general hospitals have all helped. However, many components of courses remain anachronistic, while occupying disproportionate amounts of time. Reductions in these areas would mean that there would be few logistical problems in introducing new areas of learning such as the philosophy of science, scientific methods, medical audit, and management skills. For these are the skills, alongside clinical ones, that the students' future employers are going to value. The primary responsibility of medical schools is to prepare their students for their careers. In the interests of their students, therefore, medical schools must take note of employers' views. Clearly, too great an influence by employers over educational content and standards could potentially be damaging to the health of the public. For example, if the NHS (as the principal future employer) funded medical education some longer term educational objectives might be sacrificed for short term benefits. It is therefore safer to maintain funding of undergraduate teaching by the Department of Education and Science with academic control in the universities' hands.

POSTGRADUATE EDUCATION

In contrast, funding of postgraduate and continuing education by the NHS is long established, though postgraduate deans derive their authority from universities as well as the health service. Further training has the advantage that the recipients have had experience of the subjects being taught and tend therefore to be highly motivated to learn. This provides an excellent opportunity for medical audit to be teamed up with postgraduate education to their mutual benefit. For instance, the discovery through audit of suboptimal care can act to stimulate interest in a subject and generate a demand for education. In turn, any educational intervention is more likely to be effective if the recipient perceives a need for change.

- 1 BMA. *Leading for Health. A BMA Agenda for Health*. London: BMA, 1991.
- 2 Relman AS. Assessment and accountability. The third revolution in medical care. *N Engl J Med* 1988;319:1220-2.
- 3 Smith R. Where is the wisdom...? The poverty of medical evidence. *BMJ* 1991;303:798-9.
- 4 Department of Health. *Research for health. A research and development strategy for the NHS*. London: DoH, 1991.

Medicine in Europe

European law, medicine, and the social charter

Chris Hughes

This is the fourteenth in a series of articles looking at medical issues in Europe

In 1974 Lord Denning said that the Treaty of Rome "is like an intruding tide. . . It flows into the estuaries and up the rivers. It cannot be held back."¹ He was confirming what had been apparent from the treaty: "If the Court of Justice finds that a member state has failed to fulfil an obligation under this treaty, the state shall be required to take the necessary measures to comply with the judgment of the Court of Justice." So in matters of law parliament would no longer have the last word and in many areas the law would be made by the European institutions and determined in accordance with the decisions of the European Court.

But the doctrine of the sovereignty of parliament has been a long time dying because of judicial conservatism and political prevarication. A contemporary commentator wrote of the European Communities Act 1972, "This unique act is a fascinating exercise in equivocation, a wilful manifestation of legislative schizophrenia. . . the United Kingdom government has seated parliament on two horses, one straining towards the preservation of parliamentary sovereignty, the other galloping in the general direction of community law supremacy."²

There is a time limit for European legislation to be translated into the law of member states. This has given rise to confusion over the interpretation of United Kingdom legislation, which a grudging government has passed in supposed compliance with European Community (EC) law. In addition to trying to resolve conflicts between the EC regulation and the United Kingdom law, British courts have had difficulty simply understanding the regulation. As Lord Diplock said in one leading case, "The European court, in contrast to English courts, applies teleological rather than historical methods to the interpretation of the treaties and other community legislation. It seeks to give effect to what it conceives to be the spirit rather than the letter of the treaties; sometimes, indeed, to an English judge, it may seem to the exclusion of the letter."³

The conflict over parliamentary sovereignty recently came to a head in the Factortame case.⁴ In a long

Conflicting issues

The European Commission and the United Kingdom government are in conflict over the following commission proposals⁵:

- Protection for pregnant and nursing mothers from being obliged to work shifts
- Fourteen weeks' maternity leave on full pay
- Equal rights for part time and temporary staff to pensions, holidays, training, and rights in redundancy
- Minimum wage
- Rights of workers to participate in employer decisions
- Action to assist disabled people
- Greater protection for employees threatened with collective dismissal
- Controls on hours of work

running conflict over fishing quotas parliament passed the Merchant Shipping Act 1988, which prevented foreign owned vessels registering in Britain and getting access to British quotas. Spanish owners applied to the British courts, which in turn sought a preliminary ruling from the European court. This held that British courts had power temporarily to suspend the operation of the act pending determination of whether it conflicted with European law.⁵

In an even more recent case the European court held that the relevant directive did not create obligations which could be relied upon by one private individual against another.⁶ A national court was, however, bound to interpret national law in accordance with the terms of the directive. It therefore had to disapply a provision in national law to secure compliance with the terms of the directive since the directive constituted an exhaustive statement of the relevant law even though it had not been implemented in the member state.

This decision seemed to sweep away much of the confusion, that had surrounded British equal pay cases. In one case the plaintiff succeeded because she

British Medical Association, London WC1H 9JP

Chris Hughes, MA, head of legal department

BMJ 1992;304:700-3

The European Court of Justice, Luxembourg

BARNABY'S PICTURE LIBRARY

was a public employee while another failed because she was not. Now it seemed clear that the courts could rely equally on the provisions of European legislation whether directly enacted in the United Kingdom or not. Even if parliament passed a law in direct contravention of the European legislation any right in European law would be enforceable through any relevant British court. In several recent cases in England, however, the Court of Appeal has ruled: "...does not in my opinion enable or constrain a British court to distort the meaning of a British statute in order to enforce against an individual a community directive which has no direct effect between individuals."⁶ Until such a case goes to the House of Lords and the opinion of the European court is sought this confusion will remain.

Single market and qualified majority voting

The European treaty was revised in 1986 to enable the community to accelerate the process of integration. It sacrificed the de facto right to a veto and introduced qualified majority voting in the Council of Ministers on measures necessary to achieve this end. A total of 76 votes are split between the 12 members, each member having from 10 (United Kingdom, France, Germany, and Italy) to two (Luxembourg). Fifty four votes are needed to carry a proposal. The European Commission has been criticised by Britain for "dressing up" measures advancing the social dimension of Europe as part of the single market and bringing them within the qualified majority procedure. Even where majority voting is available the Council of Europe prefers to move by consensus.

Maastricht

The public relations explosion surrounding the meeting in Maastricht in December 1991 obscured the deep confusion of the participants about the consequences and importance of their actions. The British government's deep seated objections to the commission's social action programme led to Britain not adhering to the social charter 1989. At Maastricht the United Kingdom insisted that the social chapter proposed for the Political Union Treaty (due for ratification by all 12 states in 1992 and taking effect in 1993) should not be included. Instead it was incorporated as a protocol to enable the other 11 members to proceed with the social charter proposals.⁷

Nevertheless, work on all social charter proposals will proceed initially on the basis of seeking agreement

among the 12; if that is impossible then consensus among the 11 will be sought. The agreements made under the protocol will be taken within the framework of the EC's institutions "on loan" to the signatory states. This is clearly an unstable position. The European court has already ruled that the draft agreement on a European economic area which would bring into effect a close association between the EC and the countries of the European Free Trade Association threatened the autonomy of the community's legal order and was incompatible with the Treaty of Rome. There will probably be similar difficulties with the proposed protocol. Arguments are being advanced in the European parliament that since the United Kingdom will not be bound by the proposals its members in the European parliament should take no part in the discussions.

In the meantime the government continues to oppose many of the key proposed directives that are seen by the commission as essential to maintain broad support for the "ever closer union." The commission's objective is a core of social rights applicable throughout the community. The lack of consensus in the Council of Ministers is likely to mean, at most, amendments to social and employment legislation rather than the coherent framework of rights proposed until the protocol is implemented.

Under a protocol to the economic and monetary union provisions of the treaty, the United Kingdom will be able to opt out of the move to full monetary union based on a single currency. This will come into effect between 1 January 1997 and 1 January 1999; Britain would have to exercise its option in the middle of the decade.

Health and safety

The community adopted a framework directive on health and safety in 1989 and is now adopting specific measures requiring national implementation by the end of 1992. The measures contain a healthy dose of worker participation, training, and rights of consultation as well as requirements with respect to health surveillance. The requirement that "particularly sensitive groups must be protected against dangers which specifically affect them" seems to make the offer of hepatitis B virus inoculation to many health staff mandatory and could have implications for the availability of prophylactic ziduvodine after needlestick injury.

Much of the specific provision makes explicit what was implicit in the Health and Safety at Work Act 1974. Among the directives already adopted are ones on the manual lifting of heavy loads; use of work equipment; carcinogens; safety clothing; and visual display units, which will require free eye tests and breaks from the use of the equipment. The last directive, 90/679 (national implementation by 26 November 1993), is intended to protect workers from exposure to biological agents at work. It requires regular risk assessment in accordance with a statutory classification scheme, and where risk exists exposure must be prevented or kept as low as possible. Records of exposures are required to be kept for up to 40 years.

One key health and safety proposal still under consideration would make mandatory daily rest periods of 12 hours, at least one day off a week, normal hours for night workers not to exceed an average of eight hours a shift, and prohibiting overtime for night workers in occupations involving special hazards or heavy physical or mental strain. The British government is known to be unhappy with this proposal, especially with respect to its impact on the NHS, and it is unlikely to be adopted except under the Maastricht protocol.

Health

One principle of EC law, subsidiarity, requires that the EC should not undertake tasks more suitable for national governments. Health care is recognised as one such area and it is unlikely that there will be any uniformity of provision of health care in Europe. Nevertheless, the impact of European law is profound and pervasive and directly affects many facets of medicine. Article 51 of the Treaty of Rome provides that the community shall "adopt such measures in the field of social security as are necessary to provide freedom of movement for workers." The purpose is as far as possible to abolish territorial limitations on the application of the different social security schemes. This supplements national schemes to ensure that a migrant worker is not disadvantaged by moving within the community. Regulations made under the article cover a broad expanse of benefits, including reimbursement of expenses for medical treatment, medicines, and nursing. In particular there is a right for people entitled to benefits in one member state to receive treatment in another at the expense of their own state if they obtain prior approval. There are restrictions on refusal of approval, in particular where there is some degree of urgency in obtaining treatment.

In two cases, Mrs G Pierik, a Dutch midwife on invalidity benefit, successfully challenged a refusal by the Netherlands to provide her with spa treatment in Germany.⁸ The regulations were held to apply to pensioners seeking any appropriate treatment even if it is not usually provided at home. In both cases the British government submitted arguments to the European court which would have had the effect of restricting the right to seek treatment. The system for administering this right in Britain (form E112) does not seem to be designed to encourage the exercise of this right. About 125 applications were approved in 1990; many more were rejected. The Department of Health clearly views the procedure as appropriate only in exceptional cases, and there is a strong reluctance to countenance it as a means of accelerating treatment, despite the obligation to take account of the current state of the patient's health and the likely course of the disease. As with the reluctance of health authorities to make large budgetary provision for extracontractual referrals, the department sees no reason to spend money in other European countries which it is not prepared to spend in Britain. Whether this reluctance is in accordance with the current law is debatable. These regulations are to be extended to self employed people and their families.

In pursuing an internal market for the NHS the government has sought to ensure that the market remains a British market. The NHS and Community Care Act provides for NHS contracts to be between specific NHS bodies and not to be enforceable in the courts. It is anticipated, however, that NHS bodies will enter into similar contracts with the private sector. In that case Article 59, which establishes the freedom to provide services across frontiers, seems to apply, certainly where contracts are being considered with the private sector and possibly NHS contracts as well.

Sex discrimination

A series of decisions of the European court have exposed the inadequacies of British law in relation to discrimination on the grounds of sex and required the government to bring forward the Sex Discrimination Act 1986. Barber held that discrimination on the grounds of sex in occupational pension schemes was contrary to article 119 of the treaty (equal pay).⁹ This is having a profound effect on the pensions market. In particular the decision that article 119 may not be relied on for claiming entitlement to a pension with

Data protection

The European Commission is proposing sweeping extensions to existing legislation protecting personal data including:

- Application to manual as well as computer files
- Duty of private sector processors to notify data subjects of their activities and the subject's right to ban such data processing
- Right to knowledge of and access to public sector files on the subject of the data
- A ban, except in cases of important public interest, to the automatic processing of data on racial or ethnic origin; political, religious or philosophical views; health; or sexual activities without the written consent of the subject of the data

effect before the date of judgment has created confusion. The extent to which the right to backdated or future benefits exists may be clarified in litigation related to the Coloroll pension scheme, which has been referred to the European court, and also by possible European legislation.

In 1990 the Court of Appeal decided that different age limits governing eligibility for severe disablement and invalid care allowances were not a necessary consequence of the difference in retirement age and were unlawful. But in proceedings brought by the Equal Opportunities Commission the divisional court has upheld the view of the secretary of state for social security that the minimum hours requirement for unfair dismissal rights, though indirectly discriminatory on the grounds of sex, was justifiable. This case will be the subject of appeal.¹⁰

Nationality and immigration

Article 48 of the Treaty of Rome provides for the abolition of discrimination based on nationality in employment between workers of member states, and article 58 provides for the right to pursue activities on a self employed basis. Although regulations providing for mutual recognition of medical qualifications have been in place for some years, the General Medical Council has registered only 6500 EC doctors and new registrations are running at approximately 1000 a year. It is believed that most remain for a relatively short period. The number of British doctors working in the rest of the EC is believed to be small. One problem remains: the directive currently regulating movement of doctors provides for the mutual recognition of EC qualifications of EC citizens. It discriminates against holders of non-EC qualifications who are EC citizens and non-EC nationals who hold EC qualifications. At Maastricht it was agreed to move towards cooperation on immigration and asylum policies. Explicit reference was made to respect the European Convention on Human Rights and the Convention on the Status of Refugees. In a statement condemning the increase in racism and xenophobia the Council of Europe called for steps to be taken at national and community level to combat discrimination and xenophobia and to strengthen the legal protection of third country nationals in all members states.

Medical accident litigation

The wide range of arrangements for the delivery of health care is mirrored by the variation in the law relating to medical negligence and the differences in insurance arrangements. While the basic analysis of negligence is the same, the burdens of proof vary. The community is considering legislation that would impose

Specific EC measures on health and safety require work breaks and free eye tests for users of visual display units

HEWLETT-PACKARD

a uniform code of liability for the providers of defective services.

EC studies indicate that while in the United Kingdom and Italy the burden is on the plaintiff to show negligence, in Spain, Denmark, Greece, and Belgium the burden of proof is reversed and in Germany the doctrine of the positive isolation of contractual duty has a similar effect. Furthermore, in Germany instead of the plaintiff proving that the defendant's negligence caused the damage the concept of the "sphere of risk"—that is, the factors within the control of the defendant—effectively reverses the burden in many cases. The insurance arrangements across the community are similarly diverse, with insurance being mandatory in all forms of practice in Germany, voluntary in Portugal, and mandatory or voluntary depending on the nature of the practice in Italy.

The European Commission argues that this wide variation in the substantive law has the effect of inhibiting the free market in services across Europe and has proposed legislation that would reverse the burden of proof of negligence in cases where physical damage has been caused by the defective provision of services. The proposal follows on from the directive on defective products which was the basis of the Consumer Protection Act 1987 and its introduction of the concept of a product being defective if it is not as safe as "persons generally are entitled to expect." An initial proposal for the implementation of a system of no fault liability was dropped after pressure from interest groups and because of a reluctance to take such a radical step. It seems unlikely that such a proposal will re-emerge. The wide implications of the proposals have had increasing exposure, and as a result of criticism it seems likely that there will be a separate directive dealing with the defective provision of health care. Any legislation is likely to be based on the principle of reversing the burden of proof, but it is unlikely that there will be a move towards a Swedish no fault system.

The impact of such a directive on medical negligence litigation is uncertain. It could raise expectations of the possibility of compensation and thus contribute to an American style growth in such litigation, which has been a feature of the past decade. But although the

burden is shifted, this is effective only in the absence of contrary evidence. In a civil case the burden of proof is on a balance of probabilities—that is, a fact, inference, or causal relationship is proved if it is established as having a probability of more than a half. In practice a contested case will still see the serried ranks of expert witnesses giving evidence as to what is and is not acceptable to a respectable body of medical opinion, especially since "the mere fact that a better service existed will not constitute a fault." Since the draft embodies more restrictive time limits to bring proceedings than are presently applicable there would be two classes of proceedings: those under the directive and those brought in common law. The draft directive, if enacted, would be unlikely to resolve the problems of delay, legal costs, uncertainty, and disruption inherent in the present system of medical negligence litigation.

Conclusion

Over the past 19 years, although many politicians have treated the community as an external body concerned purely with economic policy, the United Kingdom has acquired a written constitution and seen many important changes to its law and the rights of its citizens—to the confusion of politician, citizen, and lawyer alike. The changes are continuing at an accelerating pace, and the reluctance of politicians to comprehend that political power follows economic influence has caused Britain to adopt a policy in negotiations that has caused political isolation in the community and is untenable.

- 1 Bulmer (HP) v J Bollinger SA [1974]. 2 All ER 1226.
- 2 De Smith SA. *Constitutional and administrative law*. 2nd ed. London: Penguin, 1973.
- 3 Henn and Darby v DPP [1980] 2 All ER 166.
- 4 Factortame Ltd v Secretary of State for Transport (No 2) [1991] 1 All ER 70.
- 5 Marleasing SA v La Comercial Internacional de Alimentacion SA. European Court, case 106/89.
- 6 Webb v Emo Air Cargo (UK) Ltd [1992].
- 7 European Commission. *First report on the application of the European community's social charter*. Brussels: European Commission, 1992.
- 8 Bestuur van het Algemeen Ziekenfonds Drenthe-Platteland v Pierik. European Court, cases 117/77 and 182/78.
- 9 Barber v Guardian Royal Exchange Assurance Group [1990] 19 IRLR 240.
- 10 R v Secretary of State for Employment ex p Equal Opportunities Commission [1991] 20 IRLR 493.

Development of quality assurance in Italy

Andrea Gardini

Ranked fifth or sixth as a world economic power, Italy occupies 16th place in the world according to per capita income, but it has an estimated budget deficit for 1991 of nearly \$130bn, a population growth rate of near zero, a consistently high inflation rate (6-7% per year), and a high unemployment rate. Italy is divided into 20 regions, which are subdivided into 95 provinces, and governed by coalitions of three to five political parties, which have remained the same since the end of the second world war.

Initial reform of the health care system

The Italian health care system came into being in December 1978, when its national health service was founded. It consists of preventive, curative, and rehabilitative services; curative services comprise primary health care, hospital care, and tertiary level care.

Primary health care is provided by general practitioners within the health service. Their panel must

not exceed 1500 patients. Primary health care services are provided by health districts and are publicly financed organisations for health care, and within which general practitioners, nurses, social workers, psychologists, and other health care professionals collaborate to provide care. The districts function well in the densely populated and industrial north of the country and much less well in the agricultural south, reflecting the differences in socioeconomic status of the population.

Hospital care is provided by general hospitals, 10% of which are private. The hospital network comprises about 426 000 beds in the public sector, including 43 000 beds in mental institutions and 76 000 in nursing homes—that is, 7.3 beds per 1000 inhabitants.

Tertiary level superspecialised hospitals, found mainly in university clinics, have their own administration and general contractual agreements with the national health service.

All the stages of health care are directed by local health units, organisations covering between 30 000

Via Machiavelli 26, 34132 Trieste, Italy
Andrea Gardini, MD,
secretary, Italian Society for
Quality Assurance in Health
Care

BMJ 1992;304:703-5