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The IPTS REPORT

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SPECIAL ISSUE: HEALTH POLICY

EUROPEAN COMMISSION
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ABOUT THE IPTS REPORT

The IPTS Report was launched in December 1995, on the request and under the auspices of Commissioner Cresson. What seemed like a daunting challenge in late 1995, now appears in retrospect as a crucial galvaniser of the IPTS' energies and skills.

The Report has published articles in numerous areas, maintaining a rough balance between them, and exploiting interdisciplinarity as far as possible. Articles are deemed prospectively relevant if they attempt to explore issues not yet on the policymaker agenda (but projected to be there sooner or later), or underappreciated aspects of issues already on the policymaker's agenda. The long drafting and redrafting process, based on a series of interactive consultations with outside experts guarantees, quality control.

The first, and possibly most significant indicator, of success is that the Report is being read. The issue 00 (December 1995) had a print run of 2000 copies, in what seemed an optimistic projection at the time. Since then, its circulation has been boosted to 7000 copies. Requests for subscriptions have come not only from various parts of Europe but also from the US, Japan, Australia, Latin America, N. Africa, etc.

The laurels the publication is reaping are rendering it attractive for authors from outside the Commission. We have already published contributions by authors from such renowned institutions as the Dutch TNO, the German VDI, the Italian ENEAand the US Council of Strategic and International Studies.

Moreover, the IPTS formally collaborates on the production of the IPTS Report with a group of prestigious European institutions, with whom the IPTS has formed the European Science and Technology Observatory (ESTO), an important part of the remit of the IPTS. The IPTS Report is the most visible manifestation of this collaboration.

The Report is produced simultaneously in four languages (English, French, German and Spanish) by the IPTS; to these one could add the Italian translation volunteered by ENEA: yet another sign of the Report's increasing visibility. The fact that it is not only available in several languages, but also largely prepared and produced on the Internet World Wide Web, makes it quite an uncommon undertaking.

We shall continue to endeavour to find the best way of fulfilling the expectations of our quite diverse readership, avoiding oversimplification, as well as encyclopaedic reviews and the inaccessibility of academic journals. The key is to remind ourselves, as well as the readers, that we cannot be all things to all people, that it is important to carve our niche and continue optimally exploring and exploiting it, hoping to illuminate topics under a new, revealing light for the benefit of the readers, in order to prepare them for managing the challenges ahead.

Preface

I would like to devote this issue of The IPTS Report to health related issues, an area in which changes in modern society are both posing new challenges and creating new opportunities. The sometimes perplexing development of a "health market", or the serious concern over bovine encephalopathy ("mad cow" disease) raise new questions to which answers must be sought. However, developments in telemedicine, miniaturization of surgical techniques, increasing life-expectancy, are also milestones on the way to a better quality of life.

Society today is caught in the crossfire between fear and progress, hopes and worries. Biotechnology has made huge achievements, for example in protecting crops against parasites, improved conservation of foodstuffs, new treatments for disease, and so on. But many people are afraid that we are playing at being the "sorcerer's apprentice", that we are going too far, without stopping to weigh up the risks for our health and environment. Science and research must respond to these concerns.

Between 1995 and 2025 the number of people aged over 65 will increase by 7%. Naturally, the fact that we have been able to improve life-expectancy to such an extent is good cause for satisfaction. But, will we be able to adapt our health systems and medical techniques to meet the specific needs of this population?

We are able to produce goods better and more cheaply, but we should take a lesson from the consequences of what has been called the "mad cow affair". To what extent do we master the risks? Once again, only science and research can provide us the answers to these complex questions.

The Commission is aware of the concerns of the European Union's citizens. The multi-faceted nature of developments in the life sciences can even make the notion of progress itself unclear. The Commission has thus decided to give priority to research activities in the health field. The new Research and Technical Development Framework Programme should devote a specific programme to it. This is a rational and well-thought-out decision. With the fantastic developments which are taking place before our very eyes, we need to know and reassure, understand and inform, and reconcile ourselves with the life sciences.

Edith Cresson

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SPECIAL ISSUE: Health policy

EDITORIAL

Health policy

Medicine and Public Health in Europe in the 21st Century

Georgios Mezelas and Dimitrios Trichopoulos

In this issue of the IPTS Report, distinguished authors contemplate the face of medicine and public health in Europe in the next few decades. They point out that market forces are necessary but not sufficient to match the interests of pharmaceutical industry with those of patients at large; they examine how the ever larger scale of food production and distribution has necessitated the introduction of strict new standards and why early warning systems and technologies need to be developed in order to prevent food-borne diseases from becoming major epidemics; they consider the role of a European health policy, and criteria for defining it. Its objectives and limitations are considered and they demonstrate how information technology in general and telemedicine in particular can make scarce expertise available to large numbers of health professionals and patients; and they indicate that minimally invasive surgery, through laparoscopy or endoscopy, could effectively address the imbalance between demand for, and supply of, surgical care. In this brief introduction we offer our vision of the health landscape in Europe, as it is evolving under the influence of scientific discoveries, technological developments and multi-dimensional social transformations.

We will consider, in turn: disease aetiology, pathogenesis and diagnosis; disease treatment; public health and health policies; and emerging ethical issues.

With molecular biology research expanding exponentially, and the human genome project advancing rapidly, nature will be left with few secrets about the structures and processes that affect human health and disease. Imaging technologies and molecular probes will vastly facilitate and accelerate diagnostic efforts. Improvement in treatment effectiveness, however, will be much more limited for at least two reasons. Correction of molecular damage is a far more complicated task than its recognition, and it is very difficult to predict whether corrective interventions will be risk-free. Moreover, we already are at the stage of diminishing marginal returns in our efforts to surgically treat cardiovascular disease and cancer. This should not be interpreted as indicating that progress will be impossible or minimal. Optimism, however, should be tempered by the recognition of limits imposed by our own structural and functional complexity.

It should also be recognized that in an ageing population like that of Europe, striking medical successes, for example effective treatment of half of the currently untreatable forms of cancer, will add no more than about one year to our life

expectancy. Causes of death do compete, and defeating one or more of them at the high-risk field of advanced age has little effect on overall survival. It is in this context that prevention of accidents should be a priority, but we rarely think of them in this way, particularly in the Mediterranean belt of Europe.

Ethical issues are likely to dominate health policies in the coming century. Rationing of health services may become explicit rather than implicit, particularly when the battle is fought in the over 80 years domain. Quality of life during the terminal years and quality of death will be dominant issues. Biology and technology may guide medicine to unprecedented success, and health policies may address equity issues more effectively than at any time in the past. A higher proportion of people than ever before will be able to comfortably reach advanced age. It will be a daunting challenge to infuse as much happiness as possible to the material comfort of these people, who frequently will walk alone the last path of their lives.

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Health policy

Bridging the Gap between the Interests of Patients and the Pharmaceuticals Market

Silvio Garattini, *Istituto di Ricerche Farmacologiche "Mario Negri"*

Issue: Rare diseases account for about 10% of pathology distributed in about 5,000 syndromes; hundred of millions of patients in developing countries suffer tropical diseases; variable percentages of patients with common diseases are resistant to otherwise successful therapies; the majority of patients exposed to life-long drug treatments do not benefit because there is little interest in establishing criteria to identify responsive patients; and it is often difficult to make a rational selection among drugs of the same therapeutic class because of the lack of comparative studies. These so-called 'orphan' situations adversely impact patients, who are deprived of potential remedies, and national health systems which bear an unnecessary financial burden.

Relevance: There are often discrepancies between the needs of some groups of patients and goals of pharmaceutical research objectives and the priorities established by national health systems within the EU. A need may exist for an agency dealing with these issues at European level.

Introduction

In a number of cases there is a clear lack of connection between patients' needs and the goals of pharmaceutical research

This article addresses the following basic question: 'Is research on drug efficacy and safety moving in the direction of the patient's interests or do other factors predominate, creating a gap between what is being done and what is needed?'. Briefly the answer is that in a number of cases, there is a clear lack of connection between patients' needs and the goals of pharmaceutical research.

The article gives examples illustrating the problem and proposes some solutions. The intention is not to make recriminations but simply to set out the facts as they stand and the apparent imbalances which are not addressed by the current framework.

Examples

Rare Diseases

Diseases are intensively researched either because they are frequent, such as cancer, or because they arouse strong emotions in the population, such as AIDS or -often- because they affect people who are well-known, eg. muscular dystrophy. However, many diseases are not the focus of significant research efforts just because they are rare.

It is difficult to define the term 'rare diseases', which is used to describe an important but neglected area of medicine. The only available definition was proposed by the United States Congress in the ORPHAN DRUG ACT. Under this 1983 law, whose aim was to encourage the

pharmaceutical industry to work on developing drugs with little commercial value, a disease is considered to be rare when it affects fewer than 200,000 US citizens. This explains why the term 'orphan disease' is often used in place of 'rare disease' and makes the term 'orphan drug' self-explanatory. On the basis of this definition, it can be calculated that 10 to 20 million US citizens, and probably the same or a larger number of individuals in the European Union (EU), suffer from any one of the 5,000 recognized rare diseases. This accounts for approximately 10% of all human pathological conditions.

Rare diseases can be hereditary or acquired, congenital or appearing only in adult life. Diseases like muscular dystrophy and multiple sclerosis are familiar to the layman, whereas others, like hemolytic-uremic syndrome and osteogenesis imperfecta are not. Given the wide variety, rare diseases fall into various fields of medicine including neurology, haematology, dermatology, orthopaedics.

The costs of rare diseases are enormous not only in terms of money but also in terms of human suffering. Medical expenses for certain rare disorders may amount to hundreds of thousands of dollars per year. For instance, type I Gaucher's disease can now be treated using the missing enzyme, aglucerase, now available in a pure form. However, the cost of life-long treatment is so high that aglucerase is known as 'the world's most expensive drug'. In terms of suffering, rare disease patients' are often severely handicapped, thus missing educational and employment opportunities. These patients' family members usually get very involved, both emotionally and from a practical point of view.

Researchers, physicians and health authorities all recognize that our knowledge is adequate on the etio-pathogenesis of many rare diseases but that there is still too little experimental and clinical research. Thus, the chances of therapeutic breakthroughs are negligible. In addition, even if there is interest in research on orphan diseases, scientists invariably face considerable organizational difficulties. An investigation by the U.S. National Commission on orphan diseases found that 47% of the investigators interested in rare pathologies had difficulty recruiting enough patients for research projects; 75% of patients reported difficulties in obtaining information about research projects they might want to take part in; 42% of practising physicians say they need printed information for their patients but are unable to find it.

The European scenario is no better. In Europe, the greatest obstacle to studies on rare diseases is the lack of specific expertise. Consequently, treatments are frequently inappropriate, ineffective and sometimes even harmful. Anxious families pay useless visits to doctors, hospitals and healers, especially when a sick child is involved. Even so, neither a systematic review nor an orderly classification of rare diseases is available. Indeed, many of these pathological entities have not even been identified satisfactorily.

Examples of the variety of treatments used and anecdotally reported to be effective could be given for many rare diseases. There is a clear need for randomized clinical trials (RCT) to validate current therapeutic regimens and to establish the value of new therapeutic approaches.

It is fair to say that rare disease patients suffer a double discrimination: they do not receive adequate medical attention and they have little hope of effective therapeutic strategies ever becoming available. The pharmaceutical industry which, by definition pursues profit, is keen enough to produce new drugs, even drugs of the 'me-too' variety, if the market is large enough.

Health policy

'Rare diseases' are often unfamiliar to the layman and fall into a wide variety of categories, nevertheless they account for 10% of all pathological conditions

The costs of rare diseases are enormous, not only in terms of money, but also in terms of human suffering

As might be expected, the pharmaceutical industry is not interested in producing drugs for such a small market

Health policy

Countries with a high incidence of tropical diseases are generally too poor to pay for drugs. Thus a billion people remain without protection against the infectious diseases to which they are exposed

Hypotensive effect does not necessarily translate into reduced mortality or morbidity

Predictably enough, they are not interested in producing drugs for a small market. This makes it impossible to assemble the substantial resources necessary to discover and develop new drugs.

Tropical Diseases

A similar situation is observed for diseases that are widespread, but almost exclusively in less-developed countries which lack the financial resources to pay for effective therapeutic options. Malaria, schistosomiasis, filariasis, trypanosomiasis are just a few of the diseases affecting millions of people for which remedies are still scarce, and research aimed at finding new drugs is confined to a handful of specialized centres.

Once again the lack of interest is backed by economic reasons. The pharmaceutical industry cannot afford research programs for this type of patient. In spite of the potentially large market, the countries with a high incidence of tropical diseases are generally too poor to pay for drugs, no matter how low the price might be. Thus, a billion people remain without protection against the infectious diseases to which they are exposed.

Programs to develop drugs against tropical diseases, which are mainly supported by WHO and by the US Army, are clearly insufficient and under-funded and are unlikely to provide a real answer to this awesome problem.

Drug Evaluation

There is little doubt nowadays that marketed drugs undergo tougher scrutiny than in the past to determine their safety and efficacy. However, there are a number of distortions at various levels and research in the patient's interest is sometimes against the drug producers' interests. Again, I will give a few examples.

The potential market for a certain class of drugs affects the amount of research done. For example, patients with hypertension are the target of a large number of basic and clinical studies. This is because hypertension is very widespread so, logically, the pharmaceutical industry's research effort is proportional to the projected sales. The remarkable number of potential consumers of antihypertensive drugs has spurred companies not only to spend large amounts of money developing active compounds but also to investigate thoroughly their mechanisms of pharmacological action. As a result, at least six major classes of antihypertensive drugs are known, i.e. diuretics, b-adrenergic blockers, a-adrenergic antagonists, inhibitors of angiotensin converting enzyme, inhibitors of angiotensine receptors and calcium antagonists. All these classes of compounds certainly reduce blood pressure, but the hypotensive effect does not necessarily automatically translate into a therapeutic advantage in terms of reduced mortality or morbidity. Studies aimed at assessing effects on hard end-points like mortality or morbidity are available only for a minority of diuretics and b-adrenergic blockers.

Therefore hypertensive patients have the same chances of receiving therapeutically active drugs as of receiving treatments which, while lowering blood pressure, have not been proved to have a real impact in terms of survival. Thus recently developed drugs with no proven impact on mortality or morbidity are likely to be more extensively prescribed than old drugs with demonstrated efficacy. This is because new drugs tend to be more expensive than older ones, so they offer larger margins for promotion.

For any given disease there is always a small proportion of patients who do not respond to drugs that are effective on the rest of the population. There are hypertensive patients who are difficult to manage with today's drugs. By the same token,

there are subsets of depressed individuals who do not benefit from antidepressant agents and people with gastric ulcer who are not healed by anti-ulcer drugs.

It would be interesting to clarify why there are non-responsive patients and whether a patient resistant to one drug is sensitive to other compounds of the same therapeutic class. Unfortunately, apart from anecdotal reports or promotional claims, no systematic studies have been made. Again, the interests of these subsets of patients are not taken into consideration, because they are less appealing to drug producers than the majority of the population.

For each drug that is the prototype for the therapy of any given disease or symptom, many other congeners are developed. In most cases, compared to the prototypic compound, congeners only have minor chemical modifications and offer no major therapeutic advantages. These products are justly known as 'me-too' drugs. For example, there are about ten angiotensin-converting enzyme inhibitors, more than 20 non-steroidal anti-inflammmatory drugs and about 25 derivatives of cephalosporin.

It would be desirable to establish how different congeners compare in terms of efficacy, adverse reaction profile and interchangeability. Unfortunately data are generally not available and controlled studies are designed only to establish the so-called 'equivalence' of products. In most cases, however, equivalence is not attained or demonstrated and differences in efficacy reach 10-20%, given the numbers of patients in most 'equivalence' trials.

Therefore, drugs with similar indications but unknown relative therapeutic potency are simultaneously available on the market. Drug promotion campaigns can therefore heavily influence physicians' prescriptions, so patients do not necessarily get the best available treatment. In this case too, it is not in the industry's interest to do serious comparative studies because the results might eliminate the less effective drugs from the market. Furthermore, if drugs belonging to the same therapeutic class showed similar efficacy, price differences would not be justified.

Some effective treatments, such as those based on hypercholesteremic, antihypertensive and platelet-anti-aggregating agents, must be administered for many years sometimes throughout life. Some of these drugs are quite expensive and must be prescribed to many patients in order to obtain benefits in only a small proportion of the population. Thus, the majority of patients are treated with no advantage, which dramatically affects the actual cost per life saved. For instance, 1,000 patients who have had a myocardial infarction must be treated with aspirin for two years to avoid 40 major adverse events (death or other myocardial infarctions). Similarly, 1,000 cases must be treated with simvastatin, a hypercholesteremic agent, for about six years to avoid 33 deaths.

If it were possible to design studies aimed at predicting which individuals are most likely to benefit from a certain treatment, the number of people exposed to the drug could be substantially reduced. This would eventually lead to far fewer adverse effects and to a reduction of the financial burden. These studies, however, are unlikely to be done. Industry is interested in treating the largest possible number of patients whereas national health services would like to cover the costs of medication only for those who benefit from treatment.

Conclusion

For these different reasons many patients do not receive optimal medical treatment. More importantly, they have no hope of improvement in

Studies tend not to focus on why one patient responds to a drug and another does not. Producers are more interested in average performance

Comparative studies of the large numbers of similar drugs available on the market are rarely carried out. Testing usually seeks to establish equivalence rather than differences

Studies to predict which individuals are most likely to benefit from a certain treatment would eventually lead to far fewer adverse effects and to a reduction of the financial burden on health services

Health policy

the near future because there is too little research, mainly because of economic reasons. It is clear that pharmaceutical companies cannot be forced into research which is not profitable and goes against the logic of marketing. However, it is reasonable to require that new chemical entities designed after lead compounds be tested for efficacy and side effects relative to the prototype drug.

These questions concern not only individual patients but the whole community, since health expenses are frequently covered by national health systems. The lack of therapies for rare diseases and for non-responsive patients pose an additional financial burden on national health systems. Important resources could be spared if sound comparative studies were made of drugs of the same therapeutic class, as this would permit the selection of the least expensive option. Finally, identifying the subsets of patients benefiting from chronic treatment would expose fewer people to useless drugs, with a proportional decrease in expenses for national health systems.

Unfortunately, we are unlikely to see any improvement if society continues to delegate drug development and evaluation almost entirely to the pharmaceutical industry. This is not meant to underrate the significant contributions industry has made to human health. The pharmaceutical industry, however, needs continuous incentivation in its efforts to produce new drugs. The time has come to recognize that industry alone cannot cope with all the needs of patients, and that sometimes its interests conflict with those of national health systems. Thus, more space must be allocated to research into questions of public interest.

It is hoped that the 5th Framework Programme, in conjunction with other initiatives, could help to complement the industry's drug development and direct more resources towards meeting the needs of patients and health systems

Recommendations

To cope with the above needs, an entity could be established whose mission would be to highlight problems and priorities. This entity would be a totally independent body distinct from the one for approval of new drugs (EMEA), must be able to finance research in the name of public interest. It would obviously be wasteful if each European country were to implement such a program separately. Although some local problems may require specific solutions, most are common to all European countries, so it is justified to propose a joint effort.

There is, of course, already a Biomed program of the EU which could take on the task. However, it may be suggested that:

a) biomed collects answers to the researchers questions but, up to now, it has not been able to propose specific topics of interest;

b) the kind of studies proposed here require resources which are an order of magnitude larger than those available today.

The 5th framework program of the EU might offer a great opportunity to direct biomedical research towards the needs of patients and national health systems, with the aim of complementing industrial research programs. The following points illustrate potential areas of priority.

1. Rare diseases. In vitro and in vivo models are needed for rare diseases. New opportunities offered by cellular and molecular biology techniques can be exploited. Tissue culture, particularly using cells from transgenic and 'knock-out' mice, is an excellent way of testing the beneficial effects of chemical compounds. The EU countries may pool their financial resources to avoid duplication. This is an area where collaborative efforts are needed, as no single research group has all the necessary know-how and facilities to cope with the complex process of transforming ideas into marketable drugs.

A European Network of Clinical Trials (ENTC) on rare diseases needs to be set up, with the collaboration of existing centres. There is no need to stress this point because any effort by a single

country is bound to fall short, given the rarity of these patients. Collaboration on the European scale is absolutely essential to recruit enough patients to obtain statistically significant results in a short time.

A program to help patients with rare diseases should include an information centre open to physicians and to the general public. These centres should provide the means of tracking down patients with specific rare diseases, by keeping specialized registries available to interested investigators. The centres should also act as repositories for orphan drugs, particularly those not yet available on the market. Epidemiological studies and investigations on the natural history of rare diseases could be usefully coordinated by these centres.

2. Tropical diseases. Existing programs need to be upgraded, such as the WHO TDR (Tropical Disease Research) in order to expand research for drugs for diseases such as malaria, schistosomiasis, trypanosomiasis and filariasis. In vitro and in vivo tests exist but they could be improved, and more highly specialized centres are needed to do this. We need better knowledge of the physiology of parasites and must test a larger number of chemicals. The creation of better health infrastructures so that clinical trials could be organized properly in developing countries, where patients are available, is a difficult task, but has high priority.

3. Drug evaluation. Existing drugs, particularly those for chronic and severe diseases, need to be evaluated better. If a drug is to be taken life-long, the one's offering the greatest beneficial effects and most favourable profile of adverse effects must be selected. Thus, comparative studies are need. Usually these require large numbers of patients, long time-frames and cooperative groups with a suitable organization framework. Drugs of the same class should be compared on hard rather than surrogate end-points. Pharmaco-economic evaluations should be conducted within the framework of clinical trials, as these are bound to give national health systems important indications about costs and benefits. Controlled trials are needed to sort out which patients really benefit from chronic treatments. Hypocholesteremic and anti-aggregating agents are potential candidates for this type of trial. These could spare over 90% of patients from ineffective treatment and would greatly reduce the financial burden on national health systems.

Keywords

5th framework program, health care, rare diseases, tropical diseases, drug evaluation

References

- Haffner, Prospectives & Santé 1988, 45: 43-48.
- S.Garattini, Science 1997, 275: 287.
- Schieppati et al., J. Rare Dis. 1996, 3(II): 7-12.
- Scandinavian Simvastatin Survival Study Group, Lancet 1994, 344: 1383-1389.
- Antiplatelet Trialists' Collaboration, BMJ 1994, 308: 81-106.
- van Zwiete, J. Hypertension 1996, 14 (suppl. 2): S135.
- Report of the National Commission on Orphan Diseases. U.S. Department of Health and Human Services. 1989. NOTE: The complete Commission Report is published in two parts in Journal of Rare Diseases, Vol. 2, Nos. 3 & 4.

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Health policy

Early Warning System and Technologies to Prevent Food-borne Diseases: The US Experience

Robin Yeaton Woo, Kristin Digiulio, Lester Crawford,
Georgetown University Center for Food and Nutrition Policy

Issue: Driven by increasing world demand for food, the intensive nature of today's agricultural technologies and intricate food distribution systems create conditions that enable food-borne pathogens to thrive. Detection-diagnosis-surveillance-control-communication networks are seriously inadequate in coping with emerging pathogens such as E. coli 0157:H7.

Relevance: In the past food-borne disease outbreaks tended to be local or regional matters, but today they are national and global concerns. The US has initiated sentinel site and Hazard Analysis and Critical Control Point (HACCP) systems. The basic concepts of these systems and their supporting technologies and the experience acquired could provide useful background information for other countries seeking to prevent and control food-borne illness.

Introduction

Given the importance of food safety, the US recently promised to commit US $43.2 million to enhance food safety programmes, including a national early warning system for food-borne illness, improved seafood safety inspection, and expanded food safety research, risk assessment, training and education[1]. The responsible agencies -Health and Human Services, Agriculture, and Environmental Protection- were given three months to develop a strategic plan and submit a report outlining how best to improve food safety.

The strategic plan that was announced May 12, 1997, focuses on the five major points presented in Box 1. Most important is the financial commitment to make the plan work. The initiative places high priority on research, which is supported by the greatest budget allocation. Notable emphasis has been placed on prevention through enhanced Hazard Analysis and Critical Control Point (HACCP) measures, increased research and development of detection and diagnostic kits, a national early warning system that could isolate incidents and sources of infection, and public education. The public-private effort will provide auxiliary funding to establish an effective food safety campaign, an example of the trend towards innovative partnerships utilizing private funds and expertise for the common good. Finally, the proposal calls for increased coordination among the many local, state and federal agencies responsible for food safety, but falls short of creating one comprehensive agency. A single food regulatory agency may seem the logical and most efficient approach, but political realities in the US

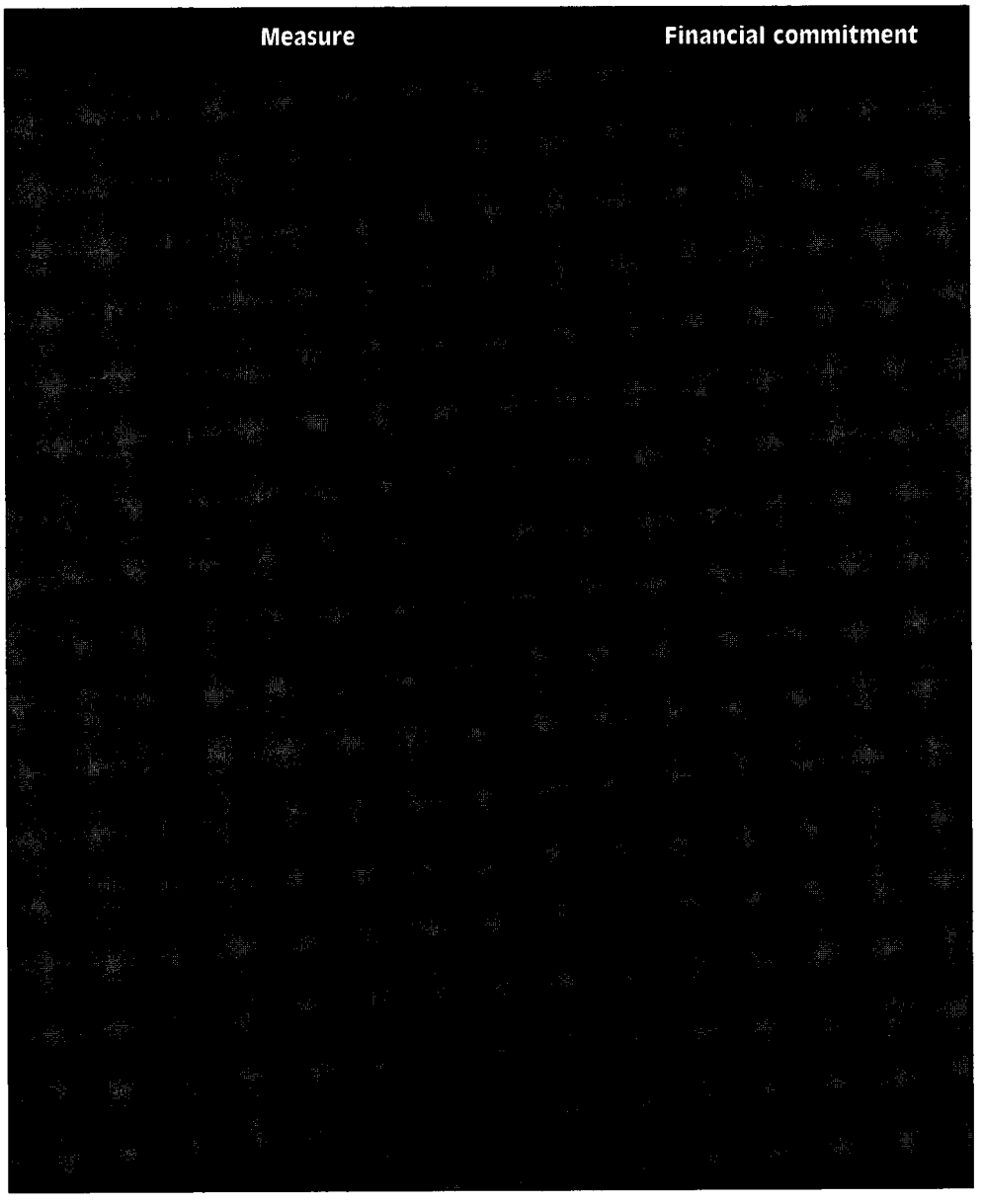
make it a virtual impossibility, although this does not rule out the viability of a single-agency approach in Europe.

HACCP

The Hazard Analysis and Critical Control Point (HACCP) system is an integrated, preventative approach that looks at the entire process that brings food to the consumer. Developed in the 1960s by Pillsbury for NASA to ensure the safety of foods on manned space missions, HACCP offers a comprehensive and scientific approach to food safety.

Increased use of HACCP has facilitated harmonization of international food safety regulations (e.g. the United Nation's Codex

Box 1. New US Five Point Plan



Health policy

Alimentarius Commission has endorsed HACCP as a regulatory tool). In the US, the Food Safety and Inspection Service (FSIS) published a final rule in July 1996 establishing the use of HACCP in USDA-inspected facilities.

HACCP is particularly suited for dealing with microbiological contamination because it emphasizes prevention, not just detection, of contamination at all points along the chain. It is a decentralized approach where the focus is not on micro-management by regulatory authorities, but on all players in the food chain, making the end product as safe as possible.

A comprehensive HACCP approach relies on safeguards from the farm all the way to the consumer's table. A plant must conduct an analysis of its production process to determine where there are potential risks to food safety and to identify critical control points (CCPs). At CCPs, controls, such as adequate chilling or food handler hygiene, can be applied to decrease risk. Stringent monitoring of CCPs and detailed records are vital.

Risk assessment includes qualitative analysis of the hazard and quantitative risk management

As the road from producer to consumer becomes longer and more convoluted, a systems approach like HACCP becomes critical. After leaving the processor, food is still vulnerable to contamination. In September 1994, for instance, Salmonella infected an estimated 224,000 US citizens nation-wide. Subsequent investigation showed that the culprit was an ice cream pre-mix transporter, an improperly sanitized truck previously used to haul unpasteurized liquid eggs. Contaminated ice cream was then distributed throughout 48 states.

A recent outbreak of hepatitis from Mexican strawberries demonstrates the added food safety vulnerability posed by international movement of foodstuffs. Although it is not yet clear where the contamination by Hepatitis A occurred, the disease has been spread to sites throughout the western US. This incident has raised the question of mandatory country-of-origin labelling for food products. Members of the US House of Representatives Agriculture Committee are currently considering proposing this option, but it is sure to be a contentious issue.

As food safety is a farm-to-fork endeavour, education of food handlers, both at public establishments and at home, will aid in reducing food-borne illness. Recently, the US Department of Agriculture (USDA) mandated food handling labels on meat products to provide information on proper storing and cooking temperatures. A meat and poultry hot-line is available to address consumer concerns about proper handling and storage. The USDA's Cooperative Extension System is establishing public and private partnerships to develop innovative education programs that will change food handling behaviours.

While measures to prevent and control food-borne illnesses can be taken, the resources to do so are not limitless. The extent of the associated risk must be evaluated, for example, with specific products, disease organisms, or susceptible human sub-populations to prioritize efforts. Accordingly, the new US plan calls for increased use of improved risk assessment methods. The World Trade Organization's Agreement on Sanitary and Phytosanitary Measures requires risk assessment as part of their safety protocol. The risk assessment process consists of a qualitative analysis of the hazard, followed by a quantitative risk management approach. Risk assessment frameworks have traditionally been used for chemical hazards, but the unique nature of microbial contamination calls for new methods to better characterize and quantify potential risks. Predictive microbiological models have been developed by, among others, the Agriculture

Research Service of USDA and the UK's Ministry of Agriculture, Fisheries and Food. These quantitative models, which are still being refined, provide valuable information in identifying CCPs and developing a working HACCP plan.

Early warning system: The sentinel sites

Food-borne diseases in the US and elsewhere historically have been reported on a passive basis. The US Centers for Disease Control and Prevention (CDC) have relied on state and local health authorities to report cases of disease. In fact, an estimated 95% of sporadic cases go unreported.

Comprehensive surveillance would require a chain of increased awareness beginning with:
(1) realization by infected victims that their illness may be due to something they ate and that it is important to see
(2) a physician who, upon verifying the nature of the illness to be food-related, would report the incident to
(3) a local public health authority, who would investigate the origin of the incident, identify related cases, and report to
(4) the CDC and a world network system. Measures to prevent further infection by the source would be implemented at each step along the way. Unfortunately, this idealized system can break down early on in the chain.

In the US approach an active surveillance system, where public health authorities systematically solicit information on food-borne disease cases, can identify risks to public health posed by food-borne pathogens. Inquiries would be made of physicians by local health officials, and of local health agencies by the state, and of the states by CDC. This system would generate more accurate numbers for risk analysis, for instance of the number of people in different age groups affected by particular pathogens, the frequency of particular modes of infection, and the relative vulnerability of different food stuffs to contamination.

In 1995, USDA's Food Safety and Inspection Service, the US Food and Drug Administration and CDC collaborated to create a new surveillance program, the Sentinel Site Study, now known as FoodNet. This programme uses active surveillance to enhance data collection and establish baseline levels of food-borne disease incidence in the US. Most importantly, this programme reveals how best to establish a network responsive to new outbreaks and emerging diseases.

Active surveillance for food-related illness was initiated in five selected sites: northern California, Oregon, Connecticut, and the greater metropolitan areas of Minneapolis/St. Paul and Atlanta. In 1997, surveillance expanded to New York and Maryland, and an additional site will be added soon. Seven pathogens have been targeted as being of special concern: Campylobacter, E. coli 0157:H7, Listeria, Salmonella, Shigella, Vibrio and Yersinia. 1996, 7,259 laboratory-confirmed diarrhoea cases were attributable to these seven pathogens.

To coordinate data and develop predictive models, three simultaneous surveys are being conducted. A laboratory survey will determine adequacy of testing for food-borne pathogens. The physician survey will measure frequency of referral of patients for laboratory analysis of diarrhoea symptoms. The third survey will determine the eating and health care behaviours of adult and paediatric populations. Case-control studies have also been initiated to study patient behaviour prior to infection.

This programme has already been effective in implicating raspberries as the vector in an 1996 outbreak of Cyclospora in California. Five

Active surveillance, seeking data on outbreaks, can be an effective way to identify risks

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additional outbreaks in 1996 were identified and attributed to specific food vectors. Campylobacter was most frequently isolated from patients, followed in order by Salmonella, Shigella and E. coli O157:H7.

It is vital to enhance system effectiveness by incorporating new technologies as they are developed through basic research. For instance, new funds allocated for the programme will allow the development of a bacterial DNA fingerprint database. This will enable food safety experts to match the patient sample and suspect foods to identify the source of food contamination by genetic identification of the specific culprit pathogen, even if the source is remote from the incident. In the future, advances in genetic research may give this system the power to identify genes conferring bacterial resistance to anti-microbials, thus facilitating treatment as well as detection.

The new database of bacterial DNA fingerprints will be instrumental in tracking food-borne diseases to their source and identifying victims

Research and development of new technologies

Research to develop quick, reliable, and affordable methods of detecting low levels of pathogens is essential. At present, no such system exists for the identification of Hepatitis A or Cyclospora; and many of the tests we do have are prohibitively expensive, unwieldy, or take too long. A fast, easy test for specific pathogens or indicator organisms would allow frequent, simple in-plant safety checks and could greatly improve the HACCP plan. In the US approach it is hoped that funding of research and development of these new diagnostics will dramatically speed up their availability over the next few years.

Government funding of research on new diagnostics could dramatically speed up their availability

Research in microbial genetics will provide answers to how pathogens become resistant to traditional food preservation techniques such as heat and refrigeration, and genetic engineering of foods may provide new control strategies. Other physical control methods such as irradiation may be employed as well.

When the concept of food irradiation was first advocated by food safety experts, it met fierce opposition from both the public in both Europe and the US who feared ill effects from nuclear radioactivity. As with cooking, marinating or freeze-drying, food irradiation may cause slight changes in the biochemical constituency of foods. Thus, US federal law requires approval of the irradiation process as a 'food additive,' and irradiated products must be labelled as such.

The World Health Organization (WHO) has carefully and thoroughly studied all aspects of food irradiation for many years and has consistently found virtually no risk, coupled with impressive effectiveness. The WHO advocates the use of irradiation not only for food safety, but for food preservation. In so doing WHO has taken note that approximately one-third of the world's food supply spoils before it can be consumed. While it cannot replace proper food handling as the single most critical food safety measure, irradiation provides many benefits that we believe could solve some of the problems caused by food-borne pathogens (Table 2).

Despite regulatory approval, irradiation is not commonly used in the US because food purveyors and processors, unwilling to challenge consumer confidence, have bowed to pressures from activist groups seeking to prevent its use. There are also some unanswered questions about the long-term effectiveness of irradiation, and what effects re-irradiation might have on food safety and extended shelf life. Actual market tests show that consumers would purchase irradiated foods if educated about the benefits and safety of the irradiation process. Given the current problems in food safety, we feel that allocating funds to study

Box 2. Advantages of Food Irradiation

Benefit	Action	Foods

* Bacterial and fungal support and viruses are not affected by the most commonly used doses levels of irradiation

Source: Food Control , Vol. 7, No 2

re-irradiation and to improve awareness about irradiation would be effective in decreasing purveyor and consumer apprehension.

Global Impact

The US plans to develop additional mutual recognition agreements with its trading partners to ensure that imported foods are produced and manufactured under systems that offer comparable safety measures. The new funds provided by the new US food safety initiative will also provide technical assistance to foreign countries on safe growing and handling practices. Use of the HACCP system would be one way to ease regulatory harmonization across countries, as it facilitates establishment of 'equivalence' in safety measures.

Conclusions

We have reviewed here the recent US reaction to the increasing perils of food-borne illness -involving a comprehensive and adequately-funded strategic plan. Europe has the expertise to develop a strategy to deal with these issues.

Based on the US experience we would emphasize that basic research is the essential first step in any effective programme for ensuring food safety, characterized by the following principal components:

- funding for basic research and development of diagnostics and microbial control methods
- incorporation of state-of-the-art science and technology in a farm-to-fork approach
- involvement and increased awareness of health professionals and veterinarians to identify
- cases early in the chain of events
- education of consumers and commercial food handlers
- active surveillance facilitating an early warning system.

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Food purveyors tend to bow to consumer apprehension, and questions remain about the long-term effectiveness of irradiation and the effects of re-irradiation

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Keywords

food-borne illness, HACCP, irradiation, pathogens

References

- Lester M. Crawford and Eric. H. Ruff. 1996. A review of the safety of cold pasteurization through irradiation. Food Control 7(2):87-97.
- Food safety from farm to table: A national food safety initiative. US Government Report to the President, May 1997.

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Note

1- Announced by President Clinton on January 25, 1997, this is the first time the executive office has become involved in food safety issues in the US.

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European Health Policy: Defining Priorities

Elias Mossialos, *The LSE*

Issue: The slow pace of the development of a comprehensive public health policy at European level is the result of current legal, institutional and political frameworks. The search for clearly defined objectives and priorities continues, and there is need to establish a methodological framework to set public health priorities Europe-wide.

Relevance: Until recently, public health has held only a tenuous foothold within the European Community. But as a result of the crisis over bovine spongiform encephalopathy (BSE), public health will feature on the agenda of intergovernmental conference on treaty reform. Defining where the European Community can act in public health and which areas should remain the domain of Member States is a task still to be faced.

Introduction

The EU Member States' relative reluctance to further develop a European health policy framework may be because of the primary emphasis on economic issues in building the European Union. This may explain why health often comes onto the policy agenda only in specific relation to the needs of the Single Market, e.g. in areas such as product safety, health and safety at work, pharmaceuticals and medical devices and the free movement of professionals (McKee, et al, 1996).

The lack of co-ordination between policies, activities and programmes has been emphasized by several researchers and commentators as well as the public health community. There have been voices in support of the development of a Directorate General (DG) for Health since the early 1970s but nothing has come of this. The new institutional and legal framework introduced by the Treaty establishing the European Union in 1991 raised hopes that new policy developments were to be introduced.

This paper reviews the legal framework within which the European Union may act in the field of health policy. It then describes the current European Commission's public health priorities and suggests a methodological framework for priority setting in European public health policy. Finally the need for institutional changes is examined and a number of recommendations are examined and discussed.

Current European Commission's Public Health Priorities

The legal framework has evolved consistently since the founding of the Community in 1956, when its health concerns were limited to those related to occupational health in the coal and steel

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Until the 1991 Treaty on European Union little attention was paid to health at European level

The Commission has developed policies and is funding research programmes in certain key health-related areas

industries. The precedent in this initiative was that a small proportion of the sales of those products was used for research in public health protection.

The most significant provision in the field of health was introduced in the 1991 Treaty on European Union. The Treaty gave new competence in public health with the introduction of Articles 3(o) and 129.

Article 3(o) stipulates that the Community should contribute to the attainment of a high level of health protection. Article 129 identifies two areas for Community action: disease prevention and health protection. There are three means through which these objectives can be achieved: research, health information and education, and the incorporation of health protection requirements in the Community's other policies. However, harmonization of the laws and regulations of the Member States are specifically excluded.

In addition, Article 129 is not entirely clear concerning the responsibility of the Member States and the Commission in terms of achieving its objectives and in policy implementation. The obligation of achieving a high level of human health protection is laid upon the Community as a whole. The Community is also responsible for directing actions towards the prevention of diseases, in particular the major health scourges. It is not clear, however, what the major health scourges are, although the one mentioned, drug dependence, may from some points of view be considered to be neither primarily a health matter nor a scourge.

Pursuant to the provisions of Articles 3(o) and 129, the Commission defined eight priority areas for European Community action, following a long process of consultation and negotiation, on proposals made by the Commission, between the various EU institutions, Member States, and other interested groups. These areas are drug dependence, cancer, AIDS and other communicable diseases, health monitoring, injuries, pollution related diseases, and rare diseases. In addition, emphasis is placed on the dissemination of information and evaluation of those policies which are most effective (EC Resolution, 1993). It is not easy to establish these priorities and satisfy all the demands for action, but we do at least have a list of priorities on which to improve public health policy, or even to develop a comprehensive health policy.

The Commission has already developed policies in such fields as AIDS and communicable diseases, cancer, tobacco, drug dependence, health monitoring, the environment and health and safety at work.

Research programmes already exist directed at nutrition, cardiovascular diseases, mental illness and the problems associated with ageing. The Commission is now preparing draft communications and proposals for European Parliament-Council decisions concerning five year programmes of actions on rare diseases, pollution-related diseases and the prevention of injuries. It has also prepared drafts -with a view to adoption in 1997- of communications and proposals for European Parliament Council instruments concerning safety and self-sufficiency of blood. The development of methodologies and capacity for the evaluation of health and health-related programmes and measures is foreseen by the health monitoring programme and preparatory work has already been carried out with representatives of Member States.

Establishing Priorities at EU Level: A Methodological Framework

Under the principle of subsidiarity and in light of the limitations of Article 129 and the general character of Article 3(o) of the Treaty of the

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European Union, the development of all-embracing health policies is the responsibility of each EU Member State as each one is faced with a unique pattern of circumstances and challenges to the health of its population. This diversity is partly a result of differences in the complex interplay of government policies and consumer preferences as they affect factors such as tobacco, alcohol, diet, and transport as well as biological and environmental factors. However, precisely because of the existence of differences, there is significant scope for Member States to learn from each others' experience as they develop their own policies. There are also many areas in the field of health promotion and disease prevention where European Community policies have an important role, ranging from agricultural policy and tax harmonization to safety legislation. Some of these problems as well as efforts to integrate health into other Community policies are described in two reports already published by the Commission (EC Report on Integration of Health Protection, 1996 and 1995). The integration of public health in other Community policies was also raised in the Commission's Green Paper on 'Commercial Communications in the Internal Market' (EC,1996) which deals with reducing barriers to the free movement of goods and services between Member States, in order to promote more efficient marketing of commodities, and thereby make available to EU citizens more goods at lesser cost. The criteria that could be used to define European Community functions are presented in Box 1.

Areas for Community-wide policy developments could include communicable disease surveillance, the free movement of people and goods including medicines and medical devices, the collection of comparative data, the standardization of definitions, health technology assessment, environmental health policies, and exchanging information on best practice in health care.

Following the Alma Ata declaration of 1978, the World Health Organization developed a series of targets known as the 'Health for All' targets. These set out in general terms a series of objectives and means of achieving them, designed to be used by nation states in Eastern as well as Western Europe. The task for the future could be to examine how they can be adapted for use in the European Union to provide an input to the investment of resources in health and health services, based on priorities of a variety of conditions and services, so as to maximize the improvement obtained in the health status of the population. However, numerical targets have a number of significant problems (Abel-Smith, et al, 1995). First, they can lead to artificial priority for that which is measurable. Second, if taken in isolation, they can represent an over-simplistic description of policy. Third, unless the target levels are carefully chosen, they can appear either unrealistic and thus be dismissed as unattainable, or simply a continuation of existing trends, requiring no additional action to achieve them.

Despite a number of problems, targets could be developed to provide a tangible means of monitoring progress and act as a stimulus for the collection of good quality data. They can also highlight important areas of strategy and help in the process of converting policy into programmes.

The specific identification of goals for improvements in the population's health is a prerequisite for the development of a strategic approach to public health policy. It is necessary to identify intermediate objectives, not only for health, but also for the important determinants of health and the processes which lead to changes in those factors. Interventions are often better aimed at individual determinants rather than specific outcomes. This is important since health outcomes display a complex relationship to multiple causes or factors.

One task is to examine how the WHO targets set by the Alma Ata declaration may be adapted to the needs of both Eastern and Western Europe

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Box 1. Criteria for defining European Community functions in the field of public health

- where there is a clear need for the coordination of activity or to learn from the experiences of other Member States,
- where functions can be performed more cost efficiently for the Community as a whole (eg. economies of scale),
- where there are issues which cross country boundaries such as epidemics, environmental issues and the consequences of the free movement of persons and goods, including pharmaceuticals,
- where action is needed to standardize definitions so as to make the exchange of information reliable,
- where the actions and policies of the Community have important health implications.

To date the Community's role has been based on a limited definition of public health, restricted to specific areas such as 'prevention', 'major health scourges', and 'drug dependence'

Priorities for health policy should, be determined using five criteria:-

- the extent and seriousness of the problem,
- whether effective preventive or curative methods are available,
- whether rehabilitation is possible,
- whether such methods can be used appropriately and efficiently,
- whether it can be left to individual responsibility.

To date the Community's role has been based on a limited definition of public health, restricted to specific areas such as 'prevention', 'major health scourges', and 'drug dependence'. This was inevitable given the limited scope for public health developments outlined in Article 129 of the Treaty. While a disease based strategy may prove politically successful such an approach has reduced the Community's ability to make a substantial contribution to the health of the European citizens (Belcher and Mossialos, 1997).

Rather than this disease-based strategy, we need greater focus on risk factors associated with diseases and determinants of health. This calls for a multi-sectoral approach that incorporates subjects such as poverty, unemployment, agriculture, transport, housing, and education.

More focus needs to be placed on risks, calling for a multi-sectoral approach

It is, therefore, very important to identify risks which are associated with particular causes of diseases. Identification of risk rather than disease does help in that some risks - eg. smoking cigarettes, alcohol consumption, blood pressure are associated with more than one disease. It is easier to convince people to tackle smoking as this will have an effect on cancer of the lung, chronic respiratory disease and ischaemic heart disease.

Priorities based on the burden of disease, which is the direction of Article 129, may hide the importance of attaching the risk factors of relevance. In addition, by identifying risk factors it is clear that action is taken to implement a public health policy involves more than the health service - eg. education, agriculture, transport and housing (Holland, Mossialos, et al, 1998). Priorities for action could include the following areas:

Smoking; alcohol-related harm; drug and substance abuse; nutrition; exercise; mental health; the physical and social environment; accidents and injuries; occupational safety and health; family planning; maternal and infant death; blood pressure control; screening for cancer; dental health; physical and sensory disability and surveillance and control of infectious diseases (including sexually transmitted diseases, HIV infection, etc.).

Priorities for public health should, ideally, be based on knowledge of the occurrence, socio-economic consequences and preventability of health problems, taking into account prediction of future trends and the expected costs and benefits of the public health measures.

The precise ranking of priorities in any area will be largely determined by local circumstances, availability of facilities, ability to mobilize effective inter-agency activity, as well as wishes of the population.

It is argued that any action at Community level should fit the 'added value' criteria which are the most quoted determinant for EU activity. This is intended to guide Community action, but there is little understanding of what it actually means in practice. Given the differences between Member States in the development of their public health policies, health systems and socio-economic status, what constitutes 'added value' is highly unlikely to be the same for all Member States. The 'added value' principle should reflect the different levels of policy and institutional evolution of the Member States, the development of human resources and services and public health needs. Within this context, knowledge transfer based on best practice available among Member States and adapted to the local environment should be a priority, indeed a target. Human resources development is another. Current initiatives under the Fourth Framework Research Programme support the mobility of doctoral, post-doctoral and experienced researchers between Member States, but is important that the Commission also support local developments and training and research centres in the Member States.

Conclusion and recommendations

It is now expected that a revision of Article 129 at the Intergovernmental Conference (IGC) will influence further developments in the field of European health policy. However, implementing a new legal framework for setting priorities must go hand in hand with reforms of European Community institutions and decision-making. Currently, health related activities are scattered throughout the European Commission without any effective central focus for health. This was obvious in the BSE crisis, in which agriculture and not health officials took the lead both in the Commission and the Council of Ministers. Health related problems are also discussed by ministers of transport and industry at European level, for example, but omitted from the agenda of meetings of health ministers. This is not altogether a bad practice as it enhances a multisectoral approach, but there is currently no effective mechanism to bring together all health-related discussions (Holland, Mossialos, et al, 1998).

It is worth noting that thirteen of the Directorates General (DGs) of the Commission headed by different Commissioners are involved in shaping health-related policies. In the work of a number of other Directorate Generals' general health issues play an important indirect or direct role (eg. Common Agricultural Policy, VAT policy etc.).

It is worth exploring the possibility of re-organizing the responsibilities on health-related matters at Community level particularly inside the Commission. This has indeed also been voiced by the European Parliament. Positive initiatives have been taken by the European Commission and President Jacques Santer to improve coordination of policy formation and implementation. These initiatives can be further enhanced by the establishment of a new entity within the Commission to coordinate currently scattered activities and programmes. The discussions at the recent Intergovernmental Conference in Amsterdam make the outlook for this seem positive.

The 'added value' principle may in practice be difficult to apply given that it is unlikely to be the same for all member states

The lack of a central point for the discussion of health-related issues in the EC encourages a multi-sectoral approach but can reduce the effectiveness of action

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A new entity could also develop -in collaboration with the WHO and other international organizations- common standards and definitions so that comparative studies can be undertaken to assess possible variations in health needs, utilization, health expenditure and outcome. A significant development will be the establishment of a European-wide system of surveillance of the incidence of communicable diseases in order to identify new problems as they arise and identify cases of changes in incidence. This is a field where considerable progress has been made. Co-operative arrangements for the evaluation of methods of treatment and technology assessment would also be desirable. Finally it should support research projects to investigate the aetiology of some of the major causes of mortality and morbidity in order to identify possible preventive strategies and sponsor appropriate experiments to evaluate different approaches to the control of diseases for which preventive measures are known.

Keywords

Public Health, European Union, Priorities

References

- McKee, M. Mossialos, E. Belcher, P. The Influence of European Community Law on National Health Policy, Journal of European Social Policy, 1996;6(4): 263-268.
- European Commission, Council Resolution on future action in the field of public health, Official Journal of the European Communities, 1993;C174:1.
- European Commission, Second Report from the Commission to the Council, the European Parliament and the Economic and Social Committee on the integration of health protection requirements in Community policies , COM (96) 407 final of 4 September 1996.
- European Commission, Report from the Commission to the Council, the European Parliament and the Economic and Social Committee on the integration of health protection requirements in Community policies , Luxembourg: European Commission COM (96) 192 final of 8 May 1995.
- European Commission, Commercial Communications in the Internal Market, Luxembourg: European Commission, COM (96) 192 final of 8 May 1996.
- Abel-Smith, B. Figueras, J. Holland, W. McKee, M. Mossialos, E. Choices in Health Policy : An Agenda for the European Union, Aldershot and Luxembourg : Dartmouth and the Office for Official Publications of the European Communities, 1995.
- Belcher, P. Mossialos, E. Health Priorities for the European Intergovernmental Conference, BMJ, 1997;314:1637-38.
- Holland, W. Mossialos, E. Belcher, P. Merkel, E. Public Health Decisions: Methods of Priority Setting in the EU Member States, Luxembourg:Office for Official Publications of the European Communities, 1998 (forthcoming).

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Health policy

Telemedicine: Fulfilling the Promise

Jeremy Holland, *The CEST*

Issue: Telemedicine is the application of telecommunications to health care delivery, primarily to enable expertise to be accessed when it is not physically present. While the benefits to society delivered by telemedicine are potentially great, telemedicine has not been taken up by the medical profession on anything other than a very tentative experimental basis. The causes of this merit further and sustained revisiting as the potential benefits in terms of health care improvement are substantial.

Relevance: The potential benefits of telemedicine include improved health care, decreased differential between rural health and urban & suburban health (and hence increased social cohesion) and decreased health-care costs. In order to achieve these positive effects the debate must be shifted from its current technological bias to one focused on health and social needs.

What is Telemedicine

The term 'Telemedicine' can be taken as referring to a broad spectrum of activities within health-care delivery. Taken literally, it is the application of telecommunications technology to the delivery of health care. This can range from a GP making a telephone call to a patient to sharing real-time Computed Tomography (CT) scans between consultants in hospitals in different continents. Some examples of different telemedicine technology modes are given in the table in box 1.

Perhaps the most succinct definition is "the investigation, monitoring and management of patients, and the education of patients and staff using systems which allow ready access to expert advice, no matter where the patient is located".

This is conventionally interpreted as the use of image and video transfer technology to enable a remote specialist to see the same information that a local physician is seeing. This form of telemedicine has been researched since the 1970s. However, the focus on one particular mode of technology is one of the problems which has frustrated progress in the sector. Consequently, the author recommends that the broadest technical interpretation be used, namely the use of telecommunications to deliver health care.

Why all the fuss?

The health sector consumes between 6 and 8% of major European member state GDPs. This is more than education or defence. Not only is the health sector a large drain on national economies, but it continues to grow as a percentage of GDP.

Telemedicine is basically the application of telecommunications technology to the delivery of health care and includes a variety of techniques

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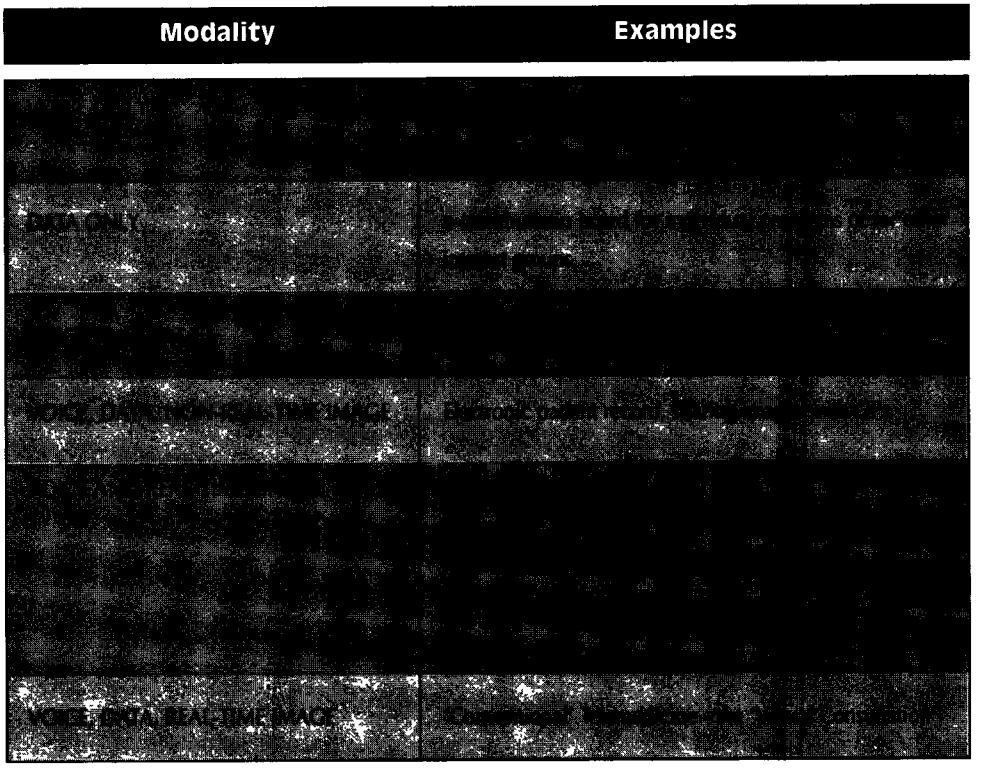
Box 1. Modalities of Telemedicine



Telemedicine has the potential to make more efficient use of medical staff, which represent the greatest cost in health care systems

Consequently, any means of reducing health care expenditure while maintaining the quality of care is eagerly sought.

Direct operational staff costs make up by far the largest proportion of the total health care budget (in some countries over 80%). Any saving in operational staff costs will therefore have a major impact on costs. It is because of its potential to significantly improve the efficiency of use of operational staff that Telemedicine has had such an enthusiastic reception.

Health care is at heart a relatively simple process: it is the efficient provision of the appropriate medical expertise to the patient at the earliest time possible. Of course, drugs, equipment, and hospitals all feature heavily, but health care is essentially a professional service. But the geographical diversity of the community and health services means that this relatively simple process is extremely difficult to deliver optimally. Patients may be difficult to access, specialist expertise may be located far from the need, or conversely a given source of expertise may not be required by the local populace (leading to expensive and disruptive relocation). Telemedicine enables expertise to be provided to a patient irrespective of its geographical location. This holds out the prospect for massive improvements in efficiency.

A number of scenarios have been described which indicate some of the situations in which telemedicine might be beneficial.
These include:

- Centralized pathology: the use of telecoms to enable one expert pathologist to provide a consultation service to several local hospitals (in a city, for example) leading to more

efficient use of resources at off-peak times (such as at night). This scenario can be easily translated to other specialisms.

- Rural service provision: the use of telecoms to enable one specialist physician to provide near simultaneous expertise to several remote rural facilities that would be time-consuming and expensive to visit physically.
- Devolution of care: the use of telecoms to enable the provision of secondary care expertise (i.e. a hospital consultant) at the primary care interface (e.g. the GP's surgery) where service is both cheaper and more convenient for patients.
- Health care in 'strange places': the use of telecoms to enable the provision of specialist expertise to locations that have been isolated from ready access to required levels of health care knowledge. Examples include boats (ferries, liners, and yachts), aircraft, the battlefield, crash sites, and so on.
- Health care export: the use of telecoms to export specialist expertise to other countries with lower levels of health expertise. Several organizations have attempted to make money this way, although no significant successes have been noted to date.
- Remote monitoring: the use of telecoms to monitor a patient's condition or behaviour from a centralized facility. This is a part of the larger 'telehealth' concept. To date, remote monitoring has been the most commercially successful telemedical sector.

Of the scenarios given above, the major benefits to the EU can be split into two areas: health benefits and rural cohesion benefits. Clearly, the more cost-effective delivery of service will enable more of that service to be provided at current levels of health care expenditures: improving health outcomes at a fixed cost. Equally significant is the benefit given to rural communities.

Rural communities often suffer poorer health than their urban counterparts, they have unique requirements based on the ageing population, the nature of employment (often farming; a relatively high-risk activity), and the comparatively poor transport facilities (ready access to a car is lower in a rural population than an urban population). As a result, health in rural areas is often significantly worse than in towns, leading to problems of social cohesion. The use of telemedicine would enable a cost effective delivery of service to meet the needs of rural populations and thus increase social cohesion.

What has been achieved?

Compared to its potential, the achievements so far have been disappointing: the promised radical improvements in medical service delivery have not been observed.

Success has been achieved in certain 'specialist' niches such as the provision of difficult-to-access expertise to the US military and the remote provision of expertise to ambulance-men, which has improved the prognosis of crash victims. However, these are relatively small-scale specialist applications, unlikely to benefit the 'mass market'.

A recent survey of telemedicine applications revealed a great number of initiatives and schemes. These are all small, local projects however, with little evidence of success in the delivery of the benefits outlined. A list of projects is given in Table 2. Although this survey was conducted mainly in the UK, the projects described are typical of those in the rest of the EU and elsewhere.

Many of the projects conducted in the EU have been funded by various framework programmes - mainly by the AIM (Advanced

The rapid availability of remote expertise offers significant advantages to rural areas and would enhance social cohesion

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Informatics in Medicine) initiative. This has run in three phases. The first phase (1988 to 1990) was exploratory in nature, being mainly concerned with establishing the feasibility of advanced informatics for health care. The second phase (1991 to 1994) focused on developing the underlying technology. The latest phase, part of the fifth framework programme, will turn to the issue of patient and service benefits. Many of these projects have taken the form of 'proof of concept' work, determining the technical feasibility and usability of advanced telecoms in health care. This focus on technology as opposed to health or service benefits is one of the main reasons for the lack of significant uptake and use of telemedicine.

Most of the research initiatives underway concentrate on testing the concepts underlying the technology rather than the possible health service benefits

Table 2. Some Telemedicine Schemes

Organization	Project area

What are the obstacles?

The obstacles to further development and adoption of this technology are the following:

- A fragmented market: different national health services, different community types (e.g. rural and urban), and different medical specialties require different functions of a telemedicine product. As a result the market for a particular telemedicine product is likely to be small and difficult to support cost effectively.
- Heterogeneous technology: there is little standardization or commonality in health care technology at present. A telemedicine service would have to integrate with hundreds of existing and different IT systems (for example, Germany uses 150 different General Practice systems).
- Complexity of service delivery: some of the services that are to be supported by telemedicine are fiendishly complex (such as radiology), meaning that the functionality of the system is correspondingly difficult to identify and provide.
- No standard economic framework: one of the reasons why no pan-European study of the health economic aspects of telemedicine has been carried out is that different national health services use very different economic frameworks. For example, in Scandinavian countries, patient time is costed whereas in may others it is not.
- Untested legal framework: there are legal issues that need to be resolved. For example, should a telemedicine service be considered as a form of drug with the legal implications this implies, or merely the exchange of expertise from one terminal of the service to another.
- Lack of standards: in order to tame the heterogeneous technical infrastructure alluded to above, and in order that different telemedical technologies can work with each other, there is a need for technical standards to be adopted. Although the standards body CENTC251 has been in existence for many years, there is still a long way to go before the standards required for the more sophisticated systems are agreed.
- Lack of continuity of funding: the introduction of telemedicine services will require long term commitment from funding bodies. To date this has not been apparent, either in European or national contexts. As a consequence, few projects have managed to get beyond the pilot stage, and many centres of excellence have been disbanded (examples of promising projects that have been 'killed' by short term funding difficulties include TEAM and Eurodiabeta).

All of these obstacles are greater the more sophisticated the form of telemedicine service is. The fact that they have held up progress tells us that many proposed telemedicine schemes depend on complex and advanced technology. This is in spite of the fact that the more successful pilots tend to use standard proven 'off the shelf' technology.

This is part of the underlying reason for a lack of widespread uptake of telemedicine, or indeed any other health informatics product: the focus on technology and the market rather than on need and benefit.

There are two philosophies at work here. One is the philosophy of the computer and technology sector. The other that of the medical/pharmaceutical sector. Telemedicine work to date has been largely influenced by the computer philosophy: Does the system work? Is it affordable? Is it state-of-the-art? Is it 'user friendly'? Is it reliable? Are the standards in place? Is the market sufficiently large? These questions are very difficult to answer in the light of the

Market fragmentation, system complexity, heterogeneity, legal uncertainty, lack of standardization and discontinuity of research funding are among the problems faced by telemedicine programmes

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problems described above. As a result the enthusiasm of the technical community for tackling the obstacles is limited.

In any event technology will not be accepted by the medical sector until the prime concern of the other philosophy has not been answered: does it do good? In what way should the telemedicine service be used to give health or rural cohesion benefits, what are those benefits, and what models of service delivery result in economic efficiencies (or at least in a cost-neutral change)? These questions are very different from those normally considered by the technical community: they are, however, central to the medical community which will not introduce a new drug until it has proven itself in extensive field trials. In short, the model should not be the computer usability test, but the pharmaceutical drug trial. As a corollary to this, any such trial would require robust and stable technologies rather than those that are 'state-of-the-art'.

The model applied in the technologies sector (state-of-the-art, affordability, user-friendliness, etc.) does not coincide with that in the medical sector (robust, safe, tested in extensive field trials, etc.)

Conclusions

The benefits to be gained from successful use of telemedicine appear to be great. However, they are currently unproven. The telemedicine debate has too often been dominated by technical considerations with insufficient focus on the needs of, and benefits for, the population that is to be served: work has been 'technology driven' rather than 'demand led'. As long as development and introduction is left to the commercial sector, it will stall. Often the work will need a large development effort, for an uncertain return: that is, the commercial market is insufficiently tempting for industry to be willing to take all the risks alone. These risks must be shared with those who have most to gain. This is, the community itself and its agencies.

As long as the debate stays in the technical camp it will not answer the key question: does telemedicine do good? The debate should be passed to more relevant stakeholders: those with an interest in the population's health, and those with an interest in the reduction of rural isolation and the increase in social cohesion.

From the point of view of the EU, it should be pointed out that health care is outside the scope of the Treaty of Rome. This might imply that EU policy makers should focus on the potential benefits of telemedicine to rural communities and the increase in social cohesion that this might yield.

Major trials of the use of telemedicine are needed, and these should be driven not only by technologists or informaticians, but also by doctors and representatives of beneficiaries. The trials need to be extensive and honest, and determine what the benefits are and how they are most efficiently delivered, and demonstrate convincingly that they have been delivered. Furthermore, focusing on proof of benefit means that it is not important to use 'cutting-edge' 'state-of-the-art' technologies. Trials should use reliable off-the-shelf technologies and simple applications so that the message is not confused by the technological barriers described above. Examples of promising application areas are telemonitoring and teleconsultation (which uses available teleconferencing technology).

Commitment from policy makers and fund-holders must be sincere, robust, and long-lasting: the alternative is wasteful and will not create the benefits argued for. It is only when the evidence of its effectiveness is sufficiently convincing that telemedicine will be taken seriously by the intended market and have a chance of delivering the significant benefits claimed for it.

In short, the debate amongst European policy makers concerning telemedicine has focused on technology and markets. Its focus should be extended to include health and social cohesion.

Keywords
telemedicine, health care, rural communities, telematics

References

- European Health care Technology Observatory: http://www.ehto.be
- The Institute of Rural Health: http://www.ihi.aber.ac.uk/ECRH/
- Watt IS and Sheldon TA (1993) Rural Health and healthcare. Editorial. British Medical Journal 306 1358-9.
- Gott: Telematics for Health - the role of telehealth and telemedicine in homes and communities, European Foundation for the Improvement of Living and Working Conditions, 1995, Radcliff Medical Press, Oxford.
- Laires, M.J. Ladeira and J.P. Christensen: Health in the New Communications Age - Health Care Telematics for the 21st Century, 1995, IOS Press, Amsterdam.
- EURODIABETA. Modelling and Implementation of Information Systems for Chronic Health Care - Example: Diabetes in Medical Informatics Europe '90 edited by R. O'Moore, S. Bengtsson, J. R. Bryant, J. S. Bryden. Berlin, Springer Verlag 1990.

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Minimally Invasive Surgery: Benefiting Patients and Health-Care Systems

Marie-Laure Spaak, Patrick Urso, *ADIT*

Issue: Minimally invasive surgery (MIS), of which laparoscopy or endoscopy is an excellent example, is an alternative to conventional, or 'open', surgery which requires large incisions. With a minimally invasive technique, only three tiny incisions are needed to insert small tubes, known as trocars, through which surgical instruments and a light source are introduced into the body for tissue visualization. Injuries to patients are greatly reduced and hospital stays are shortened.

Relevance: Overall demand for health care is on the rise in industrialized countries, particularly on account of the ageing of the population. Pressure on health expenditure necessitates maximizing cost-efficiency for every medical procedure. Minimally invasive surgical techniques reduce costs by lowering morbidity, reducing recovery time and shortening hospital stays.

Minimally invasive techniques allow patients to return to normal life more rapidly, placing a lower overall burden on the health care system

Analysis

Innovative medical technologies affect the quality and cost of health care. They raise the issues of therapeutic efficacy, safety, ethics, the impact on health care services and overall social effects. Minimally invasive techniques specifically benefit society by lowering overall medical expenses and benefit patients by reducing discomfort. Since MIS techniques do not entail major injury to the body, they produce less pain and fewer scars. Patients can resume oral food intake sooner, get back on their feet more quickly, and consequently have a lower risk of complications. In most cases, one to three days of hospitalization is sufficient; the recovery period is also shorter. For instance, a patient who undergoes laparoscopic appendectomy spends three days in hospital and can go back to work two weeks after the operation whereas conventional surgery requires five days in hospital and three weeks for recovery. The patient's sick leave costs less for the national health care system and disrupts his or her professional activities less.

Thus, although a minimally invasive operation costs more at the outset (because the equipment is disposable so can only be used once) the overall cost of medical expenses is generally lower. Another added advantage to these techniques is the possibility of broadening indications to patients who are in poorer physiological condition.

Routine use in certain fields

Certain universities (particularly in France and Germany), and private clinics pressured by patient demand, were the first to use laparoscopic surgery.

Today it has become a routine procedure for many operations, especially for gynaecology and abdominal surgery and for certain urologic operations. It is used for operations involving the thorax, the spine and the pelvis, and can be used for tumour ablation (gynaecology and digestive endoscopy), uterine fibromas, ovarian cysts, the gall-bladder or the appendix. Hernia repair and joint surgery (arthroscopy) can be performed under local anaesthesia with very small incisions. Gynaecological-obstetric surgeons have long used scopes pioneered in laparoscopic operations. Cold light sources and miniature cameras developed in the eighties prompted other specialists to use these techniques, since they could see their operations on the video screen. With the astounding progress that took place in medical imaging it was possible to adapt minimally invasive techniques to a range different fields such as neurosurgery, gastroenterology, orthopaedic surgery, urology, cardiology, vascular surgery and oncology.

A new generation of surgeons

The widespread use of endoscopic techniques requires surgeons skilled in new procedures, who have reorganized their workspace to conduct their image-guided operations with miniaturized instruments including endoscopes (optical tubes), insertion devices (trocars) and other instruments such as forceps, lancets, staplers, sutures, needle-holders, coagulators, ultrasound probes, catheters, pressure sensors, etc.

This approach has revolutionized surgical practice: the surgeon now operates remotely, so to speak, guided by the image of the tissue. In addition, since the camera can be positioned much closer to the structures being operated on, the surgeon sees human anatomy in a new light, with even more accuracy than during open surgery. Training must be adapted to these new aspects of surgery.

In order to perform such precise and delicate manipulations, the surgeon not only needs the technologies to offer a clear display of the internal tissues, but also techniques providing him/her with essential sensorial (tactile, physical or chemical) information. The physical conditions of the work station must also be optimized (for instance, using a robot to anchor the endoscope). Several research teams throughout the world are tackling these issues. These notions have led to a considerable amount of current research on surgical robots to assist the surgeon's hand with precision. In addition, the contribution of virtual reality will allow practitioners to gain skills under excellent training conditions and perform virtual operations on surgical simulators.

Major research programmes addressing the issue

Several research projects are under way in Europe in the field of surgical robots and surgical simulation, distance training for non-invasive techniques and instrument miniaturization. In Germany, the project endorsed by the BMBF (German ministry of higher education and research) under the 'Mikrosystemtechnik' programme is engineering a miniature endoscope with built-in micro-optic components, optical fibres, and real-time image processing technologies. The same ministry has also funded the Aesculap-coordinated MINOP project, with the goal of designing a minimally invasive micro-neurosurgical instrument. Great Britain is also committed to this research, namely through a program financed by the Health Ministry and supported by 1.2 million pounds of funding, called 'Minimally Invasive Therapy Video Networking Project'. The programme includes distance teaching of non-invasive surgical techniques. In France, the INRIA (Institut National de Recherche en Informatique et en Automatique) at Sophia Antipolis, working on surgical robotics, and the IRCAD (Institut de Rechreche contre le Cancers

Minimally invasive surgery has become a routine procedure for many operations, especially for gynaecology and abdominal surgery

New techniques require surgeons to learn new skills. Research is also looking at robots and virtual reality to assist surgeons to perform operations

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A number of projects in various European countries are looking at different aspects of minimally invasive surgery

de l'Appareil Digestif) at Strasbourg are among the world's leading centres in the field of endoscopic surgery. In Germany, the Kernforschungszentrum at Karlsruhe is developing a surgery simulator.

The European ESPRIT programme is backing projects in biomedicine on "standardization and improvement of minimally invasive operating techniques using advanced technologies such as miniaturization, 3D imaging, robotization, video techniques, microstructure techniques and assisted-surgery nanotechniques".

Beyond major existing programmes and projects already being funded, several actions could be launched to support medical research in this field, which suffers from the lack of means compared with the needs of practitioners. Surgical robots and simulators, for example, are still an issue for the future and the development required for these technologies to be able to enter routine use is considerable.

In this context, it would be worthwhile for Europe to support the development of a technology monitoring centre. This centre could create an information platform and use the resources of existing networks, regularly informing different (private, scientific, institutional, etc.) European partners working in the field on world-wide advances in medical technologies. Information could be disseminated, for example, with a monitoring bulletin or by creating an Internet site for minimally invasive surgery.

A data network to share medical knowledge between the different health partners could be an avenue for major development

In this light, installing a data network to share medical knowledge (scientific advances, technological developments, legislation, research programmes and projects, etc.) between the different health partners could also be an avenue for major development allowing improved diagnostic and therapeutic methods. Such a network would nevertheless require a large investment at the beginning. An example of a network of this type is CICE (Centre International

Box 1. European projects on minimally invasive surgery

Title	Programme	Goals
• Minimally invasive articular surgery	• BIOMED 2: from July 1, 1996 to June 30, 1999	• To design minimally invasive technologies for orthopaedic operations, and to introduce new technologies in arthroscopy to improve the quality of the health care provided by the surgeon to the patient
• Micro-fabrication capability and expertise for user-defined purposes	• PECO/COPERNICUS: from April 1, 1995 to March 31, 1998 (36 months)	• To engineer micro-technologies, with a focus on the design of microsystems for minimally invasive surgery

Source: Cordis

The high economic stakes

This important issue of minimally invasive surgery is not limited to research but also concerns commercial firms who have invested heavily in this area. The stakes, in terms of the economic impact of these technologies, are high: international experts predict that by the end of the century, 70 to 80% of all general surgery will be performed by minimally invasive methods - this is already the case for surgery units in Europe such as the Clermont-Ferrand University Hospital in France where the rate has reached approximately 90%. The fast growing market is currently dominated by two major American manufacturers, the US Surgical Corporation (84% of the market) and Ethicon Endosurgery (15%) - European manufacturers have started to position their products. Indeed, most of the major orthopaedic firms (Zimmer, Howmedica, Smith & Nephew, DePuy, Sulzermedica...) have committed themselves to developing allied products in arthroscopy and minimally invasive surgery.

de Chirurgie Endoscopique), which is the reference point for a network comprising other university centres in Europe carrying out similar activities: Heidelberg, Barcelona, Brussels, Milan, Palermo, Bratislava, Moscow. It also maintains a close relationship with universities in the United States (Stanford), Vietnam, Montevideo, and China. It should be noted that the European Community already supports projects for the development of information networks applied to the field of medicine; among these is the TEN Telemed (Trans-European Network) whose goal is to promote education.

Conclusion

More than ever before, surgeons today need teaching tools adapted to allow rapid learning of new operating techniques. The demand for more know-how is great. Availability of equipment and training materials (video-conferences, distance training sessions...) among others, will play a dominant role. EU-level support for the development of structures adapted to these needs could be crucial.

With the promised reduction in overall cost of patient management, minimally invasive techniques can help both medically and financially, beyond the impact on individual patients. There are positive externalities involved for society (in terms of social expenditure), which would justify public intervention, although the impact on different national health care systems is likely to vary. In any case, the acquisition of hospital equipment and initiatives for physician training deserve to be supported.

Keywords

Minimally invasive surgery, endoscopic surgery, surgical endoscopy, laparoscopic surgery, arthroscopy, laparoscopy, minimally invasive therapy, MIT

References

- ANDEM, Diffusion de la chirurgie coelioscopique en France: quels enjeux économiques? Paris.
- DUCRET (F.M.), Vers une chirurgie virtuelle? Edicom - Médecines complémentaires - Fémina; http/::www;edicom;ch:sante:conseils:altern:virtuelle;html
- WHO Regional Office for Europe, Health in Europe - The 1993-1994 health for all monitoring report, European Series, nº 56. http://www.who.dk/country/euro/part0h.htm

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BRIEF NOTE

Astrid Zwick

Health policy

Environment and Health

An article about the relationship between health and climate in the April issue of the IPTS report presented some statistics and predictions for a global warming scenario (Zwick, 1997). The consequences are serious, not only due to the direct thermal impact but also on account of an increase in temperature causing the shifting of vectors that transmit diseases to areas previously uninfected. Moreover, modern travel may turn tropical diseases into real threats for usually safe areas in the subtropical and temperate regions. In addition, extreme weather events, like droughts and subsequent heavy precipitation could cause the spreading of viral diseases like the hantavirus epidemic in the USA.

There are more threats and synergies with other environmental factors like air, soil and water pollution, the population's health status, the state of hygiene, population density and growth. In industrialized countries the increase of allergic disorders is striking. The case is serious since almost all natural compartments (atmosphere, soil, water) are more or less polluted by human activities. Not enough is known about the dose-effect relationship to justify prevention and treatment levels. More needs to be known on the epidemiology of modern pollution factors, tolerance levels and effect thresholds.

A European Commission proposal on an action programme for pollution-related diseases has been put forward in order to draw more attention on the prevention of diseases related to environmental pollution. It has been noted that one in three Europeans suffer from an allergy and this proportion is rising, translating into rising health-care costs.

The situation could be mitigated through improvement of the information about the relation between human health and environmental pollution through enhanced research; reduction of exposure through pollution prevention, avoidance and control; surveillance to help avoidance (monitoring and early warning systems), as well as, obviously, through treatment of related symptoms.

Keywords

environment, health, climate, exposure, pollution prevention

References

- European Commission (1997): European Commission proposes an action programme for pollution-related diseases. DN: IP/97/533, Date, 1997-06-19.
- Meyer,R. (1997): Environment and Health - Current state of Knowledge and Demand for Further Research. Draft to be submitted.
- Zwick, A. (1997): Global climate change: potential impact on human health. IPTS-Report, Nr.13, EC, JRC.

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IPTS publications

- ADEME; Prospectives de la biomasse pour l'énergie dans l'Union Européenne; EUR 17260 FR; Nov-96
- AG Consultores; Le transfert technologique dans la coopération inter-enterprises entre l'Europe et l'Afrique du Nord; Oct-95
- Aguado; Photovoltaic Energy - Technological Status and Trends Preliminary Analysis; Aug-94
- Aguado; Status and Prospective Analysis of the Photovoltaic Technology; EUR 16391 EN; Feb-96
- Allgeier (ed.); The IPTS Report; ISSN 1025-9384; Dec-95
- Bain; Research and Technical Prospects for Cork- Phase I Study; Jan-92
- Bonazzi; Euro-Mediterranean Policies and Olive Oil : Competition or JobSharing? - Agro-food technology transfers for sustainable development in the Mediterranean : a strategic approach for an environmentally sound food security; EUR 17270 EN; Sep-96
- Bonazzi; Il Mercato dei Diritti di Emissioni Inquinanti : Metodologie, stato dell'arte, Prospettive e una proposta per l'Italia; EUR 17269 IT; Oct-96
- Bonnaure; Les Autoroutes Electroniques et la Société de l'Information; Jun-94
- Bontoux, D. Papameletiou; Prospective technological study on materialslchemical-feedstock recycling and energy recovery from municipal plastics waste - Project 1.1 :Preliminary survey of current projects on chemical feedstock recycling from unsorted municipal plastics waste; Sep-94
- Bontoux, D. Papameletiou (eds.); Technology options for plastics waste management: Proceedings, Seville 20-21 November 1995; EUR 16460 EN; Apr-96
- Bontoux; Prospective technological study on materials/Chemical-feedstock recycling and energy recovery from municipal plastics waste - Project I.1a: Preliminary survey of current projects on plastics recycling by chemolysis; May-95
- Bontoux; Survey of current projects for plastics recycling by chemolsis:Prospective technological study on materials/chemical-feedstock recycling and energy recovery from municipal plastics waste - Project i.1.a; EUR 16459 EN; Mar-96
- Bontoux; The recycling industry in the European Union : impediments and prospects; EUR 17271 EN; Dec-96
- Braganza; Market Based Instruments for Environmental Protection; Sep-92
- Braganza; Opportunities in Environmental Technology; Oct-91
- Braganza; Pollution prevention: exploiting the technical potential; May-92
- Braganza; Some technology options for dealing with environmental pollution; Jan-92
- Brossa; Prospective technological study on materials/Chemical-feedstock recycling and energy recovery from municipal plastics waste - Project I.3: Preliminary survey of current projects on energy recovery from municipal plastics waste; May-95
- Cahill; Industrial Efficiency - A Literature Synthesis; EUR 16447 EN; Mar-96
- Canarelli; Application of Genetic Algorithms to Innovation-Related Issues; EUR 15821 EN; Jan-94
- Canarelli; Exploratory Study of the Technologies to Lessen Urban Transportation Drawbacks.; EUR 15947 EN; Jul-94
- Canarelli; Knowledge Extraction from Data Using Genetic Algorithms; EUR 16446 EN; Jan-96
- Canarelli; Neural Networks: a Tool for Analysing Real World Complex Systems; EUR 16445 EN; Jan-96
- Canarelli; The Method of Fuzzy Scenarios: Principle and Application to the Future of Congestion in Urban Centres; EUR 16444 EN; Jan-96
- Canarelli; Use of Genetic Algorithms as a Tool for Prospective Studies with Application to the Assessment of the Future of Urban Transport; EUR 16296 EN; Jan-95
- Castells; Input-Output Analysis as a forecasting tool for the Study of urban transport and Environment; EUR 15604 EN; Jan-94
- Cepeda, A.Soria; Energy Demand and CO2 Emissions from the World Transport Sector : Past Evidence and Forecasts; EUR 17256 EN; Sep-96

- CEST; La coopération scientifique et technique dans la perspective de la coopération et de la sécurité euro-mediterranéene; May-95
- De la Torre , M. González (eds.); Annual Report 1995. Institute for Pospective Technological Studies ; EUR 16405; May-96
- Demicheli, L. Bontoux; Survey on Current Valorization of By-Products from the Olive Oil Industry; EUR 16466 EN; Sep-96
- Fahrenkrog, D. Kyriakou; New technologies and employment: Highlights of an ongoing Debate; EUR 16458 EN; May-96
- Gameson, P. DiPietrogiacomo, P. Sørup (eds.); European research towards the XXIst century : IPTS workshop Sevilla, 29-30, August 1996; EUR 17257 EN; Nov-96
- Gómez*, M.L. Borra*, M. Aguado (eds.); Conclusions of the Forum "European Enterprises facing technical and legal barries to renewable energy", Seville, 23/24 November 1995 (Organised by SODEAN, UNESCO, IPTS, ECD, BESEL; EUR 16390 EN; Mar-96
- Group of Bertino S.Gomez y Paloma; East-West Agro-Food Systems Toward the Third Millennium; ART 43171; Aug-96
- Group CM International; Technology Gaps & Sustainable Regional Development: an exploratory study - case of the agri-food sector in Andalucía, Ireland, South Brandenburg and Central Macedonia; EUR 17278; Nov-96
- Hardy; Politiques de développement territorial et investissements étrangers dans les pays du Maghreb; EUR 16419 FR; Apr-96
- Harvey (CEST); AGILE Manufacturing - A Scoping Study; EUR 16469 EN; Nov-96
- Heinemeier; On the scope of qualitative structural input-output analysis in the conceptualising of a technology based development strategy: the example of the Seville Technology Park; EUR 16303 EN; Jan-95
- Heinemeier; Transnational co-operation between small and medium-sized enterprises in the European Union: Exploration of the regional pattern in BRE and BC-NET Activities; EUR 16300 EN; Jan-95
- Henry; Climate Change Research and Policy: Updates (A Periodic Survey: N°5); Oct-93
- Henry; Climate Change Research and Policy: Updates (A Periodic Survey: N°4); Jan-93
- Henry; Climate Change Research and Policy: Updates (A Periodic Survey: N°2); Nov-91
- Henry; Ciimatic Change Research and Poiicy: Updates (A periodic survey: N°1); May-91
- Henry; Climate Change Research and Policy: Updates (A Periodic Survey: N°6); Oct-94
- Henry; Climate Change Research and Policy: Updates (A Periodic Survey: N°3); Jun-92
- Henry; Science and the Greennhouse Effect; Jun-90
- Kleinknecht, D. Bain; New Concepts in Innovation Output Measurement; ISBN O 333 58818 5; Sep-93
- Krebs ; A Prospective Assessment on the Role of Renewable Energies in Response to the CO2 Problem.; EUR 16334 EN; Jan-92
- Krebs, M. Rogers, P. Pearson; A Critical Literature Survey on the Prospects for Thermonuclear Fusion Energy; Aug-90
- Krebs; Microgravity: A Future for the Space Industry? (Status and Trends); EUR 16344 EN; Sep-91
- Krol; Developing an environmental management strategy:; Mar-94
- Kyriakou; Sustainable Development: Towards a Synthesis Sustainability Accounting - a support document for preparation of the conference "Taking Nature into Account", Brussels, 31 May- 1 June 1995; EUR 16297 EN; Dec-94
- Lanza, C. Zanantoni; Nuclear Energy-Reprocessing and Recycling Are Key Issues; EUR 16319 EN; Jul-91
- Leone; Prospective technological study on materials/Chemical-feedstock recycling and energy recovery from municipal plastics waste -Project I.4a: Preliminary survey of current legislative activity in plastics waste management; Jun-95
- Leone; Survey of current legislative activity in plastic waste management (Focus on Economic instruments) - Second Interim report -; EUR 16467 EN; Oct-96
- Maghiros; Q2 Information System - Progress Report; Sep-92
- Maghiros; R&D Projects - Information Systems (Working Group on the harmonisation of data bases on research in progress - Brussels, 16.9.92); Sep-92
- Martin; Process of Innovation for Advanced Materials; Sep-91
- Mendoza; The Geographic Information Systems (GIS) for Urban and Prospective Research; Sep-94
- Moncada Paternò Castello; Studio di Pre-fattibilità di un "Agenzia Mediterranea in Sicilia per la Promozione delle Energie Rinnovabili e la Gestione Efficiente dell'Acqua"; EUR 17255 IT; Nov-96

- Naegele (Co-ordinator), P. Canarelli, H. Hernández, T. Amorelli, M. Nicolai, F. Scapolo, C. Heller; The Car of the Future, The Future of the Car; EUR 17277 EN; Jun-96
- Naegele, T. Amorelli,; The future of non-ferrous metals; Jan-95
- Nicolai; Prospective technological study on materials/chemical-feedstock recycling and energy recovery from municipal plastics waste - Project I.2: Preliminary survey of current projects on mechanical recycling of municipal plastics waste; Jan-95
- Papameletiou, M. Aguado, L. Bontoux; Opportunities in Environmental Technology - Synthesis Report; Dec-93
- Papameletiou; CO2 Removal Technologies; Dec-94
- Papameletiou; Fuel Cells - Part I and II (Final Report); EUR 16321 EN; Jan-94
- Papin; Competitivité des industries spatiales européennes Annexe 1: General Ovreview of Space Activities and Systems * Rapport V. Panin (Consultant); Sep-91
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- Rogers; The Technological Response to Global Environmental Problems - California; EUR 16323 EN; Sep-91
- Sorup; Sustainability Accounting - A support document for the preparation of the conference "Taking Nature into Account", Brussels, 31 May - 1 June 1995; Apr-95
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- Stamm'ler Jaliff, C.A. Jonsson, A. Ljungblad; Introduction of Modern Software Technology : a Case from Swedish Industry. Bilbao 26-28 September 1996; ORA/PRO 40168; Nov-96
- Weber, G. Fahrenkrog; Sustainability and technology: A framework for discussion; EUR 16457 EN; Sep-96
- Weber, M. Nicolai; The Ethical Dimension of Technology Watch and Assessment, proceedings of a seminar on 25 March 1996 at IPTS in Seville; EUR 17279 EN; Dec-96
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- Zwick; Climate change research and policy: Updates - no. 8; Nov-95

ABOUT THE IPTS

The IPTS is one of the seven institutes of the Joint Research Centre of the EU Commission. Its remit is the observation and follow-up of technological change in its broadest sense, in order to understand better its links with economic and social change. The Institute carries out and co-ordinates research to improve our understanding of the impact of new technologies, and their relationship to their socio-economic context.

The purpose of this work is to support the decision-maker in the management of change partially anchored on S/T developments. In this endeavour IPTS enjoys a dual advantage: being a part of the Commission IPTS shares EU goals and priorities; on the other hand it cherishes its research institute neutrality and distance from the intricacies of actual policy-making. This combination allows the IPTS to build bridges between EU and Member States, contributing to and co-ordinating the creation of common knowledge bases at the disposal of all stake-holders. Though the work of the IPTS is mainly addressed to the Commission, it also works with decision-makers in the European Parliament, and agencies and institutions in the Member States.

The Institute's main activities, defined in close cooperation with the decision-maker are:

1. Technology Watch. This activity aims to alert European decision-makers to the social, economic and political consequences of major technological issues and trends. This is achieved through the European Science and Technology Observatory (ESTO), a European-wide network of nationally based organisations. The IPTS is the central node of ESTO, co-ordinating technology watch 'joint ventures' with the aim of better understanding technological change.

2. Technology, employment & competitiveness. Given the significance of these issues for Europe and the EU institutions, the technology-employment-competitiveness relationship is the driving force behind all IPTS activities, focusing analysis on the potential of promising technologies for job creation, economic growth and social welfare. Such analyses may be linked to specific technologies, technological sectors, or cross-sectoral issues and themes.

3. Support for policy-making. The IPTS also undertakes work to support both Commission services and other EU institutions in response to specific requests, usually as a direct contribution to decision-making and/or policy implementation. These tasks are fully integrated with, and take full advantage of on-going Technology Watch activities.

As well as collaborating directly with policy-makers in order to obtain the best understanding of their concerns, the IPTS always seeks wider views, knowledge and opinions during research them, whilst working in close co-operation with the scientific community so as to ensure technical accuracy. In addition to its flagship IPTS Report, the work of the IPTS is also presented in occasional prospective notes, a series of dossiers, synthesis reports and working papers.

The IPTS Report is published in the first week of every month, except for the months of January and August. It is edited in English and is currently available free of charge in four languages: English, French, German and Spanish.

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