" (and "half-way") health technologies in your country? In which areas?
6. Why have not "high" (or "half-way") technologies been introduced to a larger degree? Are they not available in the world market – if so, why? Or has introduction been inhibited by domestic factors?
7. How could incentives be improved to develop "high" (or "half-way") health technologies in areas where they are missing?
8. Creating incentives for the development of new health technologies may be a different policy from creating incentives for using existing health technologies efficiently. The former is primarily an issue for industrial policy (but with important indirect consequences for the conditions for health policy-making), whereas the latter is primarily an issue for health and health care policy (but with potential repercussions on the conditions for R&D). Discuss whether this is a dilemma

or not. To what extent would your answer depend on whether your country is small or big and whether there is an industry with significant R&D in health technologies in your country? (Is your country a free-rider in the world market when it comes to the development of new health technologies?)

9. Describe some examples of the diffusion of new health technologies in your country, including different settings and across age groups.
10. Why do some providers adopt before others? Which types of technology would you expect to be adopted most quickly (and which most slowly)? What factors can increase (or decrease) the rate of diffusion?
11. At what stage of the development and diffusion processes should an economic evaluation of the new health technology be made?
12. Give some examples of technologies that have been introduced but later shown no effects on health or even serious adverse reactions. Could such negative events be avoided? How?
13. What has been the impact so far from information technology on the health sector in your country? What potential for its use would you expect in the future?

Exercise 1. Using modelling to adapt economic evaluation results from one setting to another

This exercise is based on the study by Drummond et al. *(10)* of misoprostol, a drug for prophylaxis of gastric ulcers in patients on long-term non-steroidal anti-inflammatory drugs experiencing abdominal pain. A clinical trial, undertaken in the United States, had shown that patients given misoprostol (400µg daily) for 3 months had a lower rate of endoscopically determined lesions than those receiving placebo (5.6% versus 21.7%). With a higher dose of 800µg daily the rate of lesions fell to 1.7%.

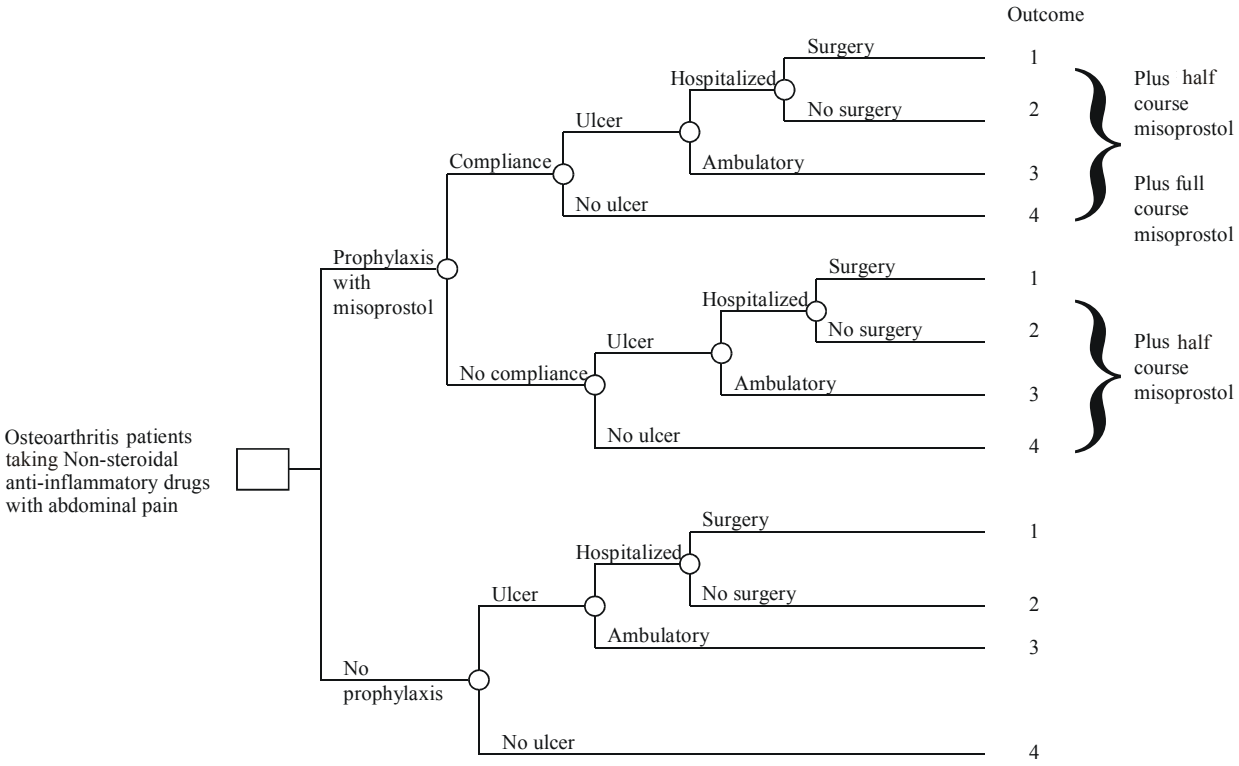
Apart from conferring clinical benefits, a lower rate of gastric lesions is likely to generate economic benefits: if fewer patients have lesions it is likely that fewer will require diagnostic work-up for suspected ulcer and few will require treatment in ambulatory care or in hospital. An economic evaluation can, therefore, assess whether these potential savings in resources justify the costs of adding misoprostol.

The influence on cost–effectiveness of setting (e.g. your country versus the United States or the United Kingdom, respectively) can be explored by using the decision tree given in Fig. 3. (See Module 5.4.1 on Modelling for more discussion of decision tree models.) The data required to populate the model for the United States and the United Kingdom are given in Table 1.

Table 1. Data for the decision-tree model

Variable	Value for United States	Value for United Kingdom
Cost of misoprostol for three months prophylaxis (400µg daily)	US $160	$120
Probability of patient complying with prophylaxis	0.6%	0.6%
Probability of ulcer (adjusted for silent ulcer) with prophylaxis	0.034%	0.034%
Probability of ulcer (adjusted for silent ulcer) without prophylaxis	0.130%	0.130%
Probability of patient with ulcer being hospitalized	0.086%	0.053%
Probability of hospitalized patient being given surgery	0.12%	0.43%
Cost of ambulatory care for ulcer	US $901	US $540
Cost of medical hospital care for ulcer (i.e. no surgery)	US $3 450	US $155
Cost of surgical hospital care for ulcer	US $15 700	US $2 530

Fig. 3. Using a decision tree to adapt data from setting to setting



Source: Drummond, M.F. et al. Issues in the cross-national assessment of health technology (*10)*.

(a) Before making the calculation, speculate on whether misoprostol will be more cost-effective in your country than in the United States or the United Kingdom, giving your reasons why.

(b) Calculate the expected costs or savings per patient for three months prophylaxis in the two countries.

In the decision tree, prophylaxis is compared with no prophylaxis. With no prophylaxis it was assumed that the ulcer rate approximated to that in the placebo group in the clinical trial, although an adjustment was made for the fact that around 40% of lesions discovered endoscopically will be "silent" (i.e. they will not bother the patient) and thus will not require costs in diagnostic work-up or therapy. In the treatment arm the non-compliers were also assigned the trial placebo ulcer rate. The difference in expected cost is driven by the clinical data, but the calculation in both arms requires data that were not gathered in the trial.

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4.4 Specific examples

4.4.1 Primary health care

Chris Buttanshaw[9]

Key messages

- Primary health care is a broad concept that covers both a way of organizing health care and a set of beliefs about the best way of improving health. It underpins HEALTH21, the health for all policy framework for the European Region approved by the WHO Regional Committee for Europe in 1998 *(1,2)*.
- Primary health care includes care directed at both individuals and communities. There is thus an important public health component that must be taken into account when economic analyses are made.
- Primary health care interventions are often diffuse and difficult to evaluate with the empirical quantitative methods frequently used in health economics.
- Primary health care resources are mainly provided by informal care by individuals, families or the community. Economic and social analysis needs to recognize and build on this co-production.
- Primary health care has much to offer in terms of cost-effective interventions, but there are many factors that prevent these services being given the appropriate priority.
- Changing demography and social patterns pose special challenges to primary health care, especially in terms of long-term care and the care of older people.
- Strong primary health care both supports and requires healthy communities if it is to be successful.

Tutors' notes

This module covers the health economic aspects of primary health care. Many of these points have been touched on in earlier modules, and some of these are cross-referenced. The module is best used towards the end of the series, as it is helpful for students to have covered the generic health economic concepts. No specialist knowledge is assumed.

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The module should be of interest to a wide audience including:

- policy-makers
- clinical staff
- managers in health and other public service settings.

The exercises are designed to be relevant to participants from different countries and backgrounds. Wherever possible it would be appropriate to tailor these by using local or topical scenarios. Each exercise is intended to be used in small groups. However, it might help if some of the exercises are worked up in advance by individual students.

Introduction

The concept of primary health care has been introduced in a number of other modules. This module is an integrated discussion of how the generic principles covered in other modules apply in primary health care. An understanding of this material will help in successfully applying the health for all approach.

The nature of primary health care

The concept of primary health care has been summarized in the Declaration of Alma-Ata *(3)* and these values are reflected in *Health21: The health for all policy framework for the WHO European Region (1)*. The concept of primary health care straddles individual practice and public health. It looks not only at the health of individuals but also at the health of communities and populations. There is no simple definition of primary health care, but a good starting point is contained in the Declaration of Alma-Ata:

> Essential care based on practical, scientifically sound, and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination.

This is a very broad concept. The term is confused in some parts of Europe with primary medical services (e.g. general practitioners) and other health services, but these are only one component. The list of further reading includes other discussions of this matter.

The approach is a holistic one that recognizes that health systems need to understand health care not just in the context of the individual, but also in the context of the family and communities to which that person belongs. Primary health care involves not only the health sector, but other sectors such as education and housing as well. The next section emphasizes that health production is an output from all sectors, and that health planning needs to reflect this. It also reminds us that health is largely a function of factors other than health services. It makes the additional point that the health of local communities is directly affected by their ability to retain discretion and control of local services and facilities across all sectors.

Primary health care is often thought of as a term descriptive of organizations, defining them as separate from secondary and tertiary care. However, the primary health care concept should permeate

all services. For instance, a tertiary cardiac service can increase its primary health care content by carrying out more operations locally, or by ensuring that patients see the same staff at each visit, or by supporting local community rehabilitation programmes. The potential for confusion between primary health care thought of as organizational units, and primary health care as a concept to inform practice across the entire health care sector, is an important barrier to achieving system goals in many settings.

Role of informal care

In primary health care, the resources for delivering health are predominantly informal. Individuals provide most care for themselves, supported by family, friends or local communities. The role of paid professionals providing formal care is to support and supplement this. This is often referred to as **co-production**. At its simplest, a giver of care (e.g. a nurse) and a receiver of care are involved. However, neither party in this simple relationship is purely a giver or a receiver. The "receiver" will normally also be providing part of his or her own care, and the "giver" will be receiving a benefit in terms of his or her own personal role in the community as well as more conventional monetary and other rewards. Broadening this example, individuals, families, friends, communities and carers must be considered as both contributors to and potential beneficiaries from any caring activity. Of course this is true of any aspect of health care, but in primary health care these links within communities are of central importance.

An increase in the supply of formal care may either support or replace informal care. Formal care may increase **independence** and interdependence and thus the health of individuals and communities, or it may generate dependence and poorer health. There is thus a double risk: additional formal resources may add to the financing burden but simply replace an existing resource; and by increasing dependence, formal services may directly reduce individual and community health.

In terms of **quality**, formal and informal care will frequently differ. For example, informal care tends to be more accessible, often being available 24 hours a day, and there is continuity of care. Informal care and formal care may vary in quality; both may be poor or inadequate. Informal care may cause carers' health to deteriorate under the strains of giving care. It can become a source of abuse. Thus it is not a question of one approach being better than the other, but of the right balance in the local context.

There are wide variations in the role of informal care in different systems. These variations are supported by historical, cultural, political and social factors. Co-production is nearly always relevant in decision-making, whether at a policy, allocation or delivery level. However, it is very often neglected.

Exercise 1

This exercise is designed to develop participants' understanding both of the limitations of formal analysis of costs and benefits in a realistic situation and the knock-on effects for patients and carers of a change in formal care. The emphasis of the discussion would be different with different participants. Policy-makers could concentrate on how the political, social and cultural climates affected the role of informal care, and the effects on communities as well as individuals. Managers could concentrate on the technical and allocative decision-making process. Clinicians could concentrate on the outcomes for patients and carers of the different approaches, and how the care processes they design would differ to maximize benefits and minimize costs.

A health authority is considering changing the nature of rehabilitation for stroke. At present, older people with stroke are admitted to a large hospital for acute care and then for a lengthy period of rehabilitation. In the alternative model, patients would be admitted for a briefer period and then be discharged to their home, where a community-based therapy team would complete the rehabilitation process.

(a) Considering the issues raised by co-production, what are the anticipated effects on costs and benefits of the proposed change? Who would bear the changed costs and benefits?

(b) How easy would it be to compare the costs and benefits of the alternative approaches?

(c) How would the specific social, cultural and political environments in your country affect such a decision?

The relevance of the primary health care concept as demography and social background changes

Changes in the demography and social norms in the WHO European Region will profoundly affect the delivery of health care. Different work patterns and an ageing population are changing the ability of communities to provide primary health care. These changes include:

- the decrease in family size and more women working outside the home
- the increased distance between where people work and live and more frequent job changes
- lower retirement ages and longer life expectancy
- the persisting or widening differential between female and male mortality
- changing expectations of who should provide care and how it should be funded.

All these factors affect the ability of individuals, families and communities to care for their own health. Set against these changes in the **capacity of the community** to care for its members, advances in care are enabling people to live longer, but with longer periods of poor health.

There have been suggestions that advances in technology would result in a "**compression of morbidity**." In other words, that the proportion of life lived with significant ill health would not increase, or might even decrease, with increasing longevity. To date this aspiration has not been met. While there has been some success in delaying the onset of certain diseases (e.g. heart disease), there has nevertheless been an increase in older people's needs for care. These are often complex, although there is the potential for advances to change this situation. For example, Alzheimer's dementia is a major contributor to the care needs of older people. The prevalence of Alzheimer's disease has been rising, both because of increasing age and because of survival time being lengthened by better care. Current research efforts are directed towards understanding the aetiology of this condition and blocking the pathological process responsible. If this were to succeed, there would be a dramatic health gain of particular importance in reducing health care needs. Such changes do occur, for example the reduction in the incidence of tuberculosis in the 1950s and 1960s. However, it seems likely that even with such important gains, the need for care will increase over the long term.

These considerations are causing health systems to review the way health care is financed and provided. On the finance side, there are debates about what types of care should be funded and how that funding should be raised (taxation, insurance or self-funding). On the provision side, the debate is about the balance between self-care, informal care from family, friends and unpaid volunteers, and formal paid care. In many countries, aspects of this care will be provided by different sectors or

bodies. For example, long-term care in mental health will involve important components of health, social security, housing and vocational care. This emphasizes the importance of an **intersectoral approach**, and the potential inefficiencies that can be generated by a sector-by-sector approach.

During demographic and system change the costs of long-term care may change and the funding burden even be shifted between generations. For instance, a reform that moved from a tax-funded service for long-term care of older people to one that was based on individual insurance would mean one generation paying both for the care of the current generation of older people (through tax) and having to save to pay for their own care in later years (through insurance premiums).

All analyses show that there is considerable capacity for health-promoting interventions to avoid morbidity and mortality and improve health. The point is correctly made that such interventions are often more efficient at generating good health than subsequent curative interventions. However, this is often translated into a reduced need for health care services in future. This may sometimes be true (for example, measles immunization reduces the incidence of measles encephalitis with its care needs), but generally is not. For example, interventions that reduce smoking levels, while clearly desirable and good for health, will not reduce care needs in the longer term. The onset of ill health may be postponed but will still occur, although over a longer life span. Plans need to be made for these consequences of better health, on the understanding that health gain does not necessarily equate to lower health costs.

However, over time, new technologies will result in extensions of morbidity. As an example, the introduction of insulin for diabetes has improved the health of a significant number of people. However, it has also greatly increased the costs of health care. Costs rise to maintain the treatment of diabetes itself, and to deal with conditions to which diabetics are prone, such as heart and kidney disease.

Because of its burden, severe and **enduring mental illness** needs special mention. All health care systems spend a significant proportion of their resources in this area, with schizophrenia in particular consuming an important proportion of total health and social care resources. In many countries, people with schizophrenia and people with learning disabilities (mental handicap), who would in the past have been placed in institutional care, are now living in community settings and their life expectancy has increased. The rationale for shifting such care to the community was that it would deliver an improved quality of life, albeit that experience has tended to show that this is at higher cost. Whether the promise of quality is delivered depends on the strength of the communities in which they live and on the appropriateness of the system for commissioning and monitoring their care. It is clear that such needs have taxed the community's capacity to care in many European countries.

Primary health care as an organizational concept

While primary health care is a description of an approach to care, it is also embedded in the organization of health services. How this works may vary from country to country, but there are certain features that are important from the standpoint of health economics.

For some or most secondary and tertiary care services, primary health care professionals act as **gatekeepers**. Different behaviour in primary health care can have profound effects on the distribution of costs and benefits. For example, decisions to refer patients with angina (chest pain) can have major consequences for the demand for secondary and tertiary cardiac services and for the equity with which such resources are used. Both effects, on demand and on equity, are important.

Primary health care practitioners operate in a complex environment in which many factors impinge on decision-making. These factors include:

- the public's and patients' expectations
- the practitioner's level of training and knowledge
- financial payment mechanisms and incentives
- the practitioner's toleration of uncertainty
- expert guidance
- marketing by providers (e.g. of pharmaceuticals)
- professional guidance on appropriate roles.

All these factors have been changing. Consider the effect of the internet on patients' expectations, or the regulation of pharmaceutical promotions. Health systems should actively consider these influences and put in place an appropriate framework with the aim of managing them to produce greater health benefits at lower costs (and monitor the equity of existing or proposed arrangements). However, the results of changes in these factors are not always correctly predicted. For example, increased training and knowledge may lead to increased referral, because more opportunities for tests and interventions are recognized, rather than decreased referral with more conditions being treated within primary health care. In either case it is important to consider whether the changes are appropriate or not.

In the case of **pharmaceuticals**, many governments try to influence the behaviour of physicians. Many, sometimes crude, incentives for lower prescribing costs have been introduced. However, low prescribing costs are not necessarily appropriate. There are areas such as antibiotic prescribing where physicians may over-prescribe, but there are areas such as asthma-preventing treatments which may be under-prescribed. The same argument applies to referral for secondary services. Effective interventions need to be carefully designed and should be informed by cost–effectiveness rather than cost-containment.

Given the complexities of intervening at the micro level, many countries are taking on board a more sophisticated approach in the concepts of managed care, and with it integrated care pathways. These more sophisticated approaches look at patient care across different settings and providers, and seek to apply evidence systematically in the routine management and monitoring of care. This **integrated approach** can work with all the above influences simultaneously. Such approaches will profoundly affect the microeconomic environment for health care providers. There is good evidence to suggest that they can make systems more efficient and more effective.

The organization of primary health care differs across Europe. It is growing in complexity with doctors, nurses, therapists, social workers and others needing to work together effectively as a team. Care is being delivered in many different settings, including people's homes, schools, workplaces and clinics. This varied practice requires an **appropriate infrastructure**, both as regards buildings and facilities and, just as importantly, in terms of information systems.

The nature of illness in ageing populations means that most resources are directed at people with multiple problems, many of them chronic in nature. No one specialist, indeed no one sector, completely meets their needs. Much poor quality care results from a lack of communication and coordination. It is an important task of primary health care to address this need for coordination. How this is achieved will vary from system to system, but at a policy level it is an important means of increasing efficiency in the use of scarce resources and the quality of care.

The generation of inequity in primary health care is more complex. Indeed **equity** itself has a number of dimensions, as has been discussed in Module 3.2.1. Primary health care resources are distributed more evenly than those for secondary or tertiary care. Therefore factors such as distance to a specialist centre will not be as important. However, important inequities can arise in primary health care; and primary health care can affect equity in the use of secondary and tertiary care. For example, research in the United Kingdom has shown that socioeconomic factors influence the length of consultations in primary health care, and there is evidence that referral for angioplasty is influenced by proximity to the treatment centre *(4)*.

In the light of the pivotal role that primary health care plays, some systems have developed reforms where primary health care practitioners (usually general practitioners) have greater control over how resources are used in secondary and tertiary care. Two of the best-known examples come from the United Kingdom in fundholding (which has been abolished) and primary health care trusts (which are currently being formed). Groves *(5)* talks about these changes.

Values, benefits and resources in primary health care

In a rational world, assisted by economic theory, decisions can be made about resource use based on the expected benefits. Economics provides us with a number of analysis paradigms, including those covered in Module 5.3.1, when discussing economic evaluation. These techniques are most effective when an intervention can be clearly defined, when it can be costed, when the outcomes can be measured, and when specific research findings can be generalized to a range of settings.

In primary health care, each of these four requirements is likely to cause difficulties. Interventions are often difficult to standardize; costs are difficult to define and ascertain and may vary considerably; outcomes are often diffuse, uncertain in terms of timing, and involve wider effects than just the patient; and there can be wide variations between different primary health care settings, so that results may be difficult to generalize. Of course, none of these points is unique to primary health care, but they are particularly complex and important here.

Exercise 2

This exercise is designed to develop understanding that lack of evidence is not necessarily evidence of lack of effectiveness. In the discussion, two points should be brought out: the difficulties of obtaining hard (e.g. randomized controlled trial) evidence for some parts of health care; and the danger that with the newer evidence-based initiatives (such as the United Kingdom's National Institute for Clinical Effectiveness), resources are allocated to areas with hard evidence and not necessarily to those areas where the needs are greatest.

Decision-makers in a health district are being asked to rate the relative priority of increasing the number of coronary angioplasties undertaken for heart disease and improving occupational therapy services for people with a learning disability. There is extensive published evidence concerning angioplasties including many randomized controlled trials. The literature for occupational therapy is less extensive.

(d) How would this difference in the available evidence disadvantage occupational therapy in allocation decisions?

(e) How could such a disadvantage be avoided?

Other modules have discussed the vexed question of **value**. Much economic analysis relies on measuring the benefits of a specific intervention and then applying some sort of analysis to allow comparison and decision-making based on a utilitarian model. In other words, the analyst seeks to identify how to use resources to achieve the greatest good for the greatest number. However, it is known that, in day-to-day life, people do not think and act in this way. They hold a series of values, which influence decisions and outcomes. Thus a utilitarian conclusion about the use of, say, a new and expensive cancer drug, may well differ from the decision that an individual or community will make. Health economics can inform decision-makers, but not take the decision.

Economic evaluations of secondary care interventions often look at the effects of a specific one-off event in isolation. The marginal costs and benefits of that intervention are then examined. But primary health care is not, in the first instance, about discrete interventions for ill health. It is about life and the **quality of life** as a whole. It is about frequent, sometimes continuous, interventions occurring in the life-span context. The individual's life span is framed by those of family, friends and community.

This highlights the problem of applying marginal analysis to what is appropriate at any given time, because there is a danger of losing the health and quality of life for individuals as a whole. Average health ceases to matter; only added longevity is a benefit. One consequence of this is that death can never be healthy. Death becomes the inability to squeeze additional life out of an individual at an acceptable cost. In other words, death is a failure.

One way of avoiding this paradox is to look at health across the whole life, and ask whether a particular intervention would make a significant difference to the average health of an individual across his or her life span. Neither approach is exclusive of the other, although marginal analysis tends to predominate in all health sectors. However, primary health care decision-making is more likely to draw on a whole life analysis than secondary or tertiary care. The decision-making of individuals, communities and professionals is influenced by these considerations. Warren et al. *(6)* explore these issues in more detail.

Exercise 3

This exercise is about thinking through values, and how people in real life think about and talk about benefits. Participants should draw out potential differences between the professional's, the individual patient's, and society's points of view, and discuss which view is predominant. For a more technical discussion, they might like to read Tsuchiya *(7)*.

Consider the following scenario: a 70-year-old person presents to his/her doctor with incurable cancer. Treatment with a toxic course of chemotherapy and radiation adds an average six months to life. Without treatment, average life expectancy is four months. End-of-life symptoms are the same with or without treatment (in other words, the final course of the illness is neither better nor worse with treatment). Treatment is unpleasant, may cause complications and involves periods in hospital. It lasts for three months. Treatment accelerates death in 10% of cases.

(a) Does analysis of marginal benefits differ from a whole-life benefits approach?

(b) Is this of any practical consequence?

(c) How important are any differences between whole-life and marginal approaches in the real world?

Community involvement

The concept of communities is at the heart of primary health care. Communities can be of many sorts. They are not just geographical but can include any group joined by a common interest. For most of us, good health includes a sense of belonging and the opportunity to participate in communities.

In many systems the burden of financing health care has become divorced from the consumption of health care. These issues were discussed in Chapter 3. If there is no payment at the point of use, and there is no direct financial consequence for a local community from consuming greater resources, then there will be an incentive to over-consume. If, in addition, expenditures in different sectors are ring-fenced and cannot be applied flexibly to achieve the greatest efficiency, then significant technical and allocative inefficiencies are likely to occur. In such situations, it is difficult to engage local communities in **decision-making processes**.

Primary health care advocates that there should be effective decision-making power vested in local communities and that their ability to exercise this power should extend across sectors. For example, a programme to help young people misusing drugs should be able to use resources flexibly across health, law enforcement, education, social services and other sectors. The means by which this happens will vary, but action can be taken both at a policy and legislative level, and at a local district level. In another example, one of the key determinants of health for older people is a feeling of security in their own community and home. Efficient systems would ensure that resources could be applied flexibly, if necessary between sectors, to meet this need. Such approaches may significantly change resource allocation decisions.

Effective means are required to involve local communities in the decision-making process. How such involvement occurs will depend very much on the specific setting. It may be through legislatively determined democratic structures, or through other means. Such participation can build the health of communities as well as contribute to specific decisions on the allocation of resources. In many areas, communities are caught in a catch 22 position. If there is no meaningful involvement in local decision-making, people do not participate. If people do not participate then there can be no process of meaningful involvement. Decision-making can easily become dominated by special interest groups.

As discussed in Chapter 3, the chief health care resource is **informal care**, provided within communities themselves. The capacity of communities to continue to provide this care is crucial, particularly for long-term care. Older people, when asked for their preferences, are consistent in their responses. They want to receive the necessary care the same as anyone else. They want to stay in their own home if at all possible. If they have to move, they want to stay as close to their home as possible and maintain their social networks.

This presents a challenge to society. It is always possible to maintain someone at home; it just becomes increasingly resource-intensive with **increasing dependence**. The demand for such care will rise with the increasing number of old people and the increase in their length of life with significant morbidities. The ability to meet this demand will depend on the social policies adopted, which will, in turn, affect the need to finance formal care and the ability to meet older (and other) people's preferences.

Throughout this module, the importance of **public expectations** is emphasized. In other modules the concept of consumer sovereignty is discussed. Public expectations work at many levels, and in very particular ways because of the asymmetry in knowledge between the consumer and the provider. Some examples of beliefs and expectations that may be widely held are:

- a sick person should see a doctor rather than a nurse
- an antibiotic should be prescribed for a cough
- specialists know more and give better treatment than generalists
- screening programmes should never give false negatives (e.g. for cervical cancer)
- doctors know best
- big acute hospitals give better care than local community hospitals
- back pain has a mechanical cause
- experts keep changing their advice on what is a healthy diet.

Of course, some of these beliefs and expectations may be true, or at least true in some contexts. But the point being emphasized is that where there is an asymmetry in knowledge about the need for treatment and the quality of that treatment, these expectations have special significance. In general, they run against the development of primary health care and overestimate the potential for clinical services to improve health. There are complex interactions between these expectations, the political processes and the media that are beyond the scope of this module. However, a reasonable conclusion is that whether it is at the individual level (e.g. prescribing of antibiotics), the district allocation level (e.g. big hospitals are better than small), or national policy level (e.g. experts keep changing dietary advice), these factors are of central importance to the efficiency and effectiveness of health systems.

Public health and primary health care

In this and other modules, examples of public health-type interventions have been discussed. Such interventions often score highly on cost–effectiveness analysis but may well involve sectors other than health. Examples given have included seat belt legislation (little health sector involvement), smoking (important component from the health sector as well as other sectors), and immunization (mostly the health sector). The need to consider health production in an integrated way across all sectors has been emphasized.

But there is a second more difficult dimension. This concerns the **orientation of health sector staff**. Traditionally, doctors and other health care staff have understood their roles in terms of a one-to-one relationship with patients. In all systems, this conception is supported by many factors, for instance ethical codes and public expectations. But there is a parallel component of clinical practice that has public health objectives.

This is most simply seen in the case of immunization. In many countries, family doctors are involved in the administration of immunizations, and in so far as an individual patient has the capacity to benefit from immunization (for instance against rubella), this can be regarded as an individual-based decision. But population coverage rates for such an immunization are crucial to its effectiveness, and immunization programmes attempt to protect through herd immunity as well as individual immunity. A dual goal of individual benefit and population benefit is, therefore, being pursued. In the case of rubella, the immediate benefits of immunization are not to the individual, but to the unborn children who might be infected during pregnancy if wild rubella virus circulates. Sometimes the advice given by clinicians immunizing a child is coloured by these differing objectives, but since the individual interest and the public interest usually coincide in immunization, it is rarely a problem.

But the public health aspects of clinical practice can be much more problematic, particularly when the **opportunity cost concept** is applied. Clinicians must ration their time between the competing

demands of patients. Time spent with one is often at the expense of time with another. Using resources for prescribing for one patient, or referring to secondary care, will limit the resources available to other patients. In some systems, this may be very immediate. For example, there may be a limit on the total cost that will be financed by the state for that doctor. In other circumstances the links may be more distant, for example that an overrun on the country's expenditure on drugs leads to restrictions on some service or another. But however it operates, opportunity cost is always pitting one benefit against another.

The important point here is that an open understanding and acknowledgement of responsibility for these wider public health consequences of individual clinical practice is likely to lead to a more efficient system and better health outcomes. Such understanding is in part a function of training and knowledge, but it is also deeply dependent on social and cultural factors that may be difficult or slow to change. However, the issue should be acknowledged, and appropriate action taken in the differing local contexts throughout the European Region of WHO.

Shifting the health care balance

Since HEALTH21 is focused on primary health care, the question arises of how the balance can be tipped towards such care. The promotion of the primary health care concept is not new. Yet, despite more than 50 years work, health care systems still invest predominantly in secondary and tertiary care. Many commentators have noted that much health care is either of unproven benefit or is known to be ineffective.

Powerful forces maintain this pattern, and understanding is required of the practical means by which change can be achieved. In this and other modules, many factors have been identified that militate against shifting the balance. These include:

- the poorly defined nature of interventions in primary health care
- the higher esteem in which specialists are held
- the invisibility of much primary health care
- the sometimes long intervals between interventions and benefits (e.g. health promotion)
- the loss of the personal interest factor in public health-type interventions
- the drama of high technology intervention in secondary and tertiary care.

So what are the opportunities for implementing this shift towards a greater emphasis on primary health care envisaged in HEALTH21? The shift is not a matter of taking from one sector and giving to another (which is unlikely to succeed), but a **reorientation** of the whole system to primary health care. Clearly primary health care is not a good in itself. It has to be justified on the basis of better health production. This will result either from lower costs than the alternatives or increased effectiveness, or both. Where it has been possible to estimate the cost–effectiveness of primary health care interventions, primary health care often looks attractive. Tables of cost per quality-adjusted life year, such as those given in the discussion of economic evaluation, show low cost per quality-adjusted life year. However, for many potential interventions, adequate economic analyses are still not available.

Two important areas where a shift has been occurring in many countries are day surgery and community care. The move to undertake many traditional inpatient surgical procedures as outpatient procedures has lowered unit costs, at least in the health service, but is equally effective. Indeed the move of such services towards primary health care probably delivers additional benefits. Moves from

residential to community-based care for those with learning disabilities (mental handicap) and long-term mental health problems have, usually, been able to demonstrate benefits for the individuals involved, although good quality has generally meant increased total costs.

Some other examples (but not a comprehensive list) of areas in Europe where the potential to develop primary health care has been recognized are:

- improved rehabilitation services enabling more people to go home rather than to institutional care;
- intermediate care inpatient facilities (such as community hospitals);
- more community-based palliative and terminal care services;
- increased use of telemedicine to aid diagnosis and primary health care management;
- managed care, often nurse-led, for chronic conditions such as diabetes and epilepsy;
- effective primary and secondary prevention, for example, in relation to high blood pressure and in aspirin prophylaxis after a heart attack;
- early supported discharge after acute and elective admissions.

The human capital approach was discussed in Chapter 2. While major illness and disability can have a large impact on individuals' health, such conditions are not common in the population. On the other hand, a great deal of ill health is related to **common chronic conditions** that are chiefly seen in primary health care. Some examples are: low back pain, anxiety and depression, and stress. These conditions not only result in poorer health for the individual, but (through work absence) have major costs for the economy in lost production. Such conditions commonly present to primary medical care, but the responses needed are varied and often involve other sectors. Alleviating the associated ill health requires an integrated approach that may include components of clinical treatment, but should also include a society-wide approach to prevention. So the potential is there, but realizing it is not straightforward.

However, the balance is only likely to tip towards a greater emphasis on primary health care if there is effective management of resources across the entire health sector and proper appraisal of new technologies before their widespread use. In particular, the effects on informal care and the impact on local communities must be taken into account. While the practical issues may differ across the sectors, these decisions need to be made (and the case for primary health care supported) by sound arguments appropriately informed by economic analysis. The decision-making process needs to be participative, and the balance tipped from professional sovereignty to community and consumer sovereignty.

Exercise 4

This exercise is designed to bring out the intersectoral nature of health, and the importance of factors such as public belief (e.g. about the physical cause of back pain injury), income maintenance systems, litigation and legislation, and employers' practices. Participants should understand the massive health impact of back pain and how dysfunctional most systems are in dealing with the problem, either from the point of view of improving health or from the point of view of production in the wider economy. An additional point could be made about treatment for back pain (it was bed rest; now the advice is to keep active through the pain), and how this change of advice is affecting the understanding and behaviour of different actors (patients, professionals, employers, judges, etc.).

In the United Kingdom, expenditure on diagnostic and treatment services for chronic back pain has increased. Yet over the last twenty years, the number of workdays lost has also increased markedly.

There is no evidence that there has been any increase in back injuries or in any disease of the spine to explain this.

(f) What might be the causes of this increase in workdays lost?

(g) What steps should a health district consider taking to improve health in this area?

In the specific context of one country's systems, consider how arrangements for working across different sectors help or hinder an integrated approach to implementing a strategy for reducing ill health in this area (or others).

Ageing and health care provision

This module has touched on a number of issues specifically related to ageing. These include:

- the importance of informal care
- the ageing demographic profile
- changing capacities in communities to provide informal care
- morbidity and complex health care needs later in life
- changing dependence ratios.

This section covers some specific issues that are important in health care provision for older people, which is an increasingly significant area in the WHO European Region.

Health promotion and prevention are often thought of in relation to children or younger people. However, it is important to realize that some health-promoting interventions are actually more effective in old age. Thus there is evidence that old people were being denied treatment with thrombolytics (clot-busting drugs) after a myocardial infarction (heart attack), although the evidence shows that such interventions are actually more cost-effective in older people because of their higher absolute risk of death and complications following a heart attack *(11)*. In general, **preventive interventions** for older people have a quicker pay off (e.g. programmes to prevent falls) and a greater absolute benefit because of the greater risk of the adverse event occurring. It is important for health systems to recognize these opportunities for improving health.

In the older age groups, health care needs are more often multiple and long-term, and straightforward conditions more frequently become complicated. This is a challenge to the organization of health care and requires more complex systems to support care adequately. Older people need access both to the best specialist care (and often a number of different specialist areas at the same time), and to good general support and care. Few health systems would claim excellence in meeting this challenge, which often gives rise to significant inefficiencies.

In responding to this challenge health systems have generally come to a number of conclusions:

- health care needs to be organized around the patient; this requires care management and the creation of care pathways;
- because many different individuals and organizations are contributing to care, communication is important; this requires increased expenditure on information systems and technologies;
- care requires coordination and cannot usually be left just to specialists; primary health care is, therefore, of particular importance as it provides the continuing generalist support.

Each health system will tackle these challenges differently. But there are a number of common features that arise.

The health sector is often working alongside a number of other sectors, particularly income support, social care and housing. Very often, there are separate ways of financing and providing care in the different sectors. Thus the funding of care in hospital may be different from that in a nursing home or at home. Or people at home may get free health care but have to pay for social care. Income support may be dependent on the setting in which a person lives. Where a system is fragmented, these **"boundary issues"** will create inefficiencies. For example, patients may stay in hospital (which is expensive), because services to meet social care or housing needs are not in place or are not funded. Different actors may try to shift costs. For example, social care providers may encourage admission of a person to an institution to avoid the costs of home care. These inefficiencies will be both in terms of additional costs and in terms of poorer quality of care (lower benefits). Avoiding these inefficiencies is both a matter of good planning and design of the health and social care system, and good protocols and working arrangements for the staff who are actually providing care.

Informal care plays a larger role in the care of older people, but there is commonly an **asymmetry** between men and women. Women, on average, live longer than men do. Therefore a man is more likely to have a partner who provides care in old age than is a woman. As discussed previously, changing social patterns will have dramatic effects on the availability of informal care. In many countries such care is supported by **voluntary** (unpaid) services, for example meals on wheels and community transport initiatives. Where informal care is strong, there is a lower reliance on institutional care. But the strength of informal care is determined by a host of factors, including the availability of formal care. Communities need to think carefully, therefore, about what type of care they want for their older people, and understand the complex interrelationships that support their current system and how interventions and secular trends will affect it.

In every system, there is a tension between the demands of secondary and tertiary care for resources to fund acute health care interventions, and primary health care, where the emphasis is on care rather than cure. This does not just concern revenue to run services, but capital to develop facilities, investment in training staff and approaches to patients. For example, if health care staff are trained in isolated specialties, and the status of generalists is perceived to be low, it will be difficult both to recruit suitable generalist staff and to ensure that specialist staff understand the importance of interdisciplinary working. Thus health care systems need to look at how they plan their health workforce, and how different disciplines are trained.

It is important to recognize the special issues that health care for older people raises. However, most older people are healthy and able and want to play a full role in society. Healthy societies will not treat older people's health and welfare as something apart, but will ensure that they have both equitable access to health services and a **full role to play in life**.

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Further reading

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4.4.2 Citizens' participation, patients' rights and ethical frameworks

Manfred Wildner and Oliver Sangha[10]

Key messages

- Traditional economic theories of individual preferences do not adequately describe the demand in health care markets, which is also influenced by providers and public health interventions.
- A knowledge of theoretical frameworks of ethics and rights and strategies for their implementation is of great importance for health economists when they regulate or influence the market.
- Citizens' participation, patients' rights and consumers' rights will play an increasingly important role in medical practice as well as in the health care market in the twenty-first century. Strategies for the implementation of these concepts range from advocacy models over implicit legal reinforcement to explicit charters of health rights.
- Utilitarian frameworks of assessment such as cost–effectiveness analyses are likely to be supplemented increasingly by approaches that are sensitive to health rights in discussions about rationing and priority-setting. Standardized strategies to assess health outcomes from a rights-based perspective are likely to be developed.

Tutors' notes

This module is highly relevant to economic thinking in relation to health and health care, although the matters discussed are often not discussed in much detail in health economics textbooks or courses. Traditional economic theories of individual preferences do not describe at all adequately the full

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complexity of the demand in health care markets. A knowledge of theoretical frameworks concerning ethics and rights as well as strategies for their implementation is highly relevant for health economists as they can regulate and influence markets and the behaviour of participants on both the supply side and the demand side. It is probable that citizens' participation, patients' rights and consumers' rights will play an increasingly important role in medical practice and in other health and health care markets in the future.

The module is relevant to all four of the groups of potential users that have been identified for these learning materials. Knowledge of the relevant theoretical concepts, the available strategies for their implementation, the main implications, and their interaction with more traditional health economic approaches (such as economic evaluations) is relevant to the following.

- Very senior decision-makers: for example, in many European countries a high proportion of citizens are very or fairly dissatisfied with their health care systems**,** and it is likely that much of this dissatisfaction is related to how patients and citizens view their rights as being met (or not).
- Managers and health professionals, who are the key components of how the health and health care systems work in practice. To the extent that many citizens and patients are dissatisfied there is, at least, room for questioning current approaches and performance, and probably room for significant improvement.
- Members of various concerned public groups. These often represent the channels through which dissatisfaction is articulated, for example, protests by unions, discussions on television or radio programmes or in the print media, comments by consumer organizations, voluntary bodies or nongovernmental organizations. The various concerned public groups often represent some of the avenues through which improvements are sought, or participate in the fora (e.g. hospital boards) where broad ethical frameworks, the specific rights of citizens and patients and decisions about priorities in the use of scarce resources interact.

The module can be used at the three levels of *appreciation, appraisal* and *analysis*. In contrast to many of the other modules, the levels of appreciation and appraisal are equally relevant in relation to this module for each of the four main groups of potential users. Even analysis, broadly conceived, could be relevant to participants from each of the four groups of users.

Indeed, this may be a module where it is particularly important that participants from all groups address the difficult issues that are raised, even if they are initially rather reluctant to do so. The ethical frameworks are relevant to them all, even if their practical implications may sometimes be uncomfortable for policy-makers, practitioners and commentators. A health service that seeks to retain the confidence of its patients, its political constituency and its funders cannot afford to ignore the important issues which are raised in this module.

The four exercises are all related to consideration of a particular example, the planned introduction of genetic screening for breast cancer predisposition, but focus on four different aspects. The first exercise is concerned with different forms of accountability; the second with different aspects of patients' rights; the third with different aspects of ethics; and the fourth with the different issues which can arise for advocacy. Each of the exercises could be used by a single one of the four groups of potential users. However, they could also be used with a group which included members of the four different groups or the different stakeholders in health and health care. They could really be members of the different groups or assume these roles for the purpose of the exercise.

Introduction

The purpose of this module is to provide an overview of patients' rights, citizens' participation and ethical frameworks in respect to health care systems. In order to do so, the module offers background in two areas: firstly, it provides a brief introduction to theoretical concepts, which are important for the understanding of these relationships. Secondly, it analyses the strategic options to strengthen citizens' participation and patients' rights in health care.

The recent surge of the patients' and consumers' rights movement in Europe is strongly influenced by developments in the United States which arose in the 1970s from a combination of factors: a higher level of public education; a rising awareness of the dangers of medical technology; distrust of experts and a professional crisis in health care; the rise of consumerism; and the civil rights movement. It has been claimed that the era of the patient has begun. Table 1 shows the level of dissatisfaction (very or fairly dissatisfied) of citizens in several countries with their health care system *(1)*.

Table 1. Level of dissatisfaction with health care systems (%)

Country	Percent dissatisfied	Country	Percent dissatisfied
Austria	4.7%	Italy	59.4%
Belgium	8.3%	Luxembourg	8.9%
Denmark	5.7%	Netherlands	17.4%
Finland	6.0%	Portugal	59.3%
France	14.6%	Spain	28.6%
Germany	10.9%	Sweden	14.2%
Greece	53.9%	United Kingdom	40.9%
Ireland	29.1%		

Source: Mossialos, E. Citizens' views on health systems in the 15 Member States of the European Union *(1)*.

The term "citizen" needs to be analysed further. Many roles of citizens as individual lay persons can be distinguished in health care: patient, insured person, employed person, consumer, customer, user, client, taxpayer, voter, member of a self-help group, parent or guardian caring for a child, or child caring for a parent. The legitimate representation of their interests is claimed by several groups: consumer organizations, self-help groups, self-appointed patients' representations, sickness funds, political and professional organizations. Their have diverse motivations: to assure market transparency and fair market competition or to achieve cost-cutting by informing consumers, to empower citizens and to strengthen consumers' rights, to advocate the needs of specific groups or to lobby professional interests.

From a neoclassical market perspective, demand for health services is determined by the decisions of individuals who spend health care money according to their preferences. However, demand in the health care sector is embedded in a complex system of financing, solidarity and accountability. Although demand for health services reacts flexibly to the resources available, there are differences from traditional markets: a surgical procedure is very different from a holiday trip, and patients may want to avoid this experience if possible. Provider-induced demand may play an important role in increasing the request

for health care services, while the availability of preventive services may lower the demand for specific services. "Regulatory" activities such as immunization, mass media campaigns, environmental sanitation or provision of clinicians' or patients' guidelines may have a marked influence on the delivery of specific services. Health rights may also be a factor in rationing and priority-setting.

It is, therefore, important to realize that the demand in the health care market is influenced not only by individual preferences but also by providers with a privileged level of information and specific interests and by population-wide public health measures. Accountability for health service delivery rests not only with economic market theories but also with aspects of health care legislation, professional conduct, public health, ethics and politics. It is evident that patients' rights and consumers' rights will gain importance in medical practice as well as in the health care market in the twenty-first century. A knowledge of theoretical frameworks of ethics and rights as well as strategies for their implementation is of great importance for health economists as they may serve to regulate or influence the market.

Theoretical concepts

Citizens' participation

Among the many roles that can be assigned to citizens in health care systems, the traditional label "patient" reflects a special situation of the sick individual which is characterized by illness, functional impairment or disability and increased vulnerability. Impairment ranges from a limited rationality due to pain and anxiety over somatic and cognitive functional deficits to a complete loss of consciousness. The patient–doctor relationship in this context is characterized by the special need of the sick individual to be protected and is best described as a relationship of trust. The role labels "consumer", "customer", "user" or "client" reflect an economic point of view and require that the sick individual is acting as a rational agent. He or she therefore needs full information and a transparent market. The doctor–patient relationship is understood as a business relationship. Role labels such as "citizen", "voter", "taxpayer" or "insured" reflect a rights-based approach and make reference to democratic values and basic rights. The doctor–patient relationship is here characterized by a contractual model.

Citizens' participation in the health care system is often discussed under the major headings freedom of choice, patients' rights, the autonomy of the patient and political influence. Freedom of choice and the autonomy of the patient are fundamental principles of health care ethics and will be discussed in this section. Patients' rights will be discussed later together with international human rights legislation. The quest for political influence of citizens on the health care sector at the systems level is the realization of a basic democratic right. The discussion of citizens' participation in the health care system can be focused by distinguishing levels of accountability. "Accountability" defines who has to report to whom and who is able to reward or punish actions. In health care systems there are various forms of accountability – clinical accountability, ethical accountability, professional accountability, legal accountability, economic accountability and political accountability.

Clinical accountability is the accountability for providing the highest possible standard of care. Clinical quality assurance may be discussed as to structure, process or outcomes criteria. Citizens or patients may be involved through participation in councils deciding on budget allocation to health care infrastructure, staff levels, training or quality assurance programmes. Moreover, they may demand information on complication rates, case mix or the volume of certain procedures in a given institution.

Ethical accountability is the accountability for the patients' autonomy and integrity. Ethical boards supervising biomedical research or supporting difficult choices help to secure the citizens' interest. At the systems level, legal mechanisms may have to protect these interests, for instance forbidding "gag clauses" (information restriction) in managed care systems or providing legal redress in the case of infringement of rights.

Professional accountability requires the setting of minimum standards for professional accreditation in health care. This accountability often lies with professional organizations and accreditation councils. The undertaking to observe codes of conduct is frequently part of the accreditation. These codes of conduct may also incorporate citizens' views.

Legal accountability relates to the legal regulation of health care financing and provision and may take place at national, regional or community level according to the constitutional provisions. Democratic procedures should assure citizens' representation.

Economic accountability relates to the efficient allocation of limited resources. There is considerable variation in practical resource allocation, as demonstrated by the variety of health care systems internationally and nationally. This variation reflects different priorities and political frameworks. Boards of overseers or councils deciding on resource allocation are entry points for the participation of citizens.

Political accountability relates health care decisions to the government and to society in a broader sense. In democratic states this means accountability to the citizens. It limits the influence of payers or providers on agenda-setting in health care. Citizens' participation in political issues may be more or less explicit, according to the political system in place.

The relative weighting of the various forms of accountability differs between countries. Tax-financed health care systems, as in the Sweden or the United Kingdom, emphasize the political accountability of health care decisions and also the professional accountability (e.g. delegating responsibilities to professional organizations). Market-oriented health care systems, as in the United States, put more emphasis on economic and legal accountability, as the health care market is regulated by a legal framework. Bismarck-type health care systems, as in Austria or Germany, prioritize professional and economic accountability in the framework of self-governance.

Exercise 1

Discuss the issue of introducing genetic screening for breast cancer predisposition under different forms of accountability. Each participant may choose a specific aspect of accountability.

Patients' rights

Patients' rights have become a high priority in health politics. The need for the development of patients' rights emanates from a new role that informed patients want to play, stemming from scientific, ethical and moral concern, and the human rights movement in health care, including experience with (mis)managed care. Patients' rights as **health rights** can be linked to human rights legislation, for example the Universal Declaration of Human Rights, the International Covenant on Social, Political and Cultural Rights, the European Social Charter or the European Charter of Fundamental Rights (http://www.europarl.eu.int/charter/, accessed 6 November 2002). Article 3 of the last-named affirms the right of informed consent, article 34 the right of access to social security and article 35 the right to preventive measures and health care at a high level, and article 38 protects consumer rights.

The "right to health" is often not explicitly specified in identifiable and legally binding obligations. Health and human rights as interlinked concepts, however, are a promising new avenue of practical and scientific progress in public health. The articles of international human rights documents follow four human rights principles: equity, dignity, participation and justice. These fundamental aspects of human rights legislation can be found in patients' rights documents under more specific formulations, e.g. respectful treatment, confidentiality and privacy, equitable access to information and facilities, and provision of mechanisms for legal redress (ombudspersons, patients advocacies, litigation, etc.).

Generally, there is a distinction between "negative" rights, which assure freedom from infringements of certain essential liberties, such as freedom from inhumane or degrading treatment, and "positive" rights, which specify entitlements like the right to decent living conditions. Negative rights have been much less controversial in the past than positive rights, the fulfilment of which may require changes in the social systems of states.

What are the potentials of a human rights approach to the health of individuals and of populations? It has been proposed to direct research in the field of health and human rights in three directions:

- first, towards the health effects of human rights violations;
- second, towards the human rights effects of health service provision or legislation; and
- third, towards the investigation of the mechanisms underlying the relationship of health and human rights.

This approach reflects a comprehensive understanding of health as expressed by, for instance, the Ottawa Charter on Health Promotion *(2)*. The political, social and psychological mechanisms underlying the relationship of health and human rights deserve attention. Political influences causing disparities in health status relate to the availability, accessibility, acceptability and quality of health care, external environmental or workplace factors, issues of governance, the globalization processes, legislation or the provision of information, among other things. The effect of social inequality on health is well established, as is the association with social class, race or ethnicity, gender, family and social networks, or work. Among psychological determinants of health, interactionist concepts are of special interest for the field of health and human rights. They focus on the health effects of the quality of relationships.

It is claimed that the patient is not only made vulnerable by illness, but also by the institutional processes of care and cure and the traditional role of the sick which legitimizes some privation of autonomy. The American Hospital Association issued a patients' bill of rights in 1972 in recognition of this special situation, and a national bill of patients' rights has been proposed for the United States *(3)*. In 1996 the WHO Regional Office for Europe issued a Declaration on the Promotion of Patients' Rights in Europe as a common European framework for action following the Amsterdam Consultation on Patients' Rights *(4)*. This document contains specific sections concerning human rights and values in health care, information, consent, confidentiality and privacy, care and treatment and their application. Patients' rights and citizens' views were endorsed by the Ljubljana Charter on Reforming Health Care of 1996 *(5)*.

There are voices in favour and against elaborating patients' rights further. An explicit consideration of health rights and of the patients' perspective however fits well with a general democratic evolutionary process in many countries. The provision of reasonable standards of care is of equal importance for countries with a poor health care infrastructure, for countries with national health systems and an ongoing debate over rationing and priority-setting, and for countries with libertarian market systems and a competitive managed-care environment.

Exercise 2

Discuss the issue of introducing genetic screening for breast cancer predisposition from a patients' rights perspective. Each participant may choose a specific aspect of patients' rights (human rights and values in health care, information rights, consent, confidentiality and privacy, adequate care and treatment).

Ethical frameworks

Distributive justice and the autonomy of patients are fundamental principles of health care ethics, next to beneficence (do good) and non-maleficence (do not harm). Inequality and inequity are concepts that are related to distributive justice. **Inequality** relates to differences in health states, e.g. between groups or individuals defined by socioeconomic status, sex, ethnicity or place of residence. Although high quality health care systems will diminish such differences in health states, e.g. by comprehensive coverage and provision of services directed to the disadvantaged, it is clear that health inequalities will persist to a certain extent under any circumstances. **Inequity** relates to issues of fairness such as the access to health services, their financing and their practical provision. Inequalities in health outcomes, such as life expectancy, quality of life and satisfaction may, therefore, be influenced by inequities in the health care system. Measurement of health outcomes and their comparative analysis for vulnerable subgroups may contribute to assuring greater levels of equity of health care and equality of health states. It is important to note that distributive justice and efficient allocation of resources may sometimes be at odds.

It is claimed that the institutional processes of care and cure and the traditional role of the sick legitimize some privation of autonomy. Patients' autonomy comprises the meanings of free action, effective deliberation, authenticity and moral reflection. Free action focuses on health rights such as the right to decide on treatment options and effective deliberation on the rationality of the decision-making process in view of information levels and cognitive ability. Authenticity requires the consistency of a choice with personal preferences and life plans, while moral reflection makes reference to consistency with beliefs and values. The information given to the patient on his or her health state and options for treatment, the right for him or her to adequate access to health care facilities, self-determination and free choice of health care provider, as well as issues regarding consent to treatment, participation in studies and participation in teaching of health care professionals are all related to choice. They are part of most charters of patients' rights and hence are important procedural and structural aspects in the evaluation of health care systems and their outcomes.

Beneficence relates to the efficacy and effectiveness of health care, non-maleficence to risks and adverse events of medical diagnosis or cure. It is clear that, generally, the risks and benefits of medical interventions have to be counterbalanced.

It is important to be aware of the broader conceptual framework within which health care systems operate. Frequently a utilitarian economic framework is used in the evaluation of health care systems. This aims at the maximization of the aggregated health state, or health gain, for a population in respect to resources spent. To this end it is bound to conflate a multidimensional health state into a single number – a "utility" – for comparative evaluations such as cost-utility or cost-benefit analyses. Considerable work has been done supplementing traditional life tables and mortality statistics with morbidity-oriented utility measures such as quality-adjusted life years (QALY) or the disability-adjusted life years (DALY) used for the "global burden of disease" study. These utilities value not only the quantity of life years, but also their quality. Their values are summed up across a population or population

subgroup (e.g. a defined group of patients), and high losses of single individuals may be balanced by a net benefit for the group as a whole.

Consequent applications of the utilitarian framework, e.g. the creation of league tables of preferred health care interventions (State of Oregon in the US) or the comparative evaluation of health systems performance *(6)* have met considerable resistance and criticism. While utilitarianism favours the effective delivery of services with benefit for everybody's quality of life, egalitarian ethics in contrast focus on the worst-off in society and their rights and would regard a disproportionate allocation of resources to these individuals as fair. In practice this could mean that under one health care ethic the allocation of resources, e.g. to dental care, is preferred, as this has some benefit for a large number of people, while under another ethical framework organ transplantation or dialysis are funded in order to save the lives of the worst-off at high costs.

Exercise 3

Discuss the issue of introducing genetic screening for breast cancer predisposition from an ethical perspective. Each participant may choose a specific aspect of ethics (utilitarian concern for the aggregate good, egalitarian concern for the worst off, issues of inequality, inequity, free action, effective deliberation, authenticity or moral reflection).

Strategies for implementation

Advocacy and patient empowerment

The health rights approach is potentially an effective way to advocate change for the protection and promotion of health. The following are examples of questions that could be asked.

- Are there provisions to guarantee fair participation in decision-making?
- What are the health rights infringements of a proposed legislation?
- Do patients or citizens have the possibility to file complaints?
- Is personal dignity protected?
- Is there discrimination between population subgroups?

Although the United Nations have installed a regular reporting system on the fulfilment of human rights in their member countries, this is not specific for health care and may miss more subtle or hidden structural infringements of health rights. Several models of advocacy exist within a rights-based approach to fill this gap: the contract model of citizens' advocacy, the self-advocacy model, a collective or corporate political advocacy and the advisory casework model of consumer self-help groups.

Examples for actions are a health rights assessment of pending legislation, a human rights-sensitive approach in the evaluation of health care, the promotion of information rights, installation of ombudsman systems, patients' advocates and patients' rights charters, the confidentiality of personal data including genetic information, participation in decision-making, rules on terminal care and palliative medicine, monitoring of abusive practices in psychiatry, legislation against genital mutilation, restrictions on compulsory treatment, rules on experimentation on humans and especially on vulnerable persons, care for migrants' health and exploration of the ethical dimensions of genetic testing and manipulation.

For effective advocacy, the first step is to bring partners together. Eight categories of potential partner can be identified, and it is useful to have links to individuals in all these categories:

(i) the professional category (health professionals, legal professionals);
(ii) public institutions (state officials)
(iii) nongovernmental organizations working with advocacy and service delivery
(iv) intergovernmental organizations
(v) ordinary citizens
(vi) patients
(vii) payers
(viii) providers/the industry.

The second step is the definition of points of entry. Five entry points can be defined:

(i) the policy-making process (e.g. councils and boards)
(ii) the norm-setting environment (professional organizations, legislature, IGOs)
(iii) the service delivery area
(iv) research agenda-setting
(v) education.

Advocacy can benefit from voluntary help, but effective action requires planning and, as a third step, funding, which may come from the potential partners listed above. Regarding the planning of actions, a typology of patient-empowerment, with options ranging from **moral suasion** through **formal political control** to **countervailing power**, has been proposed. Institutions for moral suasion could include patients' organizations, ombudspersons and patients' advocates. More formal medico-legal options are medical litigation laws or settlement councils. Economic influence can be exerted by free choice of the insurer (the payer), physicians and hospitals (the providers). More formal political control is instituted by a democratic legitimization of finances and the health services infrastructure. Patients' participation in treatment decisions is supported by the right to an option for a second medical opinion, shared decision-making or free access to medical specialists. Countervailing power is instituted by direct budget control or the budget relevance of the patients' choice of providers.

Exercise 4

Identify and discuss issues for advocacy arising from a planned introduction of genetic screening for breast cancer predisposition.

Legal provisions

There is a fear that expanding the privatization of health services restricts access to them to individuals who are privileged enough to participate in the health care market. In response, a debate has begun on supplementing economic rationalist arguments by rights-based legal standards of care for everybody. The right to health often exists only in statements of principle and has not yet been translated into positive, legally binding obligations at national level. The health rights approach constructs health as a legal entitlement, not as a privilege, a commodity or a product of charity. Laws may concern the prevention of violations of health rights ("negative" rights), or their fulfilment ("positive" rights). A monitoring capacity for the observation of health rights can be created, and the public can be informed of their health rights through the mass media and education. It is claimed that the right to health is

inextricably linked to other human rights and that they should be promoted together in a multifaceted way.

Generally three legal strategies can be distinguished: (i) not to create provisions for patients' rights, (ii) explicit parliamentary legislation of patients' rights, and (iii) the drafting of patients' rights charters by non-parliamentary conventions. A WHO-sponsored Consultation on the Development of Patients' Rights in Europe held in Gothenburg, Sweden in 1997, differentiated between European Member States which had endorsed their own national patients' rights charters (e.g. France, Ireland, United Kingdom), which had patients' charters at an institutional level (e.g. Austria), where such charters were in preparation (e.g. Sweden) or were patients' rights incorporated into different laws with varying specificity concerning patients' rights (e.g. Germany). Since then, some states have set up national patients' charters, while documents in other states have come under critical discussion.

A legal framework also has its disadvantages. The first limitation is the restriction of the obligations of the state to individuals living within its jurisdiction. This is at odds with increasing globalization and the transnational aspects of securing health care, e.g. in the European Union. The second limitation is its legalism and emphasis on the individual with highly formalized rules of process and evidence. This process may "decontextualize" and break down citizens' experiences of violations of rights and thereby disempower them. Third, the legal framework may slow down the dynamics of social change.

Health rights in health care assessment

Some problems are to be expected from the encounter of an egalitarian, rights-based approach with the current utilitarian framework of economic evaluation. This section suggests potential problem areas and strategies for overcoming them. Its speculative nature should be kept in mind, however. Only time will tell to what degree these problems and their solutions will influence the evaluation of health systems in the future.

The first problem area relates to the priority problem, that is the **recognition of a plurality of dimensions of evaluation**. This problem has been discussed in the past between economists on one side and health psychologists and outcomes researchers on the other side. There is continuing dispute about the validity of multidimensional constructs of physical and mental health in a single figure utility. The argument on this issue will gain new motion under a rights-based perspective, this time related to social and political ideas. It may be questioned whether fundamental aspects of health care, such as dignity or non-discrimination, can be traded against less fundamental dimensions such as satisfaction or even be disregarded completely. This may lead to the straightforward rejection of utility-based approaches of outcome assessment.

John Rawls, the principal proponent of egalitarian ethics, suggested the introduction of a "lexical" or **hierarchical** order *(7)*. This implies that an evaluative dimension comes into play only if those previous to it are either fully matched or do not apply. This leads to the question of which dimensions should be given priority if a hierarchical order of principles is accepted. In analogy to the **priority of basic liberties**, an equal right to the most extensive basic entitlement to health care compatible with a similar entitlement for others could be favoured.

"Efficient" systems can produce unequal access to health care and health inequalities, resulting in a discussion of the trade-off between equity and efficiency. Such social and economic inequalities are accepted in an egalitarian framework only so far as they are to everyone's advantage. Egalitarian ethicists generally give justice priority over efficiency and welfare. They may argue that the priority

of liberty and justice over the accumulated utilities assures the observation of basic human rights and health rights, e.g. standards of care compatible with human dignity, non-discrimination, participation and the right to seek legal redress against unfair treatment or denial of care. More discussion is needed about the minimum standards of a health care system that have to be met prior to further assessment of, for instance, the efficiency of resource allocation.

Independent of these pending issues, it is likely that the assessment of health outcomes in a rights-based context will result in a three-step procedure. The first step is the analysis of the fulfilment of basic health rights (priority of basic liberties). Such basic rights are typically:

- respect for the dignity of the person
- information on the patient's state of health and options for treatment
- access to adequate care
- observation of the patient's autonomy
- informed consent
- free choice
- justice and the ability to seek legal redress.

In a second step the general states of health or specific health care outcomes for vulnerable population subgroups or individuals are analysed to control for unacceptable inequalities (the priority of justice over efficiency and welfare). These subgroups may be defined by, for example, socioeconomic status, sex, age, place of residence or ethnicity.

The third step is the assessment of aggregated utility-based outcome measures across populations (such as the DALY-based measurement of the burden of disease) and advanced comparative economic evaluations (cost–effectiveness analyses, cost–utility analyses or cost–benefit analyses) to assure allocative efficiency. In short, the traditional economic evaluation of health care may be preceded in the future by a rights-oriented evaluation.

Instruments for the standardized assessment of the fulfilment of health rights or patients' rights are rare. Qualitative assessment can be based on participant observation, expert interviews or focus groups. Quantitative assessment may entail the questionnaire-based assessment of the fulfilment of the entitlements of patients' rights documents in populations or patient groups. Health rights have been discussed under their fundamental principles of dignity, non-discrimination, participation and justice, i.e. the possibility to seek legal redress. Instruments that are designed to measure health rights should capture all four aspects in typical health care settings. Patients' rights are more specialized and have been detailed above. Instruments should cover these aspects, but little work has been done on their empirical assessment so far. Subgroup analyses directed towards non-discrimination can be based on a broad array of outcome measures, ranging from life expectancy to utility measures.

Implications

Demand in the health care market is influenced both by individual preferences and by providers and public health measures. Accountability for health service delivery thus rests not only with economic market theories, but also with aspects of health care legislation, professional conduct, public health, ethics and politics. It is evident that patients' rights and consumers' rights will play increasingly important roles in medical practice and in the health care market in the twenty-first century. Hence, knowledge of (i) theoretical frameworks of ethics and rights and of (ii) strategies for their implementation, is of great importance to health economists when they are regulating or influencing the market.

Much conceptual and legal work has been done in the context of patients' rights and their advocacy. In the words of the late Jonathan Mann, a human rights analysis has the potential to "disaggregate a seemingly overwhelming problem into many component parts capable of being acted upon" *(8)*. This disaggregation of complex problems, however, requires suitable analytical tools. There is a lack of standardized and validated assessment tools for empirical research on human rights and health. Certain situations require different approaches such as expert interviews, participant observation or focus groups. Moreover, standardized strategies need to be developed to assess health care from a rights-based perspective.

Case study: genetic screening for breast cancer[11]

Scientists from the National Institutes of Health in the United States showed that three specific alterations in the breast cancer genes BRCA1 and BRCA2 are associated with an increased risk of breast, ovarian and prostate cancers. In the largest study to date involving direct testing for these cancer-susceptibility genes in a general population, the researchers found that, on average, women carrying one of the three alterations have a 56% chance of getting breast cancer by the age of 70 (compared with a 13% chance for women without the alterations) and a 16% chance of getting ovarian cancer (compared with 1.6% for non-carriers).

The study involved more than 5000 Ashkenazi Jews (those with origins in central and eastern Europe, comprising about 90% of the 6 million Jews in the United States) from the Washington DC metropolitan area. Each of the 5318 volunteers donated a blood sample from a finger-prick and filled out a brief family history of cancer. DNA from the blood samples was tested for three alterations: two in the BRCA1 gene (185delAG and 5382insC) and one in the BRCA2 gene (6174delT). The DNA analysis showed that 120 of the volunteers had one of the three mutations (2.3%).

The researchers calculated that only about 7% of the breast cancer in Jewish women is due to these alterations in BRCA1 and BRCA2. Likewise, the vast majority of breast cancers in non-Jewish women are not due to inherited alterations in these genes. Many of the over 100 alterations in each of the BRCA1 and BRCA2 genes identified in cancer-prone families are unique to a single family. In a few circumstances, identical alterations have been found in multiple families. Besides Ashkenazi Jews, recent studies reported mutations that may be unique to Dutch, Icelandic or Norwegian families. To date, no other ethnic-specific mutation in the United States has been discovered with as high a frequency as the ones specific to Ashkenazi Jews. The frequency (1 in 44) reported in this and other studies is at least several times higher than estimates of all the mutations in BRCA1 and BRCA2 for the general US population. Although volunteers in the study will not receive their individual results, they will, if requested, receive a summary of the overall results of the study.

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[11] *Source:* http://www.nhgri.nih.gov/DIR/GMBB/BRCA/media_release.html (accessed 6 November 2002). The results of the research, which involved a cooperative effort between the Washington, DC, Jewish community and scientists from the National Cancer Institute (NCI) and the National Human Genome Research Institute, were published in the New England journal of medicine of 15 May 1997 *(9)*.

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