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LEGAL AND ETHICAL ASPECTS OF THE PROVISION OF MEDICAL INFORMATION IN THE EUROPEAN COMMUNITY - IMPLICATIONS OF 1992

by

Dr Peter G.B. Bass MB BS

A Master's Dissertation, submitted for assessment for the award of a Master of Arts Degree from Loughborough University of Technology.

September 1992


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There is a wide range of literature available on the European Community as a trading area, but as neither medicine nor medical information are administered by any one section of the Community, and as there are 12 countries with differing systems and approaches to the practice of medicine, it is difficult to outline a coherent description of its medical philosophy and its legislation.

Accordingly, as the following list shows, a varied selection of publications was consulted:

- Encyclopaedias, directories and dictionaries.
- Council of Europe and Commission of the European Community pamphlets, journals and books.
- Human Rights literature.
- Literature with information on policy, statistics, general information and aspects of health and health care in Europe.
- Books on data protection law, philosophy, politics and European Community treaties.
- Journals: medical and European Community publications.

An attempt has been made to divide this topic, by chapters, into relevant sections and to give a broad final assessment.
LEGAL AND ETHICAL ASPECTS OF THE PROVISION OF MEDICAL INFORMATION IN THE EUROPEAN COMMUNITY - IMPLICATIONS OF 1992

Initially there were three Communities. The European Coal and Steel Community, established by the Treaty of Paris on 18 April 1951, the European Economic Community and the European Atomic Energy Community, established by the Treaty of Rome on 27 March 1957. In 1965 The Merger Treaty established a single council and a single commission for the three communities. It is now common practice to refer to the "European Community", but "European Communities" is technically correct usage. In 1985 Member States signed the Single European Act, with the aim of establishing a single market over a period expiring on 31 December 1992.

Membership
Currently there are 12 member countries; a number of other countries wish to join and recent developments in Central and Eastern Europe have increased the number of potential applicants for membership.

Member States are as follows:
Belgium
Denmark
France
Germany
Greece
Ireland
Italy
Luxembourg
The Netherlands
Portugal
Spain
United Kingdom

Portugal and Spain, having joined on 1 January 1986, are still undergoing the 7-year adaptation period which follows the signing of the Treaty of Accession intended to allow countries to make any necessary changes to their legislature in order to comply with Community Law.
INSTITUTIONS

Commission

The Commission is the "executive" body of the Community. It proposes and carries out policies and is responsible for monitoring the implementation of Community legislation by member states. It can take governments or firms to the European Court of Justice for breaches of law. It plays a central and very powerful role.

There are 17 Commissioners, each with responsibility for a particular area of policy. They are obliged to act independently of their own national governments. The Commission itself is divided into 23 Directorates-General, which administer general policy areas. There is no Directorate-General for Health – health care systems do not fall within the remit of the Community – but a number of Directorates-General (DGs) produce policy which has some impact on medicine and health:

D-G III Internal Market and Industrial Affairs (Commissioner R. Perissich)
Directorate D is responsible for free movement and the mutual recognition of diplomas, including the "Doctors' Directives" (see later)

D-G V Employment, Industrial Relations and Social Affairs (Commissioner J. Degimbe)
(The Europe Against Cancer programme is run by this D-G.

D-G XI Environment, Consumer Protection and Nuclear Safety (Commissioner L.J. Brinkhorst)

D-G XII Science, Research and Development (Commissioner P. Fasella
This includes medical research.

D-G XIII Telecommunication, Information Industries and Innovation (Commissioner M. Carpentier)
D-G XIII Faculty(F)/AIM is responsible for AIM (Advanced Informatics in Medicine), a major research programme.
When the Doctors' Directives were adopted in 1975, the Advisory Committee on Medical Training was set up to advise the Commission on matters relating to training. The practising profession, medical faculties and "competent authorities" are all represented on this Committee, whose opinion the Commission is obliged to take into account.

STATUTORY BODIES

Advisory Committee on Medical Training (ACMT)

The ACMT began in 1975 following the adoption of the "Doctors' Directives". These Directives provided for the mutual recognition of medical qualifications within the EC. The full remit of the ACMT, as set out in the Council Decision which established it in 1975, is as follows:
- "to help to ensure a comparably demanding standard of medical training in the Community, with regard to basic training and further training".

The means by which it is to fulfil this remit are also set out as follows:

- exchange of comprehensive information as to the training methods and the content, level and structure of theoretical and practical courses provided in the Member States;

- discussion and consultation with the object of developing common approaches to the standard to be attained in the training of doctors and, as appropriate, to the structure and content of such training;

- keeping under review the adaptation of medical training to developments in medical science and teaching methods.

The practising profession, i.e. doctors in active practice, the medical faculties of universities, i.e. those with responsibility
4.

for medical training and "competent authorities", i.e. the regulatory bodies nominated to process applications for registration by doctors from other EC countries, are all represented on this Committee, whose opinion the Commission is obliged to take into account. Member States are normally represented by one delegate and one alternate from each category.

Nominations to the Committee are made by national governments, usually on the advice of an appropriate body, such as the BMA in the case of the practising profession. Members serve three-year terms. The Committee is funded and serviced by DG III of the Commission, whose responsibility for the "Internal Market and Industrial Affairs" includes responsibility for matters relating to the liberal professions and the mutual recognition of diplomas. However, many fears have been expressed recently (1991) about the level of the Commission's funding and support, the inadequacy of which appears to be preventing the Committee from fulfilling its remit.

Committee of Senior Officials in Public Health (CSOPH)

CSOPH was also set up in 1975, as a result of the adoption of the Doctors' Directives". "Public Health" should be interpreted in its broadest sense; the Committee is made up of senior civil servants with responsibility for national health care systems. The UK is represented by a senior official of the Department of Health. In the UK individuals are required to become patients on the grounds of public policy. The Public Health (Control of Disease) Act 1934 provides for the medical examination, removal to hospital and detention in hospital of those who are (or are believed to be) suffering from a notifiable disease. Section 10 of the Act defines 'notifiable disease' as meaning cholera, plague, relapsing fever, smallpox and typhus. At the time of establishment, the Committee's remit was defined as follows:

- to discover and analyse any difficulties which might arise from the implementation of Directives 75/362/EEC and 75/363/EEC.

- to collect all relevant information on the conditions under which general and specialist medical care is given in the Member States;
5.

- to deliver opinions which could guide the Commission's work with a view to amendment of the above mentioned Directives.

The "Doctors' Directives" were followed by similar legislation governing midwives, dentists and pharmacists and other health professions will now be covered by the 1989 "general system" directive on mutual recognition of higher education diplomas, with the result that the Committee's remit has broadened since 1975.

PROFESSIONAL BODIES TO WHICH THE EMA IS AFFILIATED

These organisations are all non-governmental and funded by members' subscriptions. They are not statutory bodies.

Standing Committee of Doctors of the EC (CP)

The Standing Committee, or Comité Permanent, acts as the 'voice' of the whole profession in Europe. It was established in 1959 by the medical organisations of the six countries which signed the Treaty of Rome in 1957. It has increased in size as other countries joined the EC. Its terms of reference are:

(a) to study and promote the highest standard of medical training, medical practice and health care within the EC;

(b) to study and promote the free movement of doctors within the EC;

(c) to represent the medical profession of Member States at EC level.

The following sectoral organisations are all represented at its meetings by liaison officers and normally channel their own recommendations through it, to enable it to make recommendations on their behalf to the appropriate EC institutions.
European Union of General Practitioners (UEMO)

UEMO represents GPs and its members are professional associations representing GPs. It is particularly concerned with standards of training, practice and patient care and with the "ethical, scientific, professional, social and economic interests of European general practitioners".

The UEMO campaigned actively for the 1985 EC directive (85/457/EEC) on specific training for general practice and is now seeking to ensure that the directive is implemented in all EC Member States. It has good relations with the EC's Advanced Informatics in Medicine and Europe Against Cancer programmes.

Permanent Working Group of European Junior Hospital Doctors (PWG).

The PWG was established in 1976. It has an EC subsection, but includes professional organisations representing doctors in training grades in six non-EC European countries as well (Austria, Finland, Iceland, Norway, Sweden, Switzerland). One of its aims is to exchange information and develop a common approach to, problems of mutual interest, such as medical education, specialist training and working conditions.

The PWG is not affiliated to the European Association of Senior Hospital Physicians (AEH). The AEH is represented at the meetings of the Standing Committee of the EC.

It is also not affiliated to the European Federation of Salaried Doctors (FEYS) whose aim is to study and defend the interests of salaried doctors and to improve their working conditions "from the psychological, medical and material points of view". FEYS is also represented at meetings of the Standing Committee of Doctors of the EC.

Neither is it affiliated to the Conference Internationale des Ordres (CIO), also represented at the Standing Committee of Doctors of the
The functions of organisations in this Ordre are defined by law and include the upholding of the morality, probity and dedication essential to the practice of medicine, the adherence of doctors to professional and ethical codes and the defence of the honour and independence of the medical profession.

The organisations represented at the CIO, established 1971, all have some responsibility for the registration of doctors and for professional/ethical codes and disciplinary matters. The aims of the CIO are the study of practical measures to be taken by "orders" to implement EC legislation and the upholding of standards to protect the interests of patients. Its members regularly exchange data on a wide range of professional and ethical matters.

HEALTH CARE SYSTEMS AND PROFESSIONAL ORGANISATIONS IN THE EUROPEAN COMMUNITY

Introduction

The following is a brief summary of the types of health care systems that exist in each Member State. The professional organisations listed are those represented on the various European medical bodies of which the BMA is a member and those which are responsible for the registration of doctors. These are one and the same in some countries, as not all countries have direct equivalents of both the GMC and the BMA, but direct comparisons are not always possible. The amount of documentation available varies from country to country, but detailed questions about remuneration and terms of service are best addressed to the appropriate professional organisation in the country in question.

Doctors intending to work abroad should bear in mind the very different approach to organisation of health care in many EC Member States. Systems can be divided very roughly into two types

(a) "NHS"-type, funded by government/taxation;

(b) Insurance-based systems, funded by individual and employers' contributions, with varying degrees of government subsidy.
This type of insurance is often referred to as "social insurance" and is usually part of an overall "Social Security" system, by means of which the state provides for the welfare of its citizens.

Similarly, in some states the majority of doctors are in "liberal" practice and there is direct access to specialist treatment, whereas in others, as in the UK, referrals are made for the most part by the GP. There are also variations in approaches to matters such as confidentiality, patient access to records, advertising and complementary therapies. Doctors should check with the relevant professional organisation before starting work in any country.

The European Commission has stated that it does not intend to harmonise what it refers to as "social security" systems. The BMA interprets this as meaning that individual countries can continue to fund and administer health care in the manner of their choice. However, as the Single European Market involves the free movement of citizens as well as goods, those citizens should be entitled to receive the same standard of care and "social protection" in one country as in another.

Treatment abroad

Emergency treatment during visits abroad is the subject of a reciprocal agreement. British citizens travelling within the EC on holiday or on business should obtain form E111 from local DSS or post offices, which will entitle them to urgent medical treatment on the same basis as citizens of the Member State in question. This may be free at the point of delivery or paid for and reimbursed totally or partially afterwards. People are advised to study the accompanying leaflet on arrangements for reimbursement.

Special arrangements can be made in advance for treatment abroad when this cannot be provided within the necessary timescale in the U.K. Applications have to be made by the relevant hospital consultant to the international division of the Department of Health, but only a small percentage are likely to be accepted.
9.

Those working abroad on a long-term basis should normally slot into the system of the country in question. Advice should be sought either from a professional association or the future employer, if applicable.

The joint impact of the Single European Market and recent NHS reforms in the U.K. is as yet an unknown quantity.
BELGIUM
Population 9,947,800 (1990)

Health Care System

Public health care in Belgium falls within the "Social Security" scheme. It is based on a system of compulsory insurance, administered by a number of "mutual aid societies", which for historical reasons all have a particular religious or political alignment. These organisations have national and local branches. The government has a role in regulating the system and, to a certain extent, in funding it, but providers of health care seem traditionally to have enjoyed a large degree of independence. However, as in many other European countries, government intervention seems to be increasing.

Wage and salary earners and government employees are covered by the "general regime"; they and their employers pay contributions which are linked to their earnings. There is a separate programme for the self-employed and government subsidies cover the elderly, unemployed etc. There is a national fee schedule for doctors practising within the Social Security system, negotiated by the insurance bodies and doctors' associations. Most doctors are in "liberal", i.e. independent practice, whether they are specialists or GPs. Patients may consult specialists without referral from a GP, the freedom to choose one's doctor being a strongly held principle. Specialists share their fees with hospitals whose facilities they use.

When a patient consults a doctor, s/he pays a fee which is then reimbursed. Reimbursement is normally at 75%, or at 100% for the elderly, unemployed and certain other groups. There are third party agreements between providers and insurance bodies to cover expensive treatments. Bills for medical care in hospital are sent directly to insurance bodies, but the patient makes a contribution to the costs of the stay in hospital. There is a negotiated list of reimbursable prescription drugs; these are classified into four categories, which determine
the level of reimbursement ("lifesavers" are reimbursed at 100%). The patient pays a percentage of the actual cost of the drug, rather than a flat premium.

There is a high ratio of doctors to the population.

Registering Body

Ordre des Médecins
Place de Jamblinne de Meux 32
1040 Bruxelles

This body is responsible for the self-regulation of the profession. Moves by the government to reform its structure recently provoked strong protests from the medical profession.

Main Professional Association

Fédération Belge des Chambres Syndicales de Médecins A.S.B.L.
Ave A Solvayan 5
1170 Bruxelles

This is a national federation of medical unions, which has a high profile.
DENMARK
Population 5,135,400 (1990)

Health Care Systems

Denmark has a publicly financed health service covering the whole population, which is planned centrally and administered locally. Funding is chiefly from taxation. Hospital care and primary care services are free at the point of delivery; patients pay contributions towards the cost of prescribed medicines and dental treatment. Access to specialist treatment, except in emergencies, is normally via referral by a GP. Health insurance companies mainly cover travel insurance and services towards which the patient pays a contribution.

Primary care refers to many medical and related professionals other than the GP or family physician. It is therefore wider than general practice or family practice.

'Primary care consists of the advice given to a person or a group of persons for preventive or therapeutic purposes by one or more members of the health or related professions, acting alone or as a team' (WHO, 1970).

Apart from increased emphasis on health maintenance, the term is used to imply more active involvement of the population and of several departments of government.

Users of the health service are divided into two groups:

Group 1: Patients have a free choice of GP within a given area and can change doctors once a year. Referral for specialist treatment is via the GP. This applies to 95% of the population.

Group 2: Patients can opt to pay an extra premium in return for an unlimited free choice of doctor and direct access to specialist care. Only 5% of the population choose this option.

There are no legal obstacles to private practice, but few doctors engage in it exclusively.
Main Professional Association

Den Almindelige Danske Laegeforening (Danish Medical Association)
9 Trondheims gate
2100 Copenhagen Ø

Membership of the DMA is compulsory for GPs who wish to practise within the national health system and voluntary for other doctors. Almost 96% of all doctors are members. Registration is actually carried out by the Danish Health Board, but the DMA will provide information about the formalities and documents required. Disciplinary functions are shared, with the DMA handling alleged breaches of medical ethics and disputes between doctors, brought to its attention by doctors. The National Health Board deals with accusations of incompetence and the Patient Complaint Board deals with complaints made by patients.
FRANCE
Population 55,304,000 (1990)

Health Care System

Health care in France falls within the "Social Security" system and is insurance based. There are three main sickness funds, covering salaried employees, farmers and agricultural workers and the self-employed. The remainder of the population is covered by a number of special funds. The scheme for salaried employees, who form the largest group, is known as the "General Régime"; contributions are linked to earnings and are shared between employees and employers.

Patients may consult the doctor of their choice and may consult a specialist without referral by a GP. Most doctors are "conventionnés", that is they adhere to agreements negotiated by their professional associations with the insurance bodies. Most operate the agreed tariff of fees for service; the insurance bodies then pay contributions towards their own sickness and pension funds. Some others forfeit the latter benefits in return for fixing their own fees and a third category opt out completely. The patient normally pays for consultations and prescribed drugs and is reimbursed at a rate of 70-75%. S/he may take out a complementary private insurance scheme to cover non-reimbursable costs. There are exemptions for many patients suffering from chronic ailments.

Hospital costs are paid directly by the "Social Security", but, except in the case of maternity services and work-related accidents, a copayment is required of the patient to cover some of the costs of the stay in hospital. Direct payment is also made for outpatient diagnostic services, expensive drugs and laboratory tests.

The "Social Security" system, which has always received generous funding, is currently operating at a deficit and stringent measures are being taken to contain costs. Doctors have traditionally enjoyed great freedom in clinical decision-making and prescribing; suggestions that this freedom may be undermined have provoked widespread protests.
Access to medical studies is controlled by numerous clauses, but problems with un- and underemployment have been reported. These are waiting lists in certain parts of the country for certain procedures.

Registering Body

Conseil National de l'Ordre des Médecins
60 Bd de Latour Maubourg
75007 Paris

NOTE: The above is a central authority, and is responsible for professional regulation, but actual registration is carried at "departmental" level by the branch of the "Ordre" in the "departement" in which the doctor intends to practise.

Main Professional Association

Confédération des Syndicats Médicaux Francais
(address as above)

Translated from the French, this is a confederation of medical unions and therefore represents doctors of different crafts at governmental level. The proportion of doctors who are members varies from one part of the country to another.
GERMANY
Population 76,070,000 (1991)

Health Care System

Germany has a "social insurance" system, which has its roots in an initiative launched by Bismarck. The health component of the system is administered by a variety of sickness funds (Krankenkassen) which are obliged by law to grant identical benefits. The local funds ("Ortskrankenkassen") are open to all comers, whereas there are a number of others which cover specific groups, e.g. company employees, agricultural workers.

The greater part of the population is covered by "statutory health insurance". This is obligatory for blue-collar workers and white-collar workers earning below a certain amount. The scheme also covers groups such as the unemployed, students and the disabled. The self-employed and those earning in excess of the specified maximum income may opt in; there is no discrimination against "bad risks". Contributions are earnings-related and are shared between employers and employees. Limited contributions for pensioners are being phased in. Private insurance schemes operate in parallel, providing full cover for those who opt out of the statutory scheme or complementary cover for those within it. Their premiums are based on risk assessment.

Doctors who wish to practise within the social security system have to be registered with the regional board of "panel" doctors. Terms and fees are negotiated by these boards ("Kassenärztliche Vereinigungen") Patients insured under the statutory scheme pay a fixed copayment for periods spent in hospital. Per diem costs for hospital care are determined by regional governments. Patients may register with a doctor of their choice for a three-month period; access to specialist treatment does not require referral.

Health care in the five "Lander" of the erstwhile German Democratic Republic is currently undergoing a period of transition. Under the previous regime, primary care was provided chiefly within polyclinics,
community-based centres providing a range of services, whereas in the Federal Republic it is provided by doctors established in independent practice. Following a vigorous campaign by professional associations, the "liberal practice" system is being imposed throughout the country, but the polyclinics are being allowed to operate until 1995. The statutory insurance scheme is being introduced.

There is a considerable problem with medical unemployment in Germany, particularly amongst junior doctors. However, health care seems overall to be of a high standard; per capita expenditure on health is high and waiting lists are low. Reforms implemented in 1989 aimed to control expenditure on drugs, increase direct in-patient charges and increase incentives for doctors to carry out health promotion work.

Registering Body and Main Professional Association

Bundesärztekammer
Herbert-Levin Str 1
5000 Koln 41

NOTE: Actual registration is carried out at regional level, by the "Landesärztekamern. There are a number of professional organisations representing different sections of the profession, e.g. salaried doctors, GPs, doctors established in independent practice ("niedergelassen") and senior hospital doctors.
GREECE
Population 10,045,000 (1990)

Health Care System

There is not a great deal of information available about Greece, which does not feature in any of the publications produced for doctors by the various European medical bodies. However, the health care system seems to have been beset by a number of problems which the government has been seeking to redress, starting with the creation of a national health service in 1933. Particular problems seem to have been caused by a multitude of social insurance funds, inadequacies in the provision of primary care, overproduction of doctors and inequalities in resource allocation, this last leading to an overconcentration of doctors and facilities in major cities and deprivation in rural Greece. Until recently there were scarcely any GPs or "family doctors" trained as such.

The introduction of the National Health System means a greater state control over the provision of health care, but a major aim seems to be to decentralise planning and devolve organisational powers to regions. Other aims are to develop primary and community care, not least by training more GPs and creating health centres in rural and urban areas, and to achieve greater equality in resource allocation. The growth of the private sector is controlled and restricted; doctors working within the VHS have a full-time commitment to it.

All hospitals are now controlled by the state. Insurance bodies pay 15-20% of costs incurred by their beneficiaries and the rest is borne by the government. Health care for insured patients - who share contributions with their employers - is free at the point of delivery; there may be charges of up to 20% for dependants.

Standards of medical training in Greece, in particular specialist training have caused some concern. There is no formal assessment of trainees,
but there are final examinations, on successful completion of which specialist status is awarded.

Main Professional Association

Panhellenic Medical Association
2 Semitelou Street
Athens 11529

Details about registration should also be sought from this organisation.
Health Care System

Health care in the Irish Republic combines public and private elements. Public funding is by the Department of Health and services are organised by regional health boards. Discussions about major changes are at an advanced stage, but at present the delivery of health care is based on a system of means testing, by which patients are divided into three categories, as follows:

Category 1: Patients on low incomes, who receive all health services free of charge. Factors such as number of dependents and household expenditure are taken into account in assessing eligibility;

Category 2: Patients in the middle income bracket, who are entitled to free or subsidised access to a range of services, excluding GP services and dental and ophthalmic care. Assessment is made of personal income alone, with no account taken of other factors;

Category 3: Patients with high incomes, who have to pay for the major part of their health care. They have free or subsidised access to some services which are available on this basis to the whole population, e.g. in-patient care in hospitals and treatment for some chronic illnesses.

There is a voluntary, non-profit health insurance scheme, established by the state. Those who subscribe to it are eligible for tax relief. Access to specialist care is via the GP, who practices on an independent, self-employed basis. Fees for the treatment of Category 1 patients are paid by the health boards; other patients pay directly. Hospital consultants are permitted to practise privately outside the time contracted for public patients.

The pattern of medical training is very similar to that of the U.K.
21.

Registering Body

The Medical Council
8 Lower Hatch Street
Dublin 2

Main Professional Association

Irish Medical Association
10 Fitzwilliam Place
Dublin 2

These bodies are quite similar in function to the BMA and the GMC.
ITALY
Population 57,576,400 (1990)

Health Care System

Italy has a national health service, established in 1978. It is funded by the government and by direct contributions from employees and employers. The self-employed pay a "health tax". All citizens are covered by the service; private or company-based insurance is supplementary.

Patients register with a GP in their area, each GP being allowed to have a maximum of 1500 patients on his/her list. Consultations are free; there are fixed charges for prescriptions, but with a large number of exemptions for certain drugs and medical conditions. Referral for specialist or hospital care is normally via the GP. There is a token per diem copayment to cover stays in hospital.

GPs have to apply to their local health authorities (via the registering body) to be allowed to practise within the NHS. They are paid on a capitation system and there are negotiated fees for particular services. Some specialists are also deemed to provide primary care, for example, paediatricians provide "GP" services for children up to the age of 12. Salaried doctors are allowed to practise privately outside their 75% commitment to the NHS, if they wish. Those with a 100% commitment cannot engage in private practice.

Overproduction of doctors in Italy has led to considerable medical underemployment. There are some waiting-lists for hospital treatments and it has been noted that many Italians seek treatment abroad, particularly in France.

Registering Body and Main Professional Association

Federazione Nazionale degli Ordini dei Medici (FNOOMM)
Piazza Cola di Rienzo 90/A
00192 Roma

Actual registration is at regional level.
LUXEMBOURG
Population 374,900 (1990)

Health Care System

Luxembourg has a "Social Security" system, based on a combination of insurance and government funding. Doctors are in "liberal" practice and the majority of hospitals are not state-owned, although the Ministry of Health is responsible for identifying local health needs and authorises the establishment of new hospitals.

Those in employment must be insured by one of the 12 sick funds, which cover different groups of worker/professionals. Contributions are shared between employees and employers and paid in their entirety by the self-employed. The government pays for the care of those who are not insurable, e.g. students, the unemployed and also for maternity services and care given as a result of road accidents or injuries sustained during school sports activities. A state "risk fund" covers long-term treatment for the mentally ill and those suffering from diseases such as cancer. A national "solidarity fund" provides grants for the disabled who need constant care.

All doctors work within the social security system. There is an agreed fee schedule, with patients paying a copayment of 25% for consultations and reimbursable medicines. Insured patients pay a per diem contribution for hospital stays. Patients have free choice of doctor and access to specialists without referral. A general view seems to be that the system operates smoothly and to the satisfaction of those who use it.

There are no medical faculties in Luxembourg, so doctors are trained in other countries, in particular in Belgium and France.

Registering Boly

Ministère de la Santé
57 Boulevard de la Petrusse
2320 Luxembourg-Ville
Main Professional Association

Association des Médecins et Médecins-Dentistes
du Grand-Duché de Luxembourg
29 rue de Vianen
2630 Luxembourg-Ville

This is a highly representative body.
The Dutch system is currently being reorganised, but it is insurance-based. Under the present system, statutory health insurance has covered long-term care and an employed persons scheme has been compulsory for employed persons earning below a certain amount. Civil servants have had their own scheme and others have taken out private insurance. The aim now is to achieve greater integration by introducing one basic national health insurance scheme for the whole population, based on individual income and covering 85% of all medical costs. Discussions on greater competition and agreements on fees for GP services are now to be concluded at regional, rather than national level. The reforms are comparable to those which have recently taken place in the U.K.

Patients are registered with GPs, who are independent and remunerated either by insurance bodies or directly by those with private insurance. Referral for specialist treatment is via the GP. Many hospitals are owned by private non-profit-making organisations, although the majority of teaching hospitals are state-owned. Most specialists practise independently, although a small number are employed by hospitals. There are few waiting-lists and hospital care provision is of a high standard.

Registering Body

De Geneeskundige Hoofdinspecteur van de Volksgezondheid
(Chief Inspector of Public Health)
De Reijersstraat 19
2265 BM Leidschendam

Authorisation to practise is given on the swearing of an oath, after which administrative formalities are dealt with by the Regional Inspector of Public Health.
Main Professional Association

Koninklijke Nederlandse Maatschappij tot Bevordering der Geneeskunst
(Royal Dutch Medical Association)
Domus Medica
Louanlaan 103
3526 XD Utrecht
PORTUGAL

Population 10,336,000 (1990)

Health Care System

Portugal moved in 1979 from an insurance-based system to a comprehensive, government-funded and administered National Health Service. All citizens are covered, although they may opt for private care if they so wish.

Doctors working in the health service are salaried employees of the state. They may work in the hospital sector, general practice or public health. GPs work in health centres with lists of patients. A referral system operates for hospital/specialist care. The private sector seems to be quite buoyant, despite attempts by government to limit its growth. The right of doctors employed by the health service to engage in private practice has been a source of conflict; at present those not working full-time in the health service may do so.

Patients pay flat rate copayments for prescribed drugs and other primary health care services.

Access to medical studies is controlled, but there seem to be no difficulties with medical underemployment.

Registering Body and Main Professional Association

Orden dos Melicos
Av Almirante Reis 242, 2º Esq
1000 Lisbon

The Orden dos Melicos has branches in Porto and Coimbra, as well as in Lisbon.
SPAIN
Population 38,924,570 (1990)

Health Care System

The vast majority of the Spanish population are covered by a "Social Security" system, funded by individual and employers' contributions and central funding from taxation. The General Health Act 1985 marked a shift towards a more nationalised and integrated service, in place of one that had many tiers and differentiated between health care provision for urban and rural communities. In effect, there is a national health service, with a private sector operating in parallel.

The "Social Security" fund covers GP services, dental extractions and hospital services. The costs of medicinal products are shared, although these are free for pensioners. Provincial governments are responsible for the care of psychiatric patients. Patients are registered with GPs, who practise in primary health care teams. Access to hospital/specialist treatment is via referral by the GP.

Health service GPs are salaried, as are doctors working in public hospitals. The private sector is large and many doctors work in both sectors. Private insurance can be taken out to supplement the state scheme.

Spain has considerable problems with medical unemployment.

Registering Body and Main Professional Association

Consejo General de Colegios de Medicos de Espana
Villanueva 11
28001 Madrid

NOTE: Actual registration is carried out at regional level.
UNITED KINGDOM
Population 57,409,000 (1990)

Health Care System

The National Health Service (NHS), created by an Act of Parliament in 1946, is a comprehensive health service, not based on an insurance scheme which may be used by anyone who is ordinarily resident in the U.K. It is currently administered through 15 Regional Health Authorities (RHA). Within each Region patient care services are managed by a District Health Authority (DHA), of which there are over 270 in England and Wales. There is considerable autonomy in the RHAs and DHAs, so a nationally co-ordinated health care library system is not possible.

Apart from charges (from which there are certain exemptions) for prescriptions and dental and ophthalmic treatment, the service is free. Most of the cost of the NHS is met from taxation; of the remainder about 15% is made up from NHS contributions, while about 3% is made up from charges to patients.

Private medicine can be purchased directly from medical practitioners, or from medical insurance companies, enabling a patient to choose a consultant, the time of admission and to have pre-arranged dates. Privacy is ensured, giving an ability to carry on one's business, to have a private telephone, unrestricted visiting and a choice of meals.

Registering Body

General Medical Council
44 Hallam Street
London WC1N 6AE

Main Professional Association

British Medical Association
BMA House
Tavistock Square
London WC1H 9JP
### Table I  
**AUGUST 1991**

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<td>DG XXIII SME (Small and Medium Sized Enterprises) Task Force</td>
<td>H. von Woltte</td>
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Consumer affairs, previously in DG XI, now (February 1999) a separate directorate, not in any Directorate-General.
The European Parliament (EP)

The European Parliament does not have the legislative powers of a national parliament, but its opinion must be sought on the vast array of proposals. It is a powerful consultative body, which has already increased its powers and seems set to do so further. Its members are elected by citizens of Member States for five-year terms; they sit in political groups, rather than in national delegations. The allocation of its 518 seats is as follows:

France, Germany, Italy, U.K.: 31
Spain: 60
Netherlands: 25
Belgium, Greece, Portugal: 24

Denmark: 16
Ireland: 15
Luxembourg: 6

The Economic and Social Committee (ESC)

The ESC is an advisory group, which, like the EP, has to be consulted by the Council of Ministers and the Commission and which also produces opinions on its own initiative. Its membership is made up of three groups, intended to represent the various categories of economic and social activity within the Communities. Group I represents employers, Group II workers and Group III various interest groups including the professions. At present, there is no health professional among the UK members. Members are proposed by national governments and appointed by the Council for 4-year terms. The ESC generally appoints experts to assist study groups when proposals are considered. These are usually nominated by members.

Council of Ministers

The Council of Ministers consists of ministers from the government of each of the Member States. It formally comprises the foreign ministers of the member states but in practice the minister depends on the subject under discussion. The Council is the Community's principal decision-making body and most powerful institution. Legislation is proposed
and drafted by the Commission and voted on by the council. Presidency of the Council is held by each Member State in turn for 6-month periods. The Presidency of the EC is also held in rotation for 6-month periods, setting the agenda for and chairing all Council meetings. The Presidency serves an important function since the incumbent nation has an opportunity to pursue its own particular policy priorities. The European Council comprising the heads of government of the Member States, meets twice a year to provide overall policy direction. Established in 1974, the European Council was only formally brought within the institutional framework by the Single European Act (SEA).

The European Council holds a summit in the country holding the Presidency at the end of its period in office. The holders of the Presidency for the years 1991-1994 are:

1991  Luxembourg; the Netherlands
1992  Portugal; U.K.
1993  Denmark; Belgium
1994  Greece; Germany

Its meetings are prepared by COREPER, the Committee of Permanent Representatives, which is composed of Member States' ambassadors to the EC.

The Court of Justice

The Court rules on questions of Community Law and whether actions by the Commission, council of Ministers, Member Governments and other bodies are compatible with the various Treaties. It is based in Luxembourg. It should not be confused with the European Court of Human Rights, which is part of the Council of Europe, a body separate from the EC.
Relationship Between Institutions

EC legislative processes are complex, the following diagram illustrates the possible "lifecycle" of a successful proposal.

Commission produces text

Council of Ministers

European Parliament & Economic & Social Committee (ESC) as draft in Official Journal of the European Community"

Opinions produced

Commission amends proposal

Council of Ministers: Common position reached

European Parliament: Second reading

Council of Ministers: Adoption

Implementation & monitoring by Commission

LEGISLATION

Much national legislation now has its origin in Brussels. Once a text has been formally adopted, Member States may face infraction procedures if they do not comply with specified time-limits. (In practice, this applies almost exclusively to directives). The following forms of legislation may be issued:

Regulations immediately become law in Member States, in the form in which they are issued.

Directives are binding on Member States as far as intended results are concerned, but national authorities may decide how best to achieve these results.
Decisions are binding on all those to whom they are addressed, which may be member states or particular groups within them. A recent example was a Decision by the Heads of State adopting a 1992-1994 action plan in the context of the "Europe against Cancer" programme, involving all member states. (See later).

Opinions and Recommendations are not binding. They are advice to governments.

A term much used recently is "subsidiarity". This is a principle of de-centralisation, a nebulous but universally approved doctrin that decisions should, as far as possible, be taken by local and national authorities.

Legal aspects

In the domain of Health Informatics DG XIII reviewed the functioning of the present data protection arrangements and investigated the required actions to develop harmonization within Europe.

Harmonization is the process of fixing common laws and standards for all Member States, covering products, services, taxation, trading arrangements etc. to remove trade barriers between EC Member States.

The Advanced Informatics in Medicine (AIM) Faculty of DG XIII F/AM Working Conference, Brussels, 19-21 March 1999 on Data Protection and Confidentiality considered the domains of Assessment and Monitoring, Legal initiatives, Organisational aspects and Education and awareness.

Assessment and Monitoring

A multinational multidisciplinary group is needed to assess and monitor the extent to which data protection laws and technical measures, such as Logical Access Control, health care networks, databases, software, personal computers, smart cards, optical discs and reference centres for data protection are being applied in the EC medical informatics sector with the purpose of including all the information law aspects of health care informatics.
Legal Initiatives

To reinforce general data protection law within the Community the EC should try to accelerate the compliance of the Member States with the Council of Europe's Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data and some subsequent recommendations, especially Recommendation R(91)1 on Automatic Processing of Personal Data. As the member states have, so far, been slow to adopt this legislation a new directive regulating information law may need to be adopted.

This directive could take a detailed comprehensive approach to Information Law to enable identification of issues in medical informatics requiring general legislation and of those requiring specific regulation.

In devising these EC regulations special attention will need to be given to the following areas: confidentiality, the right to access and amendment, liability and copyright, control and enforcement mechanisms, codes of good practice in health data handling and legal requirements for health software certification.

The Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, C103, Strasbourg, 23.01.1991 is now a world standard. Although it has been ratified and implemented throughout the EC not all countries have implemented the special safeguards for personal information under Article 6, or the specific Recommendation R(91)1 'Regulations for automated medical data banks', Strasbourg, 23.01.91.

C103 Article 6 'Special Categories of Data'

Personal data revealing racial origin, political opinions or religious or other beliefs, as well as personal data concerning health or sexual life, may not be processed automatically unless domestic law provides appropriate safeguards. The same shall apply to personal data relating to criminal convictions.
Article 7 'Data security' requires appropriate security measures to be taken for the protection of personal data stored in automated data files against accidental or unauthorised destruction or accidental loss as well as against unauthorised access, alteration or dissemination, but most health information systems do not yet have a written computer security policy.

Legal Issues

It is best to consider data protection within the wider context of information law which also affects inter alia medical informatics and identifies those areas where health care informatics require special legal attention.

All the existing international documents on data protection, in general or in the health field, have no real supranational power and have to rely entirely on national governments for their transposition to the internal legal sphere.

Since the enactment of C109 and R(91)1 five Member States: Belgium, Greece, Ireland, Italy, Portugal, have not ratified the Convention and five: Belgium, Greece, Italy, Portugal and Spain have not enacted a data protection act.

Even though some EC countries are still in the phase of adopting the principles and philosophy of data protection, the Council of Europe is already rethinking them.

The AIM Executive of Directorate F, Division 6 of DG XIII Telecommunications, Information Industries and Innovation states that the problem is wider than this because the adoption of this Convention and this Recommendation on health data banks may well not be sufficient to attain a fair EC legal environment in respect of health data protection and confidentiality.
A second generation of international data protection legal instruments is now emerging due to a new wave of international concerns, not only in the specific field of health informatics, but in the wider field of data protection in general.

Ownership of Data

It is crucial that Medical Informatics professionals investigate the legal (and subsequent practical) implications of the evolution of the notion of information property law. Self-determination through information control is traditionally treated in a fundamental human rights context.

The principle of respect for human rights was established in international law by the Charter of the United Nations (UN).

The UN is an organization of 159 nations that works for world peace and security and the betterment of humanity. Countries of every part of the world belong to the UN. Each member nation sends representatives to the UN headquarters in New York City to discuss and try to resolve problems. Its two main goals are peace and human dignity. It was established on 24 October 1945 by nations opposed to Germany, Italy and Japan in World War II to work out a plan for an organization to help keep peace in the world. This plan was described in a document called the 'Charter of the United Nations' which is the constitution of the UN containing a plan for its organization and the rules by which it is governed.

The Charter has 19 chapters divided into 111 articles that explain the purposes, principles and operating methods of the UN.

In the preamble to the charter are statements reaffirming the faith in fundamental human rights (Morally and socially correct behaviour), in the dignity and worth of the human person, in the equal rights of men and women and of nations, large or small, and to establish conditions under which justice and respect for the obligations arising from treaties
and other sources of international law can be maintained, and to promote social progress and better standards of life in larger freedom, and for these ends, ..... to employ international machinery for the promotion and social advancement of all peoples, by a combination of efforts to accomplish these aims.

The UN Charter permits the General Assembly, the only major organ of the UN in which all members are represented and responsible in some way for every other organ of the UN, to create committees to help it perform its work. The Third Committee deals with social and cultural matters.

In 1946, the UN set up the Commission on Human Rights as part of the Economic and Social Council, which is devoted to improving the way that people live by encouraging higher standards of living, better health, cultural and educational co-operation among nations and observance of human rights. The Commission wrote the Universal Declaration of Human Rights, adopted by the General Assembly on 10 December 1948.


The European Convention guarantees, for the most part, civil and political rights: the right to life, liberty and security; freedom from inhuman or degrading treatment, slavery, servitude and forced labour; the right to a fair trial; freedom of conscience, of speech and of assembly.

Section I of the European Convention spells out, generally in more detailed form, most of the basic civil and political rights contained in the Universal Declaration. Section II proposed the formation of a European Commission of Human Rights, the Commission and a European Court of Human Rights. Section III specified that the Commission should consist of a number of members equal to that of the High Contracting
Parties, of which there are twenty one. The members are: Austria, Belgium, Cyprus, Denmark, France, Germany, Great Britain, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and Turkey. The problems of information property law, such as C109, R(81)1, R(93)10, on account of their commercial implications, fall directly within those areas of activity in which the EC is greatly interested. Work carried out in other areas of the EC should be co-ordinated with the AIM in order to establish the importance of its implications to the development of information property law. Future AIM activities might need the allotment of both time and effort to devise the detailed approach required in the health care sector.

An EC legal instrument is required to ensure that adequate EC rules of liability and copyright exist and a legal obligation should exist for the use of certified health software. Action must also be taken to fill in the gaps in the data protection environment in the EC so that sufficient confidence can be generated to facilitate the cross-border exchange of health records and avoid discrimination against countries with weak general data protection legislation.

Language Aspects

One of the major obstacles to the idea of the European Community is that of language. Except for Ireland and the U.K., and for parts of France and parts of Belgium and Luxembourg, none of the EC countries have a language in common with their neighbours. But Article 20.3 of Directive 75/362 states the following:

"Member States shall see to it that, where appropriate, the persons concerned acquire, in their interest and in that of their patients, the linguistic knowledge necessary to the exercise of their profession in the host country".

However, the text of the Directive is vague and the words are not seen as a formal legal obligation on the part of the migrating physician.
A lack of a sufficient knowledge of the host country's language would not legally constitute a restriction of the right of establishment (guaranteed by Article 52 of the Treaty of Rome)"...Freedom of establishment shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings, in particular companies or firms within the meaning of the second paragraph of Article 59" i.e. "companies or firms" means companies or firms constituted under civil or commercial law, including co-operative societies, and other legal persons governed by public or private law, save for those which are non-profit making. Or, perhaps, discrimination based on citizenship (also prohibited by Article 20), or as a violation of the European Convention of Human Rights, whose correct title, as drafted by the Council of Europe on 4 November 1950, is the Convention for the Protection of Human Rights and Fundamental Freedoms. Although the language barrier is not a barrier in the formal legal sense, it is inconceivable that a physician, whose civil and criminal liabilities are tremendous, would treat patients without being able to understand their complaints and risk severe malpractice suits.

'Language' and 'Language problems' will play an important role in the future of medicine in the Common Market (without also including technical, legal, medical and other associated aspects) in an extremely specialised and complex sector:

- European countries have different systems of health, of health control and of health insurance. Therefore there are several different enterprises for the interested groups.

- The associations for doctors, nurses and paramedics vary from country to country. Paramedical personnel (paramedics) are health care workers who provide clinical services to patients under the supervision of a physician. The term generally encompasses nurses, therapists, technicians and other ancillary personnel involved in medical care but is frequently applied specifically to highly trained persons who share responsibility with the physician for patient care.
The differences in medical treatment between European countries demand the creation of a common base, discussion of affairs, and the creation of a common system of terms.

Medical terminology (language) is often far removed from normal daily converse in what it means, but it is a meeting place for doctors, nurses and some patients. Direct communications between doctors, nurses, paramedics and patients may be difficult for the lay person to understand but they are unavoidable. The subject matter of medical terminology may be very complex and situated at a very high scientific level, understandable only to the initiated. It is a subject that is progressing very fast and demands an enormous flexibility in the use of language.

Medicine is not only the business of doctors and the use of language alters according to whether conversations are between doctors, between doctor and pharmacist or doctor and patient. Medical terminology often changes between surgery and hospital clinic, between doctors of different specialties and between nurses and patients. Similar problems are shown in medical literature, there being a scale from purely scientific texts to books and articles of popular medicine. For many years the majority of pharmaceutical companies have worked on an international network necessitating scientific work in several languages.

Oral and written instructions are required to ensure that treatments ensuing from medical research are used effectively. Medical knowledge is to a large extent broadcast by the methods of treatment, but at the moment descriptions of medicaments are not written in a common language understandable to patients. Recently attempts have been made to transfer scientific texts into layman's language.

Until recently there also existed a desired barrier to understanding between the medical fraternity and patients.

Medical terminology is becoming one of the most important subjects in the EC, despite being highly specialised.
The "Europe against Cancer" programme is innovatory. It is contributed to by European cancer experts, directors of cancer leagues, general practitioners and educationalists, and by officials and experts at the Commission. All these partners are contributing to the special character of the programme and to bringing the EC closer to the concerns of its citizens. This is the view of Jean Degriebe, the Director-General of DG V (Employment, Social Affairs and Education). The World Health Organization's goal is "Health for all by the year 2000", which is probably unattainable in its entirety but progress is being made.

With regard to cancer, more limited goals have been set by various national and international bodies, most of these also aimed at the somewhat mystical figure of the year 2000. The target of the European Regional Office of the World Health Organization (WHO) is a reduction of at least 15% in cancer mortality in people under 65 in Europe.

At the present time, cancer represents around a quarter of the overall mortality in most EC countries. But this figure, as high as it might be, only alludes to a small proportion of the total amount of human, social and financial costs linked to cancer. This explains the need to prevent at least some of these cancers from occurring.

A rational approach to prevention would require knowledge of cause and subsequent removal of that cause. However, some known causal agents cannot be removed, external factors, such as solar radiation, and internal determinants of disease, such as the genetic background of an individual or the hormonal milieu. Primary prevention aimed at preventing the occurrence of cancer could be achieved by the removal of identified risk factors. The goal of secondary prevention (screening) is to diagnose cancer at a very early stage or preferably to recognize the disease at a premalignant phase.
Tobacco

Tobacco is the best known and most widely used carcinogen and its use is responsible for:

- the vast majority of cancers of the lung, trachea and bronchus

- a considerable proportion of cancers of the bladder and of the renal pelvis

- a considerable proportion of cancers of the oral cavity, lip, pharynx, larynx and oesophagus, with an added large proportion of risk attributable to alcohol consumption

- a considerable proportion of cancers of the pancreas and possibly of renal adenocarcinoma.

Smoking is also related to an increased risk of developing cardiovascular diseases: coronary artery disease leading to acute angina pectoris and myocardial infarction and chronic heart disease, peripheral vascular disease and cerebrovascular diseases. There is a specific risk to women who smoke and use oral contraceptives of cerebrovascular disease. Also associated with smoking are chronic obstructive lung diseases, such as emphysema and chronic bronchitis, pneumonia, tuberculosis and peptic ulcers.

No country has yet banned the use of tobacco or tried to the legal method of discouraging its use by the imposition of very high taxes on it, and completely banning its advertising or its use in public places, nor have the ethical methods of promoting effective health education for children and adolescents, as well as for the general population been used.
Alcohol

Whereas there is no such thing as a safe tobacco product alcohol, in the form of one glass of wine per day, presents no measurable risk and may even slightly reduce cardiovascular mortality. Increased amounts of alcohol lead to increased risk of disease: alcohol is a recognized carcinogen for cancers of the oral cavity, pharynx, larynx, oesophagus and liver. The combination of drinking and smoking greatly increases these risks. Excessive alcohol intake also increases the likelihood of accidents and violence. It is easiest to express moderation of intake in quantitative terms.

Fresh Fruit and Vegetables

Although not associated with the aetiology of cancer "Europe against Cancer" stress the importance of a diet rich in fresh fruit, vegetables and cereals and low in animal fat to avoid obesity and its ensuing diseases.

Prevention of the development of occupational cancers

Work forces need to be adequately informed of possible risks and an efficient control should be maintained to prevent the emission of hazardous chemicals in the production chain.

Exposure to the sun

Excessive exposure to solar irradiation, particularly for some fair-skinned individuals, may lead to malignant melanoma of the skin. Ultraviolet (UV) machines may have the same effect.

Control of other risk factors

Immunization against hepatitis B may prevent the occurrence of viral hepatitis and also reduce the risk of primary liver cancer. In Europe,
the majority of cancers, with the exception of cervical cancer, are not known to be linked to viruses or parasites. Individuals known to be genetically at risk of developing cancer could benefit from specific surveillance.

Secondary prevention: screening for cancer can have a positive impact on cancer occurrence and/or mortality is possible through early detection. Women should be encouraged to be regularly screened from an early age for cervical cancer and for breast cancer. Colon cancer warrants considerable attention, but the expense of screening for lung cancer is hard to justify.

An important challenge for the 21st Century

The challenge for the next century will be to discover the causation of cancers and to then use this information for their prevention by the removal from the environment of avoidable causative factors. An obvious cause is tobacco, about which action must be taken in various fields: education, information, health, taxation, economics, agriculture, politics and legislation. Part of the answer may be financial constraints, but there may be a lack of creative imagination and the exhortation to lead a healthier life must also contain a moral component.

The role of cancer registration

The incidence of cancer varies between different parts of Europe, suggesting that factors associated with place of residence are important determinants of cancer risk. For this reason epidemiology, the scientific study of the distribution and determinants of a disease, is and will be playing a central role in the "Europe against Cancer" programme. Cancer registration as the presupposition of cancer epidemiology is the organized effort to collect, verify and tabulate, employ and disseminate information on the incidence of malignant neoplasms (life-threatening new growths) in a defined geographical area. Cancer registries are epidemiological institutions for cancer registration nearly always conducting research in analytical and descriptive epidemiology.
Professor Maurice Tubiana, Chairman of the Committee of Cancer Experts of the "Europe against Cancer" programme has stated the advantages of the European programme from a cancer expert's point of view:

When the European action against cancer programme was decided on in Milan in June 1985 at a meeting of the Heads of State or Government of the 12 countries of the Community three specific advantages of a European, as opposed to international, action emerged, namely:

- to exploit the prestige of a "European" label to increase the effectiveness of actions which could be undertaken at national level;
- to take advantage of the experience and help of experts from all the European countries. The European dimension considerably increased the ability of each country, not only in research but also in applying new methods of diagnosis and treatment;
- to promote legislative or regulatory measures at a time when more decisions were being taken at a European level for subsequent implementation at national level.

A major impact on public opinion was achieved by the publication and distribution to organizations of the European Code against cancer drawn up by cancer experts in the EC (see later).

Children, from the age of 5 to the end of adolescence, now receive health education in schools on aspects of the human body and the maintenance of healthy development.

The establishment of a healthy lifestyle is now promoted, assisted by the mutual support and co-operation between European countries. The Council of Health Ministers organized mass screening campaign for breast and cervical cancer.

Alongside information to the general public, training of health professionals, especially general practitioners, has been an important aim of the programme.

Community cooperation is broadening the field of clinical research from national to European centres. Cancer specialists and hospitals
in every country are cooperating, thus improving the effectiveness of research and speeding up the evaluation of new methods of treatment at shared cost.

The role of dietary factors in the development of cancer is being investigated. The difference between northern Europe and the Mediterranean area may explain why some cancers are more frequent in some countries than in others.

The European Code against Cancer was adopted by the Committee of Cancer Experts set up under the "Europe against Cancer" programme in May 1987 following wide consultation of the health ministries and non-governmental organizations involved in the fight against cancer.

European Code against Cancer

If the "Ten European commandments are followed, there will be a significant reduction in the number of deaths from cancer in the European Community, already predicted to reach 15% by the year 2000". Committee of Cancer Experts of the European Community.

CERTAIN CANCERS MAY BE AVOIDED

1. Do not smoke. Smokers, stop as quickly as possible and do not smoke in the presence of others.
2. Moderate your consumption of alcoholic drinks, beers, wines or spirits.
3. Avoid excessive exposure to the sun.
4. Follow health and safety instructions at work concerning production, handling or use of any substance which may cause cancer.

YOUR GENERAL HEALTH WILL BENEFIT FROM THE FOLLOWING COMMANDMENTS WHICH MAY ALSO REDUCE THE RISKS OF SOME CANCERS

MORE CANCERS WILL BE CURED IF DETECTED

5. Frequently eat fresh fruit and vegetables and cereals with a high fibre content.
6. Avoid being overweight and limit your intake of fatty foods.
7. See a doctor if you notice a lump, or observe a change in a mole, or abnormal bleeding.

9. See a doctor if you have persistent problems, such as a persistent cough, a persistent hoarseness, a change in bowel habits or an unexplained weight loss.

FOR WOMEN

9. Have a cervical smear regularly.

10. Check your breasts regularly, and, if possible, undergo mammography at regular intervals above the age of 50.

On the legal front Europe has made important decisions: harmonization of labelling on cigarette packets; the banning of high-tar tobacco; the banning of advertising on television; and the banning of smoking in public places.

In Europe cancer is still the second highest cause of death and the principle cause of death in the 35 to 65 age group.

Actions for a healthy diet

Eating habits, including the consumption of alcoholic drinks, play an important role in the development, and also the prevention of a number of cancers of the digestive tract and of breast cancer (Myrian Wilpart, Consultant to the "Europe against Cancer" programme, D-G V, CEC).

It is estimated that nutritional factors could be at the origin of more than one third of deaths from cancer. Proposals for action in the area of nutrition were thus incorporated in the "Europe against Cancer" programme.

The first action plan 1997-99 attempted to improve the knowledge of the possible links between diet and cancer. The second action plan 1990-94 intends to finance a large number of quality studies whose results will make it possible to clarify the guiding principles of nutritional requirements.
Since 1987, the EC has demonstrated its ability to make its own major contribution to the fight against cancer, by no longer restricting itself to its conventional activities - measures to combat carcinogenic chemicals (ECSC and EEC Treaties) or ionizing radiation (Euratom Treaty) - but by extending its sphere of action to new ideas such as discouraging the use of tobacco, improving nutrition, cancer screening, training of medical personnel, health information and education and medical research. A Communication from the European Commission to the Council, the European Parliament and the ESC of 8 May 1990 regarding the "Europe against Cancer" programme: Report on the implementation of the first plan of action 1987-99 regards the results as most satisfactory.

Legislation: Several pieces of Community legislation were announced, concerning the discouragement of tobacco use, improvement of nutrition and measures to combat carcinogenic chemicals and ionizing radiation. Out of 13 proposals, only one (on the prohibition of tax-free tobacco sales) was not drawn up on schedule. Seven out of the other twelve have already been adopted by the Council, including labelling of tobacco products, ban on smoking in public places, protection against ionizing radiation, protection against carcinogenic chemicals. The Council has adopted common provisions on three others: prohibition of cigarettes with a high tar content, nutritional labelling, protection of workers. The other two are still being discussed by the Council (tax burden on tobacco, limitation of advertising of tobacco products in the press and by means of bills and posters).

In 1985 the Council of Europe conducted a co-ordinated medical research programme on a subject chosen by the European Health Committee (CDSP). The European Health Committee commissioned a study group of experts to analyse existing hospital information systems based on the diagnosis and treatment of patients. In January the Group made a plan of work, experts were assigned responsibility for visiting specified countries and a questionnaire was drawn up to cover the points to be assessed in the study and then sent to the national health administrations of these member states:
- Austria, Denmark, Federal Republic of Germany, Greece, Italy, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom.
A report was made based on three different sources of information

- replies to the questionnaire from the national health administrations;
- information gathered by group members on study visits to these states;
- reports by group members on the situation in their own countries.

On the basis of this report the Group drew up a list of recommendations encouraging the development of hospital information systems (HIS), the use of the Minimum Basic Database (MBDS) and the grouping of patients and diagnostic related groups (DRG).

HOSPITAL INFORMATION SYSTEMS

Health care informatics

The Council of Europe reports that in recent years there have been great advances in medicine and medical technology accompanied by an ever increasing demand for health services. These developments, together with changes in the problem of diseases and environmental and social changes, have been followed by a dramatic increase in health care expenditure, especially in hospitals. At the same time there seems to be a decreasing ability to comply with the complex problems arising from these changes.

This presents a major challenge for health administration in many member states. Corresponding advances in planning, management and organization of health care systems have not developed at the same rate.

One major reason may be the lack of health care data relating to health status, resources, use, cost and outcome. In contrast to medical data associated with medical action, health care data assists policymakers, health administrators and health care providers in performing, planning, management, care delivery and evaluation. Unlike medicine, health care suffers from shortage of systematized data for use in the planning and decision-making process, from assessment of the impact
of health services on the health status of individuals and populations and the cost-effective running of the health services.

Hospitals are providers of goods and services to patients as part of the treatment process during the hospital stay. The evaluation of hospital performance can only be seriously undertaken when the products of these institutions are clearly defined, production recorded and analysed. Hospitals are information-intensive environments as well as complex organisations where information processing and communication are vital functions.

Medical informatics, defined as the "rational management of health information by the use of computers" has, during the last decade developed into a purposeful tool in the management of hospitals and health services in general.

A hospital information service is the collection of application systems around a central database - a patient index. HISs, assisted by computers, have been difficult to introduce successfully. They should be highly conversational and available. Trends in their development over the last five years have been:

- a shift of emphasis from large central processors to distributed networks of mini and micro-processors to give more user-responsive systems;
- new software tools to interface with the end-users and promote user-friendly systems. The views of end-users have expanded with user-participation in system development and interactive system design with prototypes;
- the emergence of medical informatics as a science.

The effect of these trends has resulted in increased involvement of professional health users in the new development of information systems. The main providers of health care, doctors and nurses, have had to re-examine their work in terms of increased quality of care and productivity.
In hospitals both staff and departments need information to carry out their tasks. This information might be self-generated or put at their disposal by other parties within the hospital.

However, hospital data differs from most other data because they directly affect human beings. Very often, hospital data are more sensitive than other data and may be of confidential nature. The diagnosis, treatment and care of patients rely upon complete and correct information at the proper time. Since the emergence of computers the question arises as to whether this technology has been applied in support of information handling in hospitals. A number of different computer applications exist within the hospital.

The main objective of HIS is to support authorised employees at their work-benches with all available information at the time needed and in such a way that the data is related to the needs and wishes of the user.

This objective necessitates comprehensive standardisation activities such as:
- data definitions;
- classification and colification, and
- communication procedures.

The HIS is an integrated system. An integrated system is defined by A.R. Bakker in Medical Informatics Vol. 9 No. 2 1984 in an article "The development of an integrated and co-operative hospital information system" as follows: "The sub-systems are connected and the system is more than the sum of sub-systems." This means that HIS comprises:
- data integration: data being recorded once and thereafter used by many authorised users for many purposes;
- functional integration: authorised users have the flexibility to go from one function to another, and
- technological integration: the users have access to late generation tools and data-nets in order to utilise the system facilities in a conversational mode and at the time needed.
The HIS must be able to store data over very long periods with the possibility of fast retrieval in order to satisfy patient related problems, legal aspects and research. Moreover, the majority of hospital data would be easily accessible.

It has been shown that a HIS based on the principles of easy accessibility, multiple application programmes and direct access and covering both patient data (medical as well as administrative and other hospital data will support and improve:
- patient administration;
- surveillance and treatment of patients;
- procedures in hospital, and
- the quality of information needed by staff dependent on health authorities.

Currently most HIS deal with in-patients only, out-patients are not yet included.

Health information is data relating to health status, resources, use, cost and outcome. In contrast to medical data associated with medical action, health care data assist policy-makers, health administrators and health care providers in performing, planning, management, care delivery and evaluation. Unlike medicine, health care suffers from shortage of systematised data for use in the planning and decision-making process, and assessment of the impact of health services on the health status of individuals and populations, and the cost-effective running of the health service.

Today, there is a need for information on utilisation of resources, the efficiency and effectiveness of the health care delivery systems and the assessment of changing trends. Not all HIS include data which meet these requirements.

Future developments in medical informatics should give priority to the development of new computer software which would facilitate integration of information regarding costs and benefits into the decision-making process at all levels.
In addition to new computer software, modern managerial techniques should be employed. The European Health Committee of the Council of Europe stated in 1993 in "Aspects of a policy to reduce the growth of hospital expenditure without creating disadvantages for patients or hampering the advance of medical science" that such methods and techniques include among others:

- system analysis;
- data modelling;
- decision support systems;
- health economics, and
- health statistics.

Data Integration in Information Systems

Hospital information systems, collections of application systems around central data bases—patient indexes, are aimed at increasing the productivity of the health care system. They integrate data from many sources and the information is used by many at different organisational levels. The core of a hospital information system should be the most commonly available set of data items with the most extensive range of uses. Standardisation of information becomes an important factor.

Comparable health statistics require the use of common terms, classification and coding schemes. Until now hospital information systems in many countries have developed with hardly any co-ordination. This has resulted in a variety of systems often based on a different understanding of major terms. The establishment of a common definition of terms is necessary in the further developments of hospital information systems. Common denominators will greatly facilitate integration of information at local, national and international level.
The following figure shows the different levels of hospital information:

Figure 1.

(3) common denominators

(2) common denominators

Medical record summaries

(1) specialised records

At level 3 the data set is made available for health planning, steering and evaluation at central or regional level and abstracted from level 2 where the more extensive local records are (e.g. medical record summaries). The specialised records (e.g. individual patient records) are found at level 1.

The principle of these three levels of information taken from a study carried out for the Commission of the European Communities by Roger F.H. "The minimum basic data set for hospital statistics in the EEC", 1981, has acquired importance during the last decade. There is a need for relevant comprehensive, accurate, complete and timely data for the following reasons:

- to facilitate decentralisation of services and still maintain the planning, steering and evaluation structure of the national health services;
- to facilitate cost containment and cost control, and
- for epidemiology and health services research.

The core of such an information system is a HIS which facilitates the consolidation of information on the use of resources and the
medical activities within the hospitals. Communication between hospitals, primary health institutions and health authorities at different levels has become as necessary as electronic data processing for the functioning of the health institutions as well as for health authorities at all levels.

Communication will function satisfactorily only when the following criteria are fulfilled:

(a) any report must be derived from the operational data within the hospital i.e. the data must have a meaningful purpose at local level;
(b) no data should be recorded at a higher level if the report does not result in action or reaction in one way or another, and
(c) only data based on standardised coding systems and definitions should be reported.

Results of the Study ("State of Art")

An enquiry carried out by the COE in 1995 on the global objective for HIS given by member states revealed the following results. Only those results given by member states to HIS and the extension of standardised HIS are described.
Certain countries do not link their objectives to HIS as defined above (with medical Minimum Basic Data Base MBDB). The countries listed are those who ranked in 1st or 2nd place on at least one of the three levels (national, regional, institutional) the objectives proposed by the questionnaire grouped according to an "administrative purpose" (right hand column) or a "medical purpose" (middle column).

14 countries out of 17 have adopted at least one of the following objectives linked to the HIS: planning, management, budgeting.

+ EC countries
* EFTA countries

Turkey is an applicant to the EC.
Extension of Standardised HIS

The availability of nation-wide HIS varies considerably from country to country. Each country has developed its own method of collecting data from hospitalised patients. The methods of collection are influenced both by culture and history.

Nation-wide HIS services exist in some countries for statistical purposes (morbidity), in other countries they relate more to the cost of care. One of the advantages of Europe is the variety of its member states which enables the sharing of experiences in developing HIS.

All the countries covered by the COE study have computerised HIS at the institutional level. Nation-wide HIS was available in three distinct groups of states.

1. Denmark, Finland, Ireland, The Netherlands, Sweden, United Kingdom used nation-wide standards for collecting data and had the longest experience with computerised nation-wide HIS.

2. Belgium, France, Greece, Norway, Portugal have established plans for nation-wide HIS in order to collect nation-wide comparable data.

3. Austria, Germany, Italy, Spain, Switzerland, Turkey, mostly federal states, collect nationally comparable hospital data mostly by sampling.

Table 1 summarises the availability of nation-wide HIS and the degree of standardisation achieved.
<table>
<thead>
<tr>
<th>Country</th>
<th>National coverage</th>
<th>Planned (project)</th>
<th>Sampling (collect)</th>
<th>Regional</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>yes+</td>
</tr>
<tr>
<td>Belgium</td>
<td>no</td>
<td>yes+</td>
<td>no</td>
<td>no</td>
<td>yes+</td>
</tr>
<tr>
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<td>-</td>
<td>-</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>Finland</td>
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<td>-</td>
<td>-</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
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<td>no</td>
<td>yes+</td>
<td>yes</td>
<td>no</td>
<td>yes+</td>
</tr>
<tr>
<td>Fei. Rep. of Germany</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>Greece</td>
<td>no</td>
<td>yes+</td>
<td>no</td>
<td>yes</td>
<td>yes+</td>
</tr>
<tr>
<td>Ireland</td>
<td>yes+</td>
<td>-</td>
<td>-</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>Italy</td>
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<td>yes</td>
<td>yes+</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>Netherlands</td>
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<td>-</td>
<td>-</td>
<td>no</td>
<td>yes+</td>
</tr>
<tr>
<td>Norway</td>
<td>no</td>
<td>yes+</td>
<td>yes+</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
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<td>yes+</td>
<td>no</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>Spain</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>yes+</td>
</tr>
<tr>
<td>Sweden</td>
<td>yes+</td>
<td>-</td>
<td>-</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>Switzerland</td>
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<td>no</td>
<td>yes+</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>Turkey</td>
<td>no</td>
<td>no</td>
<td>yes+</td>
<td>yes+</td>
<td>yes+</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>yes+</td>
<td>-</td>
<td>yes+</td>
<td>yes+</td>
<td>yes+</td>
</tr>
</tbody>
</table>
The primary goal of the hospital is to provide patient care in which it is assisted by HIS.

Some of the broad statistical uses of HIS data are:

(a) simplifying complex problems by providing objective data for use in decision-taking;

(b) forecasting probable consequences of different actions and measuring the effectiveness of intervention;

(c) discovering ways of improving performance in health services and assessing the skills necessary;

(d) comparing results in different groups or against specified objectives, and

(e) assessing the resources required to maximise benefit at minimum cost.

The use of routinely collected data can be classified as primary, secondary and tertiary.

Primary use: that for which the data is immediately collected, e.g. patient administration, hospital financial records.

Secondary use: typically local statistical use of data and local planning processes.

Tertiary use: mainly regional and central level planning, steering and evaluation.

In all countries covered by the COE study computer-assisted HIS have been established. Such systems are found in the majority of hospitals only in a minority of countries. These countries are Finland, United Kingdom, France, Denmark and the Netherlands. Sweden
and Belgium have a high incidence. In Finland and Denmark national registers of patients record all in-patients. Sweden has both regional and central registers. Norway has a patient discharge information system covering 70% of all discharges. This system includes the European EDBS. Achievement of national coverage was planned for 1999. In Ireland full national coverage by the patient discharge system is an objective.

The biggest problem in member states is the lack of universal standardisation and codification systems. Another unresolved problem in many countries is the development or adaptation of hardware in the health care field. Hospitals tend to be isolated institutions which are slow to change leading to inadequate education of hospital staff and a lack of motivation in end-users.

In Appendix II of the COE Health booklet 'Computerisation of medical data in hospital services including university hospitals', Strasbourg 1998, Recommendation No. 8 (37) 23 of the Committee of Ministers to Member States on Hospital Information Systems is printed which includes the following Appendix:

Member states should take the following measures:

1. Hospital Information Systems (HIS)

1. Encourage the use of medical informatics as a tool by managers and practitioners in the health care area.

2. Implement and use computer assisted (interactive) information systems comprising both medical and managerial data to improve management, planning and administrative practices, facilitate the maintenance of quality of care standards, the evaluation of health services and the optimisation of the productivity of the health services in the member states.

3. Promote awareness of the overriding need to protect the confidentiality and security of medical data.
4. Consider establishing standards for different data sets (medical, financial and managerial data, etc.)

5. Extend hospital in-patient information systems progressively to long-term, day cases and ambulatory care.

**THE MINIMUM BASIC DATA SET (MBDS)**

A more detailed set of basic data can be used (level 2, Figure 1), particularly demographic and medical data.

**THE MINIMUM BASIC DATA CONCEPT**

**Definition**

The minimum basic data set (MBDS) has been defined by Lambert P.H. and Roger F.H. in "Hospital Statistics in Europe", North Holland Publishing Co., Amsterdam, 1982 as "that minimum array of items having the greatest range of uses which should be available in any information system".

**Content**

Thirteen items have been included in the European MBDS for in-patients undergoing acute care in hospital.

i. hospital identification;
ii. patient's number;
iii. sex;
iv. age;
v. marital status;
vi. place of residence;
vii. month and year of admission;
viii. duration of stay;
ix. discharge status;
x. main diagnosis;
xi. other diagnosis;
xii. surgical and obstetric procedures, and
xiii. other significant procedures.
By "minimum" it was implied that each hospital had to collect "not less than" these items in a uniform way. Definitions were given for each item in order to obtain comparable data.

This set could be modified by subsequent agreement or expanded locally. Two items suggested for consideration were department identification and source of admission (emergency or not).

Uses

The MBDS should be collected for every patient hospitalised in defined geographical areas and used as a basis for management, planning and evaluation of patient care.

Confidentiality in Health Informatics

The concept of confidentiality varies culturally and geographically. The most frequently taken measure in European countries to protect the individual's right to privacy concerning medical data was the obligation to go through the physician in charge of the case in order to have access to nominative information.

Informatics, from the Russian word 'informatika', is the discipline of science which investigates the structure and properties (not specific content) of scientific information activity, its theory, history, methodology and organization.

Patient identifiable data are needed at the hospital level for patient care and medical research. Results from the COE enquiry clearly demonstrated that the protection of access to identifiable medical data included for research purposes is a very important issue in all European countries.

For international purposes it was accepted that the MBDS should not contain information which directly identifies a patient. However, it is desirable that an institutional identification number be provided
in order to facilitate access to case records through the physician responsible for the patient's care. Even in the three countries where a national identification number is associated with diagnoses and operations, Denmark, Finland and Sweden, specific rules have been issued to protect the patient's right to privacy.

A patient should always feel ensured that data and information about him is collected, stored, communicated and used in a lawful and safe manner by authorized persons. This includes the use of information for research purposes and the transfer of information at the European level.

The COE has elaborated a number of legal instruments to give a lead to member states in the field of privacy protection.

The EC must seek to harmonize the position around Europe by requiring that all staff in the health care sector who have access to personal data be bound by a set of minimum confidentiality regulations. This is in line with the COE's legal instruments C109 and Recommendation No. R(81)1, particularly Article 8.

'In addition to the members of the health care staff, the data processing personnel and any other persons participating in the design, operation, use or maintenance of a medical data bank, must respect the confidential nature of the information and ensure the correct use of the medical data bank.'

R(81)1 recommends that as a general rule information may be given only to medical staff and, as far as national law or practice permits, to other health staff, each person having access to those data needed for a specific purpose. Once these people have exercised their functions, they may no longer store, modify, erase or gain access to the data, save by special agreement with the person or body to whom decisions must be submitted for approval, who supervise the use of the data bank and to whom appeal is made in the event of a dispute. Whoever has access to data in the course of their work may not use such data for a purpose
different from that for which the access to the data was originally granted, unless the information is put in such a form that the data subject (patient) cannot be identified, or such different use has been imposed by law.

In order to achieve confidence in the European Health informatics environment it is urgent that the institutions should try to solve the existing legal gaps in EC countries.

The EC could have a very important role to play in building upon the work achieved by the COE, due to the EC's ability to make regulations which are binding upon its Member States. A detailed health sectorial approach is required irrespective of progress registered in the field of data protection at large.

Code of Confidentiality

DG XIII F/ATM, the Faculty of Advanced Informatics in Medicine of the Directorate-General for Telecommunications, Information Industries and Innovation believe that guidelines for behaviour should be developed with an emphasis on self-regulation, when possible. In order to ensure that the confidence between patient and doctor or other Health professional adviser is maintained it is necessary that there should be a Code of Confidentiality which describes the basic rights and responsibilities of individuals holding personal health information.

The details of these codes should be developed primarily by the health professionals within the EC legal and information environments. In general the basic requirements are that:

1. Health professionals should have access to information about individual patients, at the level of detail necessary to discharge their functions at competent, professional level, where they are not part of the clinical team caring for the patient, with the actual or implied consent of this patient.
2. Informaticians should have access to personal health information only when it is required for the purposes of operating, supporting, maintaining or requiring health information systems and they must make no disclosures of such information other than as required by an appropriate health professional in the course of their activities noted above. Such access should be recorded and monitored.

3. General managers should have access to personal health information when it is required for the management of the institution at the level of detail required for that purpose. Such access should be recorded and monitored.

4. Basic training of health professionals, computer users and informaticians should be carried out on dummy training data bases....

5. Where research can be carried out without identifying individual patients, this should be done. However, it will normally be necessary for each recorder to be identified in some way so that the research can raise questions with the original source of the data such as its accuracy or whether it relates to distinct records rather than, for instance, duplicated records. This may often be achieved by encrypting (converting to an unintelligible form by means of a cryptographic (code) system) the identifying number at the originating institution without passing over the decryption key. Even when such data is technically anonymous the collected data base must be kept secure from an unauthorised attack or query manipulation which might uncover individual identification of the data.

Where a researcher does have access to personal information for agreed research purposes appropriate steps are required that no identified personal information is released.

6. Exceptional Disclosures: There are several legal exceptions to these strict rules that vary between the Member States of the EC and daily practice accepts additional disclosures.
It is desirable that a European Code of Confidentiality should be developed to ensure harmony within the EC and that exceptional disclosures should be recorded for subsequent audit or advice to the patient.

7. Sanctions for Mis-Use of Authorisations: The Codes of Conduct for Health Professionals and Informaticians in Health care should be backed up by contracts of employment for all staff as well as the sanctions or penalties that may be imposed for the misuse of confidential information or information systems.

It will take some while to develop a code of practice for informaticians in the safe and reliable design, operation and maintenance of secure health data systems, but such a code should be developed.

In the field of privacy the COE has elaborated further legal instruments including Recommendation No.4(93)10, 23 September 1993 at Strasbourg, for the 'Protection of personal data used for scientific research and statistics'.

This recommendation that the governments of member states should take as their basis, in their domestic law and practice concerning the use of personal data (any information relating to an identified or identifiable individual). An individual should not be regarded as "identifiable" if the identification requires an unreasonable amount of time, cost and manpower, for research which also comprises the collection and processing of personal data, irrespective of whether such data are processed automatically or manually, for statistical purposes, and statistics, the principles and guidelines being set out in the appendix to the recommendation.

Wide circulation of this recommendation in the public and private circles concerned with scientific research and statistics was requested.

The appendix states that member states may apply the following principles and guidelines to information relating to groups of persons, associations, foundations, companies, corporations and any other bodies consis-
ting directly or indirectly of individuals, whether or not such bodies possess legal personality.

Respect for privacy: the privacy of individuals should be guaranteed in any research project requiring the use of personal data. Research should be undertaken with anonymous data whenever possible.

Consent of the person concerned: any person supplying data about himself must be adequately informed about the objectives of the project and whom is receiving the information.

A person is not obliged to provide data, he is free to give or withhold co-operation, and should be able to withdraw at any time without giving reasons.

If, given the purpose pursued, personal information cannot be disclosed either in whole or in part before the data are collected, the person concerned should be fully informed after the collection is completed, and be free to continue or withdraw his co-operation and, in the latter case, be entitled to request the erasure of the data collected.

Persons unable to defend their interests or to give free consent for the collection of data should have special protection measures taken. This section would seem to be relevant to medical research.

Use of the data: personal data obtained for research should only be used for that purpose. A person should not be affected by the use of this data outside the context of the research, unless special permission is given. Personal data collected for a specific research project may only be used for other substantially different research, if permission is given so to do. However, if too much time should lapse or a large number of persons are concerned, the previously collected data may be used in conformity with other safeguards laid down by domestic law.

Public and private bodies may use personal data collected for their own research purposes for administration. The consent of the person
concerned must be given for the addition of, or the alteration of this personal data and for these new files to be made available to administrative personnel. Personal data may be released by public or private bodies for the purpose of research only with the consent of the person concerned or in accordance with other safeguards laid down by domestic law.

Collection of samples: researchers should be allowed to use public population registers to obtain samples which may reveal, subject to limitations imposed by national authorities, name, address, date of birth, sex and occupation.

Access of the person concerned to the data: an individual may be restricted in his right to obtain and rectify data concerning him which are collected and held solely for statistical or other research purposes, which do not identify him, where his privacy is guarded and are conserved for future use; but, if an individual can demonstrate a specific interest in this type of research which deserves protection, this provision should not apply.

Data security: medical databases, both computerized and the traditional forms of documentation, aim in general at:

- high availability, accuracy, integrity and consistency of stored data, as well as at medical professional secrecy and confidentiality (Hippocratic Oath), and
- privacy as an individual's constitutional right to 'informational self-determination', in particular to determine and effectively supervise the collection, maintenance, use, dissemination and selection of data.

The former properties, technical in nature, basically require that the database system is actually helpful for medical care and, in particular, is not harmful to patients by denial of appropriate services.
The latter properties require that fundamental 'ethical principles' are not violated by employing database systems, but instead are actively enforced by technical means as essential prerequisites for effective medical care in democratic societies.

Research projects should make express provision for technical and organisational measures to ensure the security and confidentiality of data. Since the early 1970's legislation has been passed to stipulate the conditions under which personal data may be collected, stored, transmitted or used.

Personal data used for research should not be published in identifiable form unless the persons concerned have given their consent and other safeguards laid down by domestic law are obeyed.

Research is bound by the same fundamental rules as any other activity involving the use of personal data. The laws on data protection do not recognise privilege but, even though they may adapt their requirements to the particular structure and specific objectives of the information process, they do not allow any exception to the duty to observe their restrictive principles. Data protection legislation is clear in its attitude and its consequences. With or without data protection, etiology of heart diseases and the efficiency of certain forms of treatment cannot be understood without access to information on the behaviour of patients. Any critical analysis of social policy rests largely on the availability of microdata. Research on any of these subjects should not be abandoned on the grounds of data protection.

Article 9 'Exceptions and restrictions', section 3 of C103 states 'Restrictions on the exercise of rights specified in Article 8, paragraphs b, c and d, may be provided by law with respect to automated personal data files used for statistics or for scientific research purposes where there is obviously no risk of infringement of the privacy of the data subjects (patients).

Article 8 'Additional safeguards for the data subject', says that any
person shall be enabled:

b. to obtain at reasonable intervals and without excessive delay or expense, confirmation of whether personal data relating to him are stored in the automated data file as well as communication to him of such data in an intelligible form;

c. to obtain, as the case may be, rectification or erasure of such data if these have been processed contrary to the provisions of domestic law giving effect to the basic principles set out in Articles 5 and 6 of this convention.

Article 5 'Quality of data': Personal data undergoing automatic processing shall be:

a. obtained and processed fairly and lawfully;

b. stored for specified and legitimate purposes and not used in a way incompatible with those purposes;

c. adequate, relevant and not excessive in relation to the purposes for which they are stored;

d. accurate and, where necessary, kept up to date;

e. preserved in a form which permits identification of the data subjects (patients) for no longer than is required for the purposes for which those data are stored.

Article 6 'Special categories of data': Personal data revealing racial origin, political opinions or other beliefs, as well as personal data concerning health or sexual life, may not be processed automatically unless domestic law provides appropriate safeguards. The same shall apply to personal data relating to criminal convictions.

Article 8: to have a remedy if a request for confirmation or, as the case may be, communication, rectification or erasure as referred to in paragraphs b and c of this article is not complied with.
Conservation of data: in each research project, it should be specified as far as possible whether, on completion of the project, the personal data collected will be destroyed, rendered anonymous or kept, and, if so, under what conditions and with the subject's permission. If it has not been possible to obtain permission to conserve the data, they may be kept on condition that conservation is performed in accordance with safeguards laid down by domestic law.

Before a decision is taken on the destruction of personal data held by public authorities, the possible future use of such data for research must be examined, preferably in consultation with the institutions responsible for the conservation of public records.

Personal data that have been used, but have not been destroyed or rendered anonymous on completion of a project, should be deposited with institutions entrusted with the task of keeping data under adequate security.

Diagnosis Related Groups (DRGs): The European experience

Introduction

The HIS, its modernisation and the extension of the DRGs have been used, since 1980, to develop patient classification schemes. They share the common goal of defining subgroups of patients possessing similar clinical attributes, but there is some variation in the specific criteria applied to the definition of patient groups and the number of groups defined.

DRGs are one of a number of patient classification schemes developed in the USA. Other schemes include Patient Management Categories, Severity of Illness Index, Disease Staging and the International Classification of Diseases, 9th revision Clinical Modification, ICD-9-CM (developed in the USA).

The only system currently providing the basis for research and experimentation in Europe are the DRGs, which relate exclusively to acute
in-patient care. The Ambulatory Visit Groups (AVGs) classification scheme has been developed for outpatient care. European countries are, however, more concerned with this system's contribution to improving planning, utilisation review and hospital management practices.

Development of Diagnosis Related Groups

Outputs of the hospital may be considered to be the goods and services provided for patients as part of the treatment process during the hospital stay. Inputs of the hospital include the labour, material and equipment used to provide the outputs. The product of the hospital is the particular combination of outputs provided to each patient.

During the hospital stay both the treatment process and the patient's condition decide the amount and type of services provided to the patient. Attempts at developing patient classification schemes began in the 1960s and 1970s with attempts to measure and control both the efficiency of the process, which is the relationship between a standardised unit of output and the inputs required to produce that output and the effectiveness with which these services are utilised by providers, must begin with a definition of the hospital product.

These schemes were based on the recognition that to differentiate the product of the hospital the definition of subgroups of patients must be consistent in clinical terms and must be homogenous in terms of resource utilisation. Both of these objectives were used for the development of DRGs by the Health Systems Management Group at the Yale University School of Organisation and Management. The basic aim of DRGs was to relate "the demographic, diagnostic and therapeutic characteristics of patients to the output they are provided so that cases are differentiated by only those variables related to the condition of the patient (e.g. operation) that affect the utilisation of the hospital's facilities". (Fetter R.B. et al, Yale University "Case-mix definition by Diagnosis Related Groups", Med. Care 18: 1-53 (Suppl.)

DRGs therefore include surgical procedures, basic information on the patient together with primary diagnoses and subgroups of patients with
similar clinical attributes, and output utilisation. A multi-variable system which defines the hospital product in terms of patient classes which utilise similar sets of services. (Fetter, R.B., Freeman, J.L. Diagnosis related Groups: A Product-Oriented Approach to Hospital Management (manuscript)

Construction of DRGs

DRGs were constructed in 1980 to develop a methodology capable of being used in different settings and meaningful to both medical and non-medical users. The specific objectives of DRGs, in the hospital setting, are:

1. A medically interpretable scheme with subclasses of patients from homogeneous diagnostic categories.

2. Definition of individual classes according to criteria that are available on medical records of either the patient's condition or the treatment process which are linked to the output utilisation.

3. A manageable number of mutually exclusive and globally exhaustive classes.

4. The classes should consist of patients with similar expected measures of output utilisation.

5. Stable class definitions across different coding schemes.

DRGs were originally constructed on the basis of an analysis of data from acute-care hospitals using an interactive statistical system to establish relationships between certain in-patient demographic and clinical attributes and their consumption of hospital resources.

A revised DRG classification scheme came into use in 1982 (Health Systems Management Group (1982)). The revised system is based on the ICD-9-CM coding scheme, the International Classification of Diseases, Ninth
revision, Clinical Modification, which is a list of diseases, injuries
and causes of death, compiled by the International Conference for the
ICD, convened by the World Health Organization (WHO) in Geneva, Switzerland, from 30 September to 5 October 1975, arranged according to aetiology and anatomic localisation, intended to ensure by international agreement comparability of mortality and morbidity statistics. The list does not constitute a nomenclature of diseases and injuries, but a classification intended primarily for statistical use.

Some measure of utilisation was used to construct the DRGs.

Firstly the process of developing the DRGs involves partitioning the
data base into mutually exclusive and exhaustive principal diagnostic
areas, called Major Diagnostic Categories (MDCs). The classification
of MDCs is according to organ system rather than aetiology following
the organisation of medical specialties and therefore a better representa-
tion of medical technology.

The second step in DRG classification is marked by an initial split
within most MDCs according to whether or not an operating room procedure
was performed.

The third stage in the DRG construction process takes into account medi-
cally meaningful complications and secondary diagnoses which signifi-
cantly affected average length of stay. Complications and co-morbidities
were used for grouping patients if average length of stay was increased
by at least one day, 75% of the cases in the original DRG data base.
The remaining criteria for the classification are age and discharge
status. Figure 2 illustrates the typical DRG structure for a Major
Diagnostic Category.
In the development of DRGs the emphasis was placed on treatment patterns rather than disease processes. DRGs are therefore designed to represent clinically coherent patient groups with similar expected patterns of resource consumption. Data on DRG projects and experiments planned or in progress were collected as part of the COE survey of information systems in member countries.
Results of the Study

The extent to which DRGs are the subject of research in member states is presented in Table III

Table III - DRG Use in Member States

<table>
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<th>DRG experiment (past or present)</th>
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<td>United Kingdom</td>
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A DRG experiment is underway in at least one pilot hospital in the country.

The coding obstacles to inter-European comparison and widespread implementation of DRGs

The main problem revealed by the study is that of defining and disseminating a European classification of DRGs to permit comparison of performance between countries for different DRGs. This is vital to European co-operation on reviewing hospital budgeting and management practices.
The current classification of DRGs has been developed using the ICD-9-CM scheme for diagnoses and procedures. Use of less precise coding schemes would result in a less valid grouping, resulting in two obstacles to comparison despite the widespread use.

The current classification of DRGs has been developed using the ICD-9-coding scheme for diagnoses and procedures. Use of less precise coding schemes would result in a less valid grouping and in two obstacles to comparison and wide implementation to this new type of approach:

1. Use of ICD-9 for coding of diagnoses.
2. Use of international, national or sub-national classifications for procedures.

1. Use of ICD-9 for coding of diagnoses

All states use or are going to use ICD-9 (with the exception of Denmark which uses ICD-3 and Belgium and the Netherlands which use ICD-9-CM) in accordance with WHO recommendations. ICD-9 is less precise than ICD-9-CM, and therefore does not enable the grouper currently available to be used as it stands where data are coded in ICD-9.

The advantages of the use of ICD-9-CM would be the general use of the grouper and similar collections of data at European level. Cross-national comparisons would be possible also with the USA, but ICD-CM is currently only available in English, French and Dutch. However, everything will have to be reconsidered as ICD-10 is now available.

2. Procedure classifications

As different countries are still using different schemes and procedures play a paramount role in classification harmonising solutions will have to be found to these problems.
Three kinds of solution have so far been adopted, and a fourth is envisaged:

(i) Mapping each classification into ICD-9-CM to be confirmed by each country's practitioners and in the USA, especially where degrees of precision differ (France, Portugal, Ireland, Netherlands). The use of the grouper permits a maximum number of comparisons without entailing re-organisation of the manner of data collection. There may be a problem of validity of comparison if mistaken choices are made, not only in the nature of the procedure, but also in its place in the hierarchy of procedures in the MDC.

(ii) Re-defining DRGs with different classifications and their own hierarchy (UK). This requires more organisation of the manner of data collection, but the work is considerable for all European countries, and valid comparisons cannot really be made.

(iii) Use of ICD-9-CM, as in Belgium, allows the use of the grouper, permitting the maximum number of comparisons with clear procedure classification in relation to the DRGs.

(iv) Develop a European (international) classification of procedures in which procedure classification is clear in relation to DRGs and the same grouper is used by all countries adopting it. However, this would involve substantial work in harmonization between different language and technical practices. WHO has not decided (by October 1985) to include procedure classification in the 19th ICD revision.

DRG experiments and project are developing rapidly in 15 of the 18 countries which replied to the COE questionnaire. Despite the diversity of objectives in the different member states, the differences in classifications of medical techniques, operations and diseases, and hence DRGs, the applications in Europe for this technique differ from the applications
in the USA. Common characteristics prevail in its use as an incentive towards greater hospital efficiency in countries in which health insurance is compulsory.

The importance of the problem of efficiency in health services and hospitals for the member states and the development of Hospital Information Systems (HIS), including MBDS must be recognised. With the applications of DRGS in a considerable number of those states, it is reasonable to suggest it is now the time for a co-ordinated European approach (standardisation) in the field of knowledge and aid to medical and medical-economical decision-taking, on the one hand, and in that of Hospital Information Systems and their computerisation, on the other.
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CHAPTER 8: SUMMARY AND CONCLUSIONS

It would seem that there is no particular policy on health in the EC as there is no one Directorate-General or Faculty in the administrative hierarchy dealing specifically with either 'health' or medical information. D-G V, which runs the 'Europe against Cancer' programme has a particular interest in the protection of workers in hazardous employment, but there is no overall policy on the mental and physical soundness of the population.

One of the specific objectives of the Treaty of Rome was the improvement of living and working conditions in the EEC. President Delors has stated that there can be no social progress without economic progress; and no economic progress without social cohesion. Social measures are the vital counterpoint of the construction of a single economic market. However, some Member States (notably the UK) have expressed concern at the level of interference with national social measures of policies which the Commission deems to be an essential part of its role. This is likely to change when the SEA begins to take effect as agreement on proposals by majority is specifically allowed, in particular on the alignment of national standards on occupational health and safety and on the laws concerning the functioning of the EC, which may or may not include some social measures.

This problem could be compounded after the start of the European Economic Area (EEA), a free trade zone which will unite the EC with the European Free Trade Association (EFTA), politically agreed on 21 October 1991, and due to commence in 1993, which will allow the free movement of citizens of these countries among their territories. The EFTA member states are: Austria, Finland, Iceland, Liechtenstein, Norway, Sweden and Switzerland. Switzerland is only prepared to finally sign the EEA agreement as a step to full EC membership, Austria intends to join the EC and Finland and Sweden are considering joining.

Formally transferring EC laws into EEA laws will be the job of an EC-EFTA joint committee, but the Community will have the right to 'rebalance' the agreement. EFTA countries will have to accept all the EC regulations issued since the formation of the 'Common Market' in 1957. The EC's internal market 'The Single Market' due for completion on 31 December 1992, defined as "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured" will be extended to the EFTA nations. From 1993 EEA individuals should be able to live, work and offer services throughout this highly sophisticated trading bloc. Some legislation was in place before the signing of the SEA—for example, the directives providing for doctors to move freely within the Community were adopted in 1975 and will apply in the EEA and legislation is being drafted and adopted constantly in the approach to the Single Market deadline.

Despite the current legal moves toward political unification, it would appear that medical treatment and information will remain essentially, at least for the time being, the concern of the individual nation.


