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.

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- 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

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Italian quality assurance: as heterogeneous as its pasta

and 250 000 inhabitants, depending on the population density. The local unit is the functional, organisational, and operative unit of the system and is governed by a political commission chosen by the municipality concerned. Each is supervised and funded by the regional government, whose major task is to administer regional health care programmes at a higher level. Regions in turn are financed by the National Health Fund, which is supported by state income derived from direct taxation of employees and their employers to central government. Every person is fully covered by the national health service for any kind of health problem, except second level dental care (which is always private) and some charges for certain tests or medicines.

Subsequent reform of the health care system

In 1989 the evidence that the health service was not functioning well coincided with a general economic crisis in public services as a result of an "Italian style" deregulation, and this has led to reform under the Minister of Health, Dr De Lorenzo. The number of local health units are being reduced and professional management is to be introduced. Many problems are being encountered, and the changes are proceeding with considerable difficulty. The principal difficulties are strong resistance by the political parties to surrendering their power over the local units (4000-5000 local politicians stand to become unemployed); an excess of doctors, there being one doctor to every 220 inhabitants (1989 figures), because of lack of regulation of the number of medical students; and a lack of nurses as a consequence of the low economic and social status of the profession.

Absolute beginners in audit

In the context of these difficulties, a movement for the promotion of quality in health care began developing in Italy during the 1970s and '80s. Those groups active in the movement were "absolute beginners" in the sense that they were considering the problem of quality of care from several different viewpoints and experiences. They include consumer groups, especially groups united under the Movimento Federativo Democratico, an association interested in patient's rights; professional, cultural, and scientific organisations; and scientific and research institutions.

Among the organisations are the Cultural Paediatric Association (Associazione Culturale Pediatri); the Italian Association of Epidemiology (Associazione Italiana di Epidemiologia), whose members first introduced the works of Cochrane, Holland, and other British epidemiologists to Italian providers and proposed concepts and methodologies for evaluating clinical care; the Italian College of Nursing (Collegio IPASVI), which is extremely interested in introducing the concepts and practices of nursing into professional

schools and everyday practice; and the Italian Medical Association (Ordine dei Medici), whose interest in audit mainly derives from avoiding control of clinical performance by non-medical staff.

Among the scientific and research institutions there is in the public sector the National Health Institute (NHI—Istituto Superiore di Sanità) in Rome, whose epidemiology department has been organising courses in epidemiology, statistics, and clinical epidemiology for doctors since the early '80s. Its contribution has been great because these subjects are taught only marginally in medical schools. Participants in the courses have subsequently formed ad hoc groups, such as those among gynaecologists, neurologists, paediatricians, psychiatrists, and surgeons, to implement evaluative experiences. In the private sector the Mario Negri Institute in Milan is a top level institution of clinical research on the use of drugs and, recently, on the quality of care in oncology.

Italian Society for Quality Assurance in Health Care

In 1984, the same year as the World Health Organisation established the targets for its programme "Health for All by the Year 2000" and affirmed that by 1990 all member states should have established effective mechanisms for ensuring quality of health care, the various professional groups and institutions met to discuss possible common strategies of introducing audit practice in Italy at a four day workshop on methods of improving health care quality, organised by Friuli-Venezia Giulia regional government. As a result the Italian Society for Quality Assurance in Health Care was founded.

A multidisciplinary scientific society, it assumed the task of studying, teaching, and promoting methods in quality assurance. The society's headquarters are in Udine, where its president, Professor Perraro, is also head of the emergency department of the general hospital. Altogether there have been about 1100 participants in the society's programmes, about 80% of whom were physicians, 15% nurses, and 5% other professionals; the membership is spread throughout Italy and is now organised into 12 regional sections. The society publishes a bimonthly journal entitled *QA*, now in its fourth year of publication, which contains articles on local experiences and methods.

Quality assurance

Quality assurance activities in Italy are documented in congresses acts and papers published in *QA* or other Italian and international journals. To date there have been about 170-180 attempts at what might be called tentative quality assessment or improvement, or both, and two major teaching hospitals, in Padua and Monza, are implementing formal programmes in quality assurance.

Among the most meaningful of the studies—that is, those in which a concrete improvement in quality of health care was shown—are those of a change in use of antibiotics for common pneumonia,¹ use of blood,^{2,3} prescribing albumin,⁴ use of radiography of the skull in head trauma,⁵ and keeping nursing records.⁶

Future development

The teaching hospital at the University of Padua is the first in Italy to project and implement a formal quality assurance programme which involves the whole hospital and is guided by the medical director⁷ and is a model for health care in Italy, having established the feasibility of audit. Up to now audit activities were purely voluntary and performed by isolated, enthusiastic professionals; with the introduction of

professional management to hospital administrations, as mentioned previously, they will increase. Quality assurance is an immediate priority of the health service, as recently stated by Dr De Lorenzo (workshop on quality assurance in Italian health care system, Tropea, 1991), and quality assurance programmes will be implemented by special quality commissions working on a national, regional, and local level.

Evaluation and training

We know that it will be necessary to evaluate the effectiveness of our audit programmes, and the general opinion of experts is that it will be difficult to consolidate audit activities in Italy if such activities are not introduced into teaching programmes. According to the working group on training in quality assurance of the WHO regional office for Europe, "quality assurance activities should be taught at all levels of training for physicians and nurses: at base, post-graduate, and continuing education levels."⁸ At Turin University's school of public health and Bari University's school of medicine teaching programmes have just begun, and they are being followed with great interest.

Conclusions

In common with experience in other countries, the introduction of quality assurance in Italy has been neither a smooth nor linear process. Voluntary quality assurance activities are currently giving way to formal quality assurance programmes, and those enthusiastic professionals who have been seeking to be agents of change since the early '80s suddenly find themselves in a situation where their hopes of a consolidated quality assurance system may be realised.

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- 4 Selle V, Favaretti C, Alberti V, Marcolongo A, Orsini A. L'appropriate impiego di albumina umana nell'ospedale di Padova. Valutazione di un processo terapeutico: approccio metodologico. *QA* 1990;3/4:11-6.
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For Debate

NHS Reforms: The First Six Months—proof of progress or a statistical smokescreen?

Radical Statistics Health Group

The impact of the changes in the NHS is clearly of great interest during this pre-election period. Anxiety about the NHS is shared by politicians and public alike. The debate provoked by the NHS Management Executive's booklet *NHS Reforms: The First Six Months*,¹ which was launched on 14 January, needs critical examination of the way that competing claims were presented.

In his introduction to the booklet, Duncan Nichol stated that: "Changes in the way the NHS is organised have helped to re-focus our activities. They are leading to improvements in the quality of care, greater responsiveness to individuals and even better value for money for the growing NHS."¹ In support of this he singles out four aspects. Three of them—hospital admissions, waiting lists, and primary care as measured by immunisation rates—are largely statistical. The fourth aspect is described as "a vast range of local initiatives." This article looks at the way statistics were selected, presented, and interpreted in support of these claims and discusses whether its conclusions are justifiable.

The approach

The document compares statistics for England for the current financial year, 1991-2, with data for the previous year. Immunisation rates are presented as evidence of the success both of the changes in the NHS in April 1991 and of the new contract for general practitioners, which came into force on 1 April 1990. The document is unreferenced and the sources of the statistics are not identified. The figures are not compared with data from earlier years to see if the estimated changes are part of longer term trends, and no mention is made of factors outside the NHS, which

lead to increasing demands for NHS services—notably the increasing numbers of very elderly people.

Several regional comparisons are made, often in a way which is not statistically valid. For example, some of the graphs such as that showing numbers on waiting lists present regional totals without allowing for differences in the size of each region's population. Other graphs exaggerate regional variations by using vertical axes that start above zero. The extent of regional variations is cited as evidence that there is "scope for improvement." Although the variations may simply reflect differences between the populations of the regions, it is assumed that the region with the highest or the lowest value must be performing optimally.

In addition, the document and accompanying press releases claim that opinion polls show public support for NHS trusts and the new contract for general practitioners. No comparison was made between trusts and directly managed units, or between successive polls of people's views before and after the changes took place.

Acute sector activity

The document starts with statistics for the numbers of patients treated as inpatients, day cases, and outpatients in the acute sector during the first six months of the financial year 1991-2. These six month figures were simply multiplied by two to produce estimates for the full financial year and were then compared with data for 1990-1, which were not shown in the document.

Percentage increases were calculated and the document claims increases of 1.5% in inpatient activity, 13.6% in day cases, and 4.2% in outpatient attendances. Adding inpatients to day cases produced "an overall