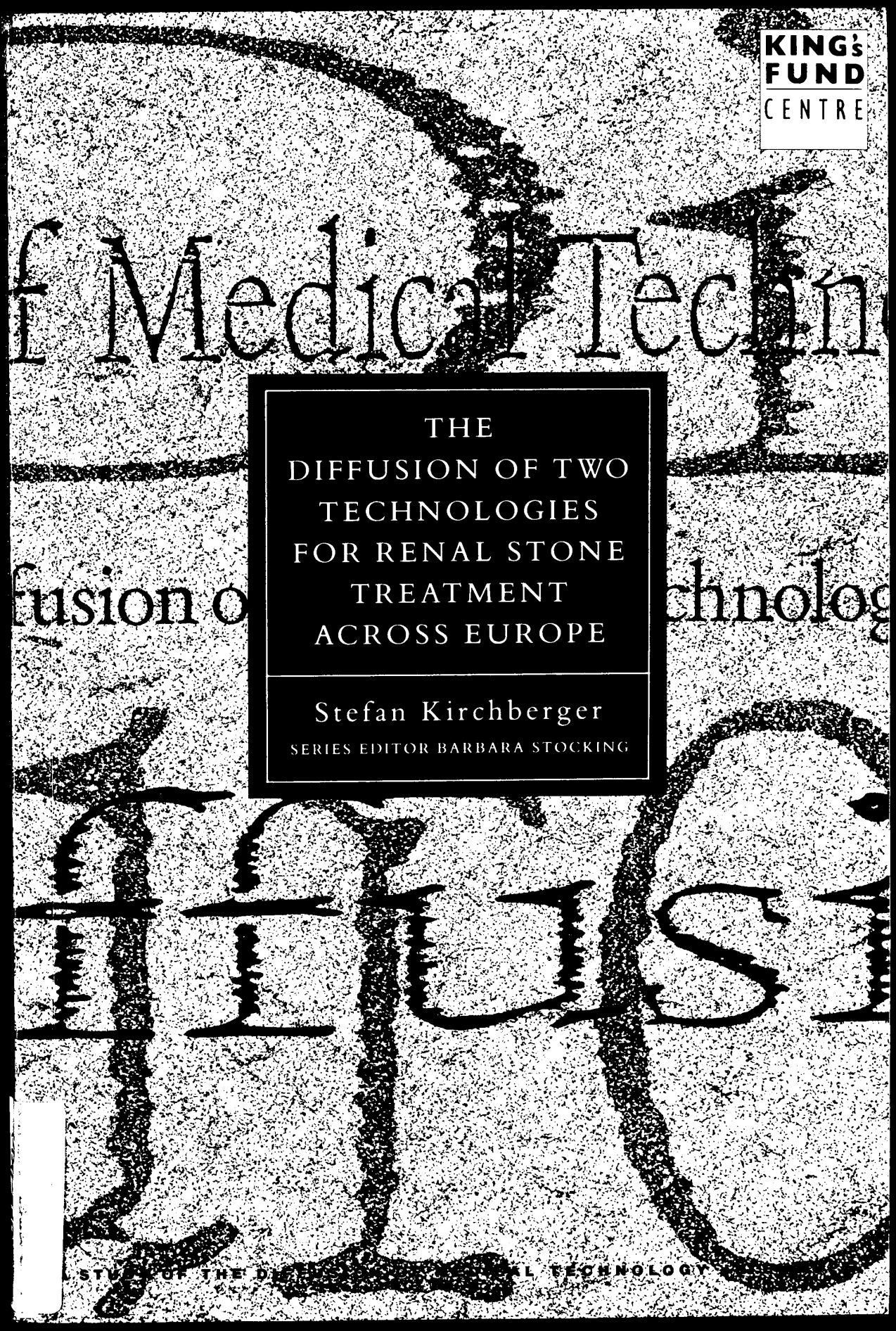
KING's FUND CENTRE
THE DIFFUSION OF TWO TECHNOLOGIES FOR RENAL STONE TREATMENT ACROSS EUROPE
Stefan Kirchberger
SERIES EDITOR BARBARA STOCKING

A STUDY OF THE DIFFUSION OF MEDICAL TECHNOLOGY IN EUROPE

THE DIFFUSION OF TWO TECHNOLOGIES FOR RENAL STONE TREATMENTS ACROSS EUROPE

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and based on country reports from all EC Member States and Sweden

plus

FACTORS AFFECTING THE DIFFUSION OF THREE KINDS OF INNOVATIVE MEDICAL TECHNOLOGY IN EUROPEAN COMMUNITY COUNTRIES AND SWEDEN

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The King's Fund Centre is a health services development agency which promotes improvements in health and social care. We do this by working with people in health services, social services and voluntary agencies, and with the users of their services. We encourage people to try out new ideas, provide financial or practical support to new developments, and enable experiences to be shared through workshops, conferences and publications. Our aim is to ensure that good developments in health and social care are widely taken up.

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A STUDY OF THE DIFFUSION OF MEDICAL TECHNOLOGY IN EUROPE

How can a society afford to pay for the often expensive new technologies introduced into health care, assess their ethical and social impact, and prevent or restrict their diffusion from the innovating centres to general medical services if their drawbacks appear to outweigh their benefits? Are formal or informal regulatory mechanisms the more effective? Is diffusion easier to control in countries with predominantly public health services? Is this to patients' benefit?

In the belief that these questions would be illuminated, both for health policy makers and for the protagonists of new methods of medical treatment or disease prevention, the European Commission, via its committee COMAC HSR in DG XII, commissioned a study in each EC country and in Sweden of the diffusion of three recently introduced technologies:

- renal stone treatment, particularly by lithotripsy
- organ transplantation, with particular focus on liver and heart transplantation
- prenatal screening, particularly for Down's syndrome and open neural tube defects.

Rapporteurs were identified for each of the countries, as well as a single author to write an overview drawing on these country reports and other material. Three of the country reports are published here in addition to the overview; they were selected from those received either because they illustrate a particular factor operating strongly in that country or an unusual (or typical) diffusion pattern. Unpublished country reports are available either from me or from the EC committee named above.

The three types of technology were chosen because they have very different characteristics. Lithotripsy involves a large capital investment in an expensive machine. Organ transplantation demands the exercise of high surgical, scientific, and above all organisational skills under emergency conditions, and raises serious ethical questions. Prenatal screening uses relatively cheap materials and equipment but again raises ethical and religious problems, and draws the attention of special interest groups. The diffusion of each of the technologies is discussed in three companion volumes, of which this is one.

I attempt at the end of this volume (and in the two others) to draw some general conclusions about factors affecting the diffusion of new medical technologies, pointing to similarities and differences between the three technologies studied. The authors of the overviews, of course, discuss similarities and differences between countries within each technology.

I am grateful to the EC for funding the study, to COMAC HSR for help in identifying some country rapporteurs and particularly to Martin Buxton of Brunel University for his support throughout. Stefan Kirchberger conducted extensive correspondence with the rapporteurs for this study; thanks are due to him as well as to the rapporteurs themselves. They are listed in the Foreword. Finally, all the chapters (including mine) have benefited from the editorial skills of Peter Woodford.

Barbara Stocking, Project Leader
Director, The King's Fund Centre, London NW1

CONTENTS

FOREWORD AND ACKNOWLEDGEMENTS

This review discusses the introduction and spread of two new techniques for removing urological stones and the resultant changes in medical care in the EC countries and Sweden. The basis of the review is primarily the accounts received from the rapporteurs in each country. These varied enormously in the degree of detail provided, and this must be held responsible for the unevenness of my overview, which obviously concentrates on developments in some countries at the expense of others.

Some of the rapporteurs are not mere passive observers of the developing scene, but have played an active part in the policy decisions affecting the spread of lithotripsy, and they warn the reader that their point of view may be prejudiced. Of course, this is balanced by the fact that they have inside knowledge of how the decisions and arguments were arrived at, something denied to those rapporteurs who were entirely dependent on published work and press reports. My own overview suffers from the same drawbacks: I have necessarily put my own interpretation on the material I report.

I wish to thank all the rapporteurs for the information they provided, in particular Messrs Bos, Durieux, Kamper-Jorgensen and Mays, the last three of whose accounts follow this overview. The rapporteurs for each country are listed below. I also wish to thank Ms Barbara Stocking for providing the opportunity to write this report and Martin Wrede for much support and practical help.

Belgium: C Decoster, Ministère de la Santé Publique et le L'Environnement, Service d'Etudes, Cité Administrative de l'Etat, Quartier Vésale, 1010 Brussels

Denmark: F Kamper-Jorgensen, Danish Institute for Clinical Epidemiology, 25 Svanemollevej, 2100 Copenhagen

Federal Republic of Germany: S Kirchberger, Institut für Medizinische Soziologie, Westfälische Wilhelms-Universität, Domagkstrasse 3, 4400 Münster

France: P Durieux, C Viens-Bitker, Assistance Publique de Paris, 3 Avenue Victoria, 75100 RP Paris

Greece: A Cranidis, School of Health Sciences, Division of Medicine, University of Crete, 71409 Iraklion, Crete

Ireland: J Barry, Health Research Board, 73 Lower Baggot Street, Dublin 2

Italy: G Blasetti, D Bravar, Centro di Valutazione delle Apparecchiature Biomediche, Area di Ricerca di Trieste, Padriciano 99, 34012 Trieste

Netherlands: M A Bos, Health Council of The Netherlands, PO Box 90517, 2509 LM Den Haag

Portugal: F Ramos, Escola Nacional de Saude Publica, Avenue Padre Cruz, 1699 Lisboa

Spain: A Granados-Navarette, Direccio General d'Ordenacio y Planificacio Sanitaria, Travessera de les Corts, 131–159 Pavello Ave Maria, 08028 Barcelona

United Kingdom: N B Mays, Department of Community Medicine, St Thomas' Hospital, London SE1 7EH

Sweden: P Carlsson, Centre for Medical Technology Assessment, Linköping University, 58183 Linköping

In this volume, reports are included from Denmark, France and the United Kingdom. The *Danish* report describes the discussions which were held as Denmark tried to delay purchase of lithotripsy machines until it was able to manufacture its own. When, by 1989, this machine was still not on the market urologists and others had lost confidence in the Danish project and purchased machines from other countries. However, during 1990 a few Danish machines have in addition been put into operation, under full clinical evaluation.

Denmark was not the only country to try to develop its own machines and prevent the purchase of imported machines until the domestic product was available: France provides another example. Both cases illustrate a general dilemma for countries with advanced technical industries.

The *French* report illustrates also the power of individual urologists in lobbying for new technology. An interesting dimension is the way all the different urological services in Paris had access to the first machine, rather than only those based at the hospital where it was installed. The report also discusses the role of legislation concerning the purchase of expensive equipment in controlling technology diffusion.

The *UK* report is included both because it describes the introduction of a new technology in a highly cost-constrained environment and also because the issue of evaluation met with such resistance from the professional groups involved – as indeed it had in France, Belgium and The Netherlands. Only in Sweden did the government succeed in making formal evaluation a precondition for installation of the first machine.

1 EARLY HISTORY AND CHARACTERISTICS OF THE TWO TECHNOLOGIES

> 'Until recently, the only method available for removing renal stones was open surgery, a lengthy procedure under general anaesthesia with a prolonged convalescence. The last decade has seen the development of two techniques which have revolutionised the surgical management of renal stones, namely percutaneous nephrolithotomy (PCN) and extra-corporeal shock wave lithotripsy (ESWL).'[1]

Open surgery on vital organs like the kidneys carries not only a (small) risk of mortality and of permanent damage to the organ but imposes psychological stress on the patient and significant morbidity in terms of pain and prolonged post-operative discomfort. Less invasive methods are therefore always desirable. On the other hand, chemical dissolution of kidney stones is successful only when the stone composition is suitable.

Around 1950, the idea arose that kidney stones might be fragmented by use of physical energy, the fragments subsequently being excreted without difficulty. 'Our belief that calculi in the human body might be disintegrated ... by ultrasonic energy was prompted by reports of industrial testing methods....'[2] It was easy to prove that renal stones could be split up by ultrasonic energy, but how to do this without damage to surrounding tissue was not so obvious.

Two methods were considered feasible:
- focusing the ultrasonic energy on the stone from outside the body, or
- leading the energy source to the stone with the help of appropriate endoscopic instruments.

Both methods turned out to be impractical at that time. The extracorporeal application of ultrasonic energy destroyed not only the stone but also the intervening tissue (see ref 8 in the Danish country report, p 67 and instruments then available for intracorporeal application were too unwieldy to be used without causing damage. A percutaneous needle puncture to effect access to renal concrements was also impractical at that time, although there had been isolated experiments with such a technique. However, the two methods came to fruition towards the end of the 1960s.

The decisive impetus for the development of **extracorporeal treatment of kidney stones** resulted from a research investigation, supported by the FRG Ministry of Defence, by the Dornier firm of Munich into the interaction between shock waves and tissue in animals. They observed that shock-wave energy was able to penetrate the human body without harming it. Until then shock waves had been used in medicine only in a single case, with the aid of an apparatus developed in the USSR in the 1950s to disintegrate bladder stones, having been brought up to the stone endoscopically.

In 1972 Dornier began a collaboration with the urology department of Munich University Hospital and in 1973 submitted a patent application for their method of generating the shock wave. A year later the Federal Ministry for Research and Technology grant-supported the development of an

[1] References p 50.

apparatus for the extracorporeal destruction of kidney stones. Various lithotripter models with different focusing and imaging systems were tried out. The animal experiments were completed by the beginning of 1980. After some 200 patients had been successfully treated in a first phase of the testing process, the production prototype of the Dornier equipment was installed in the University Clinic in Munich-Grosshadern in May 1982. (For a full description of the development of ESWL see ref. 3.)

By contrast, many clinics and manufacturers participated in the development of **endourological methods**. The instruments for manipulation of the stone and the energy source were progressively miniaturised until by the mid-1970s endoscopic ultrasonic lithotripsy of *bladder stones* had become a recognised clinical treatment. Stones in the *ureter* could be similarly treated only when sufficiently small lenses for the optical control could be developed in the late 1970s using new materials. For the removal of *kidney* stones, direct percutaneous access proved more advantageous. In 1976, Fernstrom and Johansson (Stockholm) reported the first successful **percutaneous nephrolithotomy (PCN)**, a technique which was quickly adopted and developed in Mainz[4] and London and other urology departments. By 1981/82, the methods were used routinely in all the large academic hospitals in Europe.

Thus, at about the same time, two new methods for the treatment of kidney and ureter stones were available to medical care. Five years later it was claimed[5] that more than 90 per cent of stone patients who had previously been treated by open operation could be treated with one of these non-invasive or less invasive techniques.

Characteristics of new technologies

We are confronted here, in principle, with competing methods or treatment alternatives[5]. However, from the point of view of the minimising of invasiveness and morbidity, the view has become widely accepted in the scientific literature on the subject that these methods relate to one another in a hierarchical manner. The idea of 'multimodal stone therapy' is based on the precept that the least invasive technique, ESWL, should be the first choice for simple stones, with PCN being used as a complementary or possibly sole method of stone removal only when the presence of large or complex concrements or other factors present problems.

Cost

There is a large price difference between ESWL machines, which cost 1–3.5 million DM, and the endoscopic instruments at 40–60,000 DM. While there is obviously no financial barrier to the rapid diffusion of endourological methods, only a small minority of urology departments can purchase a lithotripter, which creates 'haves' and 'have nots' among urology departments. For the same reason, ESWL is prestigious, and possession of the machine is good for a clinic's reputation.

One of the selling points most emphasised by urologists and manufacturers eager to encourage investment in and spread of ESWL was the long-term

cost savings which would result from replacement of *open operations* by this non-invasive treatment which carried no risk of tissue damage. These claims (which are discussed later) may yet prove to have been ill-founded, but their influence in the medical and lay press has been considerable.

Paradoxically, those clinics which had played an important part in developing endourology were also usually those of sufficient size and reputation to be reasonably sure of receiving one of the first ESWL machines. It would not have been in their interest to counter the ESWL manufacturers' comparison with open surgery with the information that the latter was no longer 'state of the art'. The comparison should have been with PCN, where the advantages are by no means so clear-cut.

Skill requirements

The technique of ESWL can be delegated to non-medical personnel after a short transitional period, whereas endourology demands surgical skills[6] and, often, specialist qualifications. The risks of treatment are low. Endourological methods or PCN remain invasive surgical procedures, requiring at least epidural anaesthesia, whereas ESWL required anaesthesia only up till 1987, when the second-generation machines were produced.

Appeal of ESWL to clinicians and patients

For most patients, ESWL and/or PCN are superior forms of treatment to open surgery. However, the ESWL machine is much more 'visible' than endourological methods. To the lay public, it is a revolutionary technique in making a therapeutic procedure possible without surgery, in much the same way as X-rays in the late 19th century captured the imagination by making the inside of the body visible without (apparently) harming it. Although the sensation caused by the discovery of X-rays can hardly be compared with that caused by lithotripsy, the fascination of the latter invention should not be underestimated. West German newspapers constantly emphasised the contact-free nature of the treatment. By contrast, although endourology is an immense advance for clinicians, it is perceived still as a surgical intervention, a difference from open surgery only of degree.

This revolutionary factor made it possible to mobilise public opinion in favour of the spread of ESWL in a way that would have been unthinkable for endourology. Note here Chaussy's remark that patients' high expectations 'could not be met immediately'.[3] Clearly, doctors had communicated their own expectations only too easily.

Urologists were quickly captivated by the revolutionary technique of ESWL. Before the end of the experimental phase, many travelled to Munich to observe the animal experiments personally. Subsequent consequences of the visits from the UK and France are interestingly different.

Professor John Wickham, director of the Institute of Urology, University of London, visited towards the end of 1978. He was so impressed that as early as 1979 he tried to persuade the Department of Health and Social Security (London) to order the equipment for the UK National Health Service. Civil

servants were sceptical about investing in an experimental technology, and the first equipment to be installed in the UK was in fact in a private (non-NHS) hospital under Wickham's direction.

Professor Dubernard, head of urology at the Hôpital Edouard Herriot in Lyon, visited Munich at the beginning of 1979. He reacted differently, and initiated a research project together with the Centre d'Études et de Technologies Appliquées à la Clinique (CETAC) and the Institut de la Santé et de la Recherche Médicale (INSERM), with the object of developing a French machine, an important motivation being the inordinately high expected price of the Dornier machine.

Similar ideas were being discussed almost simultaneously in Paris, Saarbrücken and Mainz: even before the new method had been tested on a human being or had established itself in the medical field, urologists were so certain of success that the green light was given for the development of a second generation of machines. At the end of 1986, four years after Dornier had installed its first machine in Munich, these came on the market. They included two French machines (EDAP's LT01 and Technomed's Sonolith) and two German (Siemens' Lithostar and Wolf's Piezolith 2000), which differed from the first machine both technically[7] and in their considerably lower price (1–2.8 million DM).

2 SPREAD OF THE TWO TECHNOLOGIES IN EC COUNTRIES AND SWEDEN

GENERAL OBSERVATIONS: ESWL

At the beginning of 1990, eight years after the first machine for ESWL was put into operation at the Munich University Clinic, there were in the countries of the EC and Sweden about 300 ESWL machines in operation, ie one machine per 1.1 million population. At the start of the diffusion process, health politicians in some European countries calculated the future requirement to be one machine per 1.6–3.0 million inhabitants. The average level of provision in the EC and Sweden is therefore already much higher than this, and diffusion is still in progress. Table 1 shows that only the UK and Portugal have fewer machines than the originally estimated requirement, and in four countries the ratio is as high as 1 machine per 800,000 population.

Table 1
ESWL machines in operation in Europe (31 December 1989)

Country	No. of ESWL machines	Population (millions)	Population per machine (millions)
Spain	50	38 505	0.77
Belgium	12	9 858	0.82
Italy	69	57 141	0.83
FRG	72	61 024	0.85
Greece	10	9 942	1.0
Netherlands	11	14 491	1.3
Sweden	6	8 360	1.4
France	36	55 170	1.5
Denmark	3	5 113	1.7
Ireland	2	3 540	1.8
Portugal	4	10 157	2.5
UK	15	56 617	3.8

The new technology spread in two phases. From mid-1982 until late 1986 Dornier was the only manufacturer, with a production capacity of only 15 machines in the first year. By late 1986 Dornier had installed 44 machines in the EC countries and Sweden. In expectation of the arrival of less expensive second-generation machines, the number of new installations declined somewhat during 1986 and then increased again in the following three years (Tables 2 and 3).

Table 2
New installations of ESWL by year

Country	1982	83	84	85	86	87	88	89	Total
FRG	1	3	8	7	5	12	16	20	72
UK		1		1		6	3	4	15
Italy			1	6	3	11	27	21	69(74?)*
Spain			1	7	1	11	14	16	50
France			1	2	7	16	3	7	36
Netherlands				1		2	5	3	11
Sweden				1			3	2	6
Belgium					1	3	7	1	12
Greece					1	2	3	4	10
Denmark						1	1	1	3
Ireland						2			2
Portugal						2	1	1	4
Europe	1	4	11	25	18	68	83	80	290

* See text.

The numbers shown do not correspond to the present number in operation, a few of the first-generation machines having already been taken out of service. Danish-made NITECH machines are not included: two were being installed by the end of 1989. A further five Siemens machines are believed (according to information from the manufacturer) to be in operation in Italy, but since their location could not be ascertained they are not included. A few of these lithotripters are used exclusively or primarily for gallstone treatment (although gallstone lithotripters are capable of disintegrating kidney stones provided these are detected by ultrasound), so that the number at the disposal of kidney patients is somewhat lower than that shown.

Table 3
Distribution of ESWL machines in each country

Country	No. of machines	No. of city locations
FRG	72	48
Italy	69	40
Spain	50	18
Belgium	12	8
Greece	10	2
Denmark	3	3
Netherlands	11	9
Sweden	6	5
France	36	20
Ireland	2	1
Portugal	4	4
UK	15	8

Table 3 gives an impression of the distribution of the machines within countries. Although the regional distribution is fairly good in most countries, the large cities have the lion's share, as with all large pieces of equipment.

These cities do of course also provide a service for the surrounding area, but their number is in many cases so large that they can hardly operate in an economically viable manner. Table 4 shows some places with a particularly high machine density. The total catchment population for these cities is not available.

Table 4
Cities with five or more ESWL machines

Country	City	Number of		Inhabitants per ESWL (1,000)
		inhabitants (millions)	ESWL machines	
FRG	Munich	1.27	9	141
Italy	Naples	1.21	7	173
Italy	Milan	1.5	8	188
Spain	Madrid	3.21	14	229
Italy	Rome	2.8	10	280
Spain	Barcelona	1.75	6	292
Greece	Athens	3.03	6	505
France	Paris*	6.1	11	555
UK	Greater London	8	7	1143

* Départements: Ville de Paris, Hauts-de-Seine, Seine St Denis, Val de Marne.

GENERAL OBSERVATIONS: PCN AND URS

The few available data concerning the spread of endourological methods are disparate and can scarcely be compared. After the introduction of PCN in academic and other large urology clinics in the early 1980s, it had spread by 1983 to medium-sized and smaller hospitals, where the endoscopic removal of stones from the ureter (uretero-renoscopy, URS) was already routine.

The diffusion pattern of endourology is basically different from that of ESWL. The spread of lithotripsy occurred as a result of investment decisions which depend on whether and when the requisite funds are available.

Unlike ESWL, which can be learned simply and quickly, endourology requires a period of training, during which a urologist may work as an assistant for a few weeks at an experienced centre, learn the methods and then apply them at his own base. However, only large clinics can afford to send a doctor elsewhere to learn a new technique, and this method of diffusion may be rare. Legal requirements differ considerably among the EC member states as to further specialised training of doctors and how this is dealt with in practice. Of course, newly specialising doctors will learn the technique during their training in approved training centres and will then train others in it when they join the staff of other hospitals, so that knowledge of the technique snowballs.

Strikingly, the medical literature, like many country reports, frequently confuses qualitative requirements with empirical reality. Thus one country report states 'Since it took almost two years before the second ESWL became available most of the urologists had to use PCN as the procedure of first choice', but gives no information on whether PCN was used outside large clinics or if open surgery continued to be the general rule. Tables 5 and 6 give a few pointers to the spread of endourology.

Table 5
Number of clinics performing PCN at different dates

Country	Year	Ref	Number of urology depts	
			Total	*Performing PCN*
UK	1985	8	115	73 (63 %)
	1986	8	85	58 (68 %)
FRG	1984	9	160	84 (53 %)
(NRW)*	1987	*	111	82 (74 %)

PCN, percutaneous nephrolithotomy.
* Nordrhein-Westfalen, author's calculations based on Ministry of Labour data for NRW which, in contrast to other studies, include all 111 urology departments.

Table 6
Percentage of endourology in stone treatment

Country	Source	1983	1984	1985	1986	1987	Remarks
Denmark	CR*	2%	13%	26%	31%		PCN only
Sweden	CR*			22%	37%	44%	PCN only
UK	Ref 8			30%	33%		PCN only
FRG	Ref 10**	4%	6%	12%	16%		PCN only
	***					25%	PCN only
	***					44%	PCN + URS

PCN, percutaneous nephrolithotomy; URS, uretero-renoscopy.
* Country report
** Figures for Lower Saxony (Niedersachsen).
*** Author's calculations for Nordrhein-Westfalen.

The tables make it clear that ESWL and endourology spread independently. Because ESWL requires large capital investment, it remains concentrated in few locations whereas endourology gradually spreads to all urology departments. For this reason, and in opposition to the concept of 'multimodal stone therapy' in which both techniques are used at each location in complementary fashion according to the patient's needs, the methods come into competition with each other. Urologists who practise ESWL have to treat as many patients as possible in order to use the machines to full capacity and justify the

investment. For the majority of urologists, who have no chance of receiving a machine, endourology is a handy alternative. They are reluctant to refer their patients to another clinic and thereby waste the skill they have acquired. Furthermore, endourology usually has the advantage of being available nearer the patient's home.

SPREAD OF ESWL IN INDIVIDUAL EUROPEAN COUNTRIES

There follows a very brief account, drawn from the country reports, of the course of diffusion of ESWL observed in each EC member state and in Sweden from 1983 to the end of 1989. Case histories are picked up in more detail in the course of this review to illustrate and exemplify particular points, and country reports from Denmark, France and the UK are reproduced in full at the end of the review.

Belgium

The diffusion of large items of medical equipment is directed centrally by means of certificate-of-need legislation by the Health Ministry. Treatment is paid for by the health funds if and only if it has been performed on machines for which approval has been granted within the framework of the planning of requirements. This regulation makes the running of large machines without authorisation impossible. The spread of ESWL was prevented by the health authorities until the cheaper second-generation machines became available (1986). Approvals for ESWL then followed generously (ten installed in 1987–88), so that Belgium is today one of the four European states with the highest density of machines.

Denmark

The most telling problem, resulting from the low and dispersed population, stemmed from the centralisation demanded by the small number of machines required. There was an attempt at national dialogue planning between central and decentralised health authorities in which the planning goals remained controversial. The central authorities' attempt to delay investment decisions by the counties was intended, among other things, to gain time for the Danish ESWL development group, but when success eluded the NITECH firm the counties finally (1987) installed machines on their own initiative – facilitated by one firm's ingenious marketing in one location and by private donation in another.

Federal Republic of Germany (FRG)

The diffusion of large items of medical equipment is directed by the individual states by means of certificate-of-need legislation. The health insurance funds nevertheless also pay for treatment on machines that are not approved within the framework of the planning of requirements, so that it is difficult to constrain diffusion effectively. With the argument that a rapid, extensive

supply of machines would bring about not only an improvement in quality but a lowering of costs, 21 machines were put into operation within four years (1983 to 1986 inclusive). Shortly after that, the second-generation machines became available. The lack of political interest in restraining diffusion of ESWL has meant that the FRG had for some years the highest density of machines in Europe, although it has now been overtaken by Italy, Belgium and Spain (*Table 1*).

France

The diffusion of expensive and highly specialised medical technology is directed centrally by the Health Ministry by means of the 'Carte Sanitaire'. ESWL has been subject to this regulation since 1984, which allows authorities to prevent the installation of machines outwith the ministry's requirement and location planning, and also to dictate the type of machine to be purchased. This was used to protect the development of the French machines made by EDAP and Technomed, which have been available since 1986. This has worked perfectly: since the installation of three German machines in 1984–85, 32 French machines but only one further foreign machine have been installed. Authorisation has been sparing, and France is still in the middle range of machine density (1:1.5 million population) in Europe.

Greece

A national health service has been under construction since 1983. The main aims are the improvement of quality of service and of qualifications of personnel, unification of the various catalogues of services of the former health insurance funds, unification of the financing of services, decentralisation of decision-making processes, and equalisation of standards of medical care in urban and rural areas. The pattern of installation of ESWL machines illustrates some basic problems: the private sector is free from central planning decisions and dominates the development of ESWL as it has for other large items of equipment. Of the ten ESWL machines installed to the middle of 1989, eight are in private clinics. Decisions on location have been based on expected profit or competition, so that a rather large number of machines has been installed (overall machine density 1:990,000), all of them in Athens or Thessaloniki. This pattern contributes only minimally to the improvement of medical care: access is difficult for large sections of the population and the high density of machines ties up funds that might be used to adjust the unequal standards of care.

Ireland

The first submissions to the Department of Health for purchase of an ESWL machine were made in 1983, but these were refused on the grounds of insufficient knowledge of the effectiveness and side-effects of the treatment and the high costs involved. With the advent of the cheaper second generation of

machines, permission and two-thirds of the cost were granted (mid-1986) for treatment within the NHS. Towards the end of 1987 a second machine was installed, this time in a private clinic.

Italy

The Italian Servizio Sanitario Nazionale resembles the NHS in Britain in many ways, including the restrictive allocation of funds by the health ministry. However, unlike the UK, private providers of medical services are integrated into the care of NHS patients by a 'conventionalising' process whereby the NHS may pay for treatment of patients in approved institutions in the private sector if the treatment is not available in public hospitals. This enabled private clinics to operate ESWL profitably. In 1989, 85 per cent of all the machines were in private clinics. Competition for prestige and patients led to a disproportionate number being installed, above all in some large cities (Milan, Naples, Rome, see Table 4, above). Because the private sector is not subject to any planning restrictions, Italy is one of the European countries with the highest machine densities (1:828,000).

The Netherlands

The Netherlands was the only country which attempted from the start to control the installation of ESWL in terms of the overall cost savings in the treatment of renal stones promised by manufacturers. 'Passing the buck' between the health ministry and the health insurance funds in trying to reach agreement on the location of the small number of machines calculated to be necessary successfully delayed purchase of all but the first machine until 1987, after which planning restrictions were lifted. The health insurance funds' attempt to finance ESWL by redistributing the existing budget was only partially successful, but as a result most machines were bought and operated cooperatively by several hospitals, so that the treatment became accessible to a large number of urologists. The resultant diffusion was thereby restricted, not to the calculated desired extent, but to a point which left the country in the middle of the 'league table' of machine densities (1:1.3 million).

Portugal

As in Greece, the health care system in Portugal has been under reconstruction since the early 1980s. The aim, not completely achieved by 1989, was to create a regionally subdivided national health service, financed entirely by taxation, and repairing the considerable gap between urban and rural areas in quality of health care. Only four machines (density 1:2.5 million) have been purchased, regionally well distributed.

Spain

Spain's mixed health care system is partly controlled centrally and partly in a decentralised way by the authorities of the individual Autonomias. In contrast to other countries, the Spanish mandatory health insurance funds also own and run hospitals and out-patient units. In some regions the system of state subsidies predominates and the system is becoming increasingly like an NHS. Private providers are integrated into the system by individual contracts. The private sector is on the increase but has as yet only a small share of the total health budget.

As in the other countries where there are private providers of health care, these took the leading role with ESWL: of the first nine machines installed between 1984 and 1986, only one went into a public hospital. Competition between public and private sectors and the lack of effective regulation of medical equipment led to unimpeded diffusion of ESWL, the highest machine density in Europe, and clear over-capacity in major cities.

Sweden

Initially, ESWL was subjected to a common national requirement planning process by the decentralised authorities, which raise funds by local taxation. The die was already cast as far as the course of diffusion was concerned by an early decision on the location of the first machine, facilitated by the decision of the county in question to finance a technology assessment centre whose first task would be to subject ESWL to a medical, economic and planning evaluation. This also allowed the county councils to postpone investment meanwhile; their cooperation was ensured by placing ESWL on the national referral list. After the planned number (three) of machines had been put into operation, other counties were allowed to procure further machines on their own initiative, and a further three have been purchased.

United Kingdom

The planning and development of services within the British NHS are the responsibility of the decentralised health authorities whose funds, which are distributed by the health ministry, derive from national taxation. The government's restrictive policy in public expenditure confronted NHS authorities with the problem of financing new services from static budgets. Since ESWL was accorded no priority in this process, the installation of machines remained for the most part dependent on the skill of interested parties in raising funds through donations, loans, joint financing with, for example, university or trust funds, and the placing of contracts with other district or regional authorities. Two machines were partly or wholly financed by the central authorities, for technology assessment purposes (one for the evaluation of gallstone treatment).

The small number of public purchases of machines provided private clinics with an attractive sphere of activity. However, the small number of privately insured patients made the economic running of their machines dependent

also on referral of NHS patients and thus on the NHS budget, so that relatively few machines were installed in the private sector too. The UK has the lowest machine density of all the countries dealt with here.

3 PLANNING CONCEPTS AND HEALTH CARE PRACTICE: THE EXAMPLE OF NORDRHEIN-WESTFALEN (FRG)

On the introduction of ESWL, the manufacturers and urologists had announced that it might well replace more than 70 per cent of open stone operations. This statement was accepted by those Member States which attempted to control the spread of machines, as a basis for the calculation of the number of machines needed. The number of open operations per year currently performed was obtained, although in most countries the figures were only estimates drawn from limited statistics.

This procedure had several implications:

- The new technology was viewed exclusively in terms of substitution. Economically, one could therefore speak of a rationalisation investment.
- The criterion of the patient's need of an operation was raised to the level of a norm for the application of ESWL, although no one considered whether the application of this norm was practicable or verifiable.
- It was assumed that all doctors, including those who did not have an apparatus at their disposal, would accept this norm.

The economic argument is dealt with in the next section. There follows first a discussion of the two other implications.

In the opinion of politicians involved in health care, replacement of the open operation by ESWL was the critical factor which justified the spread of the new technology, despite the high costs involved. The clearly defined indication for treatment, they thought, simultaneously offered the possibility of determining the precise number of machines required. However, it soon became clear that the operation rate was not well known. Only a few European countries keep hospital statistics, and only Denmark and Sweden keep sufficiently detailed data to allow determination of the number of stone operations performed across the country. In the FRG at the beginning of the 1980s, statistics on diagnosis existed in only one federal state. Even from these one could only estimate, given additional information, how many of the patients with a diagnosis of renal stone were operated upon. Belgium, France and The Netherlands also had some information on which to base estimates. Although the UK has usable statistics, their use was by no means the determining factor in the calculation of the number of machines required. In Italy and Spain no estimates were made of requirements for ESWL.

Table 7 shows the estimates in different countries for the operation rates before the spread of ESWL.

Table 7
Number of renal stone treatments per 100,000 population before the advent of ESWL in EC countries and Sweden

Country	Source	Year	Open surgery	PCN	URS	All
Belgium	Ref 11	1978–83	27–30			
Denmark	Ref 12	1984	19	4	9	32
	CR	1986	11	8	7	27
FRG	Ref 10*	1983	36	3		39
	Ref 13*	1977–79			75	
France	Ref 14	1980	20.5		5.4	26
Netherlands	CR	1984	34			
Sweden	Ref 15*	1970				35
	Ref 16	1975–84	25			
	Ref 17	1981	27			
Ireland	Ref 18*	1964–74	11			

CR, country report.
* Estimated on the basis of regional statistics.

Except for the number calculated by Schaefer[13] at the request of the Dornier firm (which included bladder stones and stone removal by loop), the estimated numbers of surgical stone removals ranged from 20 to 40 per 100,000 inhabitants. If the treatment capacity of each machine is at least 800 patients per year, or two million total population, the requisite number of machines for the treatment of all patients who needed stone removal had already been attained in all EC countries except Portugal and the UK (see Table 1) by the end of 1988.

Nevertheless it must be assumed that by no means all patients requiring stone removal who could be treated with ESWL are in fact currently so treated. No statistics are available anywhere on quantitative changes in renal stone therapy, but there is abundant anecdotal evidence to the effect that in most countries a considerable proportion of the patients are not referred for ESWL treatment. There is no evidence either for claims (country report for the Netherlands, and elsewhere in the European literature[19]) that the number of open operations has declined to less than 5 per cent: this is true only of clinics with an ESWL machine. However, we know just as little today about the treatment of stone patients outside the clinics with ESWL as we used to know about the number of stone operations before the spread of the new technology.

A formal investigation of this question was performed (for 1987) in Nordrhein-Westfalen,[20] a state in the FRG of 17 million inhabitants. If one assumes an operation requirement of 40 per 100,000 this gives 6800 patients per annum. If 80-90 per cent of these patients can be treated with ESWL, this would mean 5400–6100 treatment cases. In 1987, six lithotripters were in operation in Nordrhein-Westfalen. Five of these machines had already been in operation for more than two years and one had been installed during 1986.

About 6200 patients were treated by ESWL during 1987, so the treatment rate per machine was 1030 patients, 25 per cent more than the assumption of 800 per machine per year quoted above. The following table must be considered against this background.

Table 8
*Stone treatment in Nordrhein-Westfalen, 1987**

	Number of treatments (not patients)		
	in hospitals with ESWL	in hospitals without ESWL	all
ESWL	7517	–	7517
PCN	1096	2912	4008
URS	696	2474	3170
Open renal surgery	41	600	641
Open ureter surgery	30	1037	1067
Sum	9380	7023	16405

*Data for all 111 urology departments in the state.
The number of stones removed in departments of general surgery is not known.

Treatments, not patients, were counted. The number of patients is certainly lower: some ESWL sessions have to be repeated as well as unsuccessful endourological interventions.

The table shows an enormous number of treatments – 94 – per 100,000 inhabitants: this is more than double the predicted treatment rate of 40 per 100,000. The Netherlands, England and Sweden also report a marked rise in the number of treatments, for instance from 31.7 (1985) to 47 (1988) per 100,000 in The Netherlands, and in Sweden[16] from 29.5 (1984) to 58.6 (1986) in the county in which the first machine had been installed.

What is the reason? Vrolijk and Straten[21] attribute the increased number of treatments in The Netherlands to:

- implementation problems with the new technology, manifested in the frequency of the repeat treatments and the combination of ESWL with endourological methods
- ESWL treatment of patients for whom the risks of surgery were considered to outweigh the benefits
- extension of ESWL treatment into preventive action.

In Vrolijk and Straten's view, the last point is quantitatively the most significant. They see it as the result of the present surplus of ESWL capacity. 'The present shift from curative to preventive use of the ESWL method derives from the deregulation which was introduced by the Dutch government at the beginning of 1987. If ESWL capacity had been restricted by government regulation, the application of ESWL technology would probably have been confined to curative treatment.' Undoubtedly, a shortage leads to the selection

of patients according to the criterion of urgency, and eliminates or decreases the number of elective treatments. However, in 1987 Nordrhein-Westfalen did not have a surplus of ESWL capacity: the number of machines was barely adequate, at least according to the estimates and assumptions.

Since repeat treatments took place primarily in the ESWL centres, and it is also only there that endourology is employed in an auxiliary manner, one can assume that about half of all patients were treated outside the six clinics provided with ESWL. And since it is improbable that endourological methods were employed outside ESWL centres either for small stones, which can be treated just as well conservatively, or for asymptomatic stones, it can be assumed that all patients who were treated endourologically outside the ESWL centres required stone removal. From this, one can draw two conclusions:

- Urologists who had no lithotripter at their disposal were by no means prepared to refer all patients who required stone removal for ESWL treatment.
- Since only some of the stone patients who required operation were referred, there was over-capacity in the ESWL centres, despite the 'shortage', which could be used to treat patients not previously thought to require treatment.

The concept that all open operations would be replaced by ESWL had evidently failed to take into account the competition from endourology. As long as urologists had the necessary qualifications to apply endourological methods – and this was true in most clinics in 1987 – it could scarcely be claimed that they were not treating their patients in accordance with best current practice.

This would explain the rise in the number of treatments noted in several countries concurrently with the spread of ESWL. This effect would not be banished by the installation of still more ESWL machines; this would merely increase the over-capacity.

The following two chapters describe the decision-making preceding installation of the first ESWL machine, and then a detailed examination of the diffusion process, in different EC countries.

4 THE FIRST ESWL MACHINES

The first machines in Italy, Spain and the UK were private investments. Despite the high purchase cost, the ESWL is an attractive investment in public relations terms, and seemed likely anyway to offer a good return. In countries where there are both public and unregulated private health care sectors, the contrast between reactions to the advent of ESWL is instructive.

The UK fell back on private financing because of the convictions of the leading urologist involved, Professor Wickham. In 1983, the same year in which he received his machine, Wickham had published his book 'Percutaneous Renal Surgery'.[22] In the preface to this book, he wrote that PCN 'is starting to revolutionise the whole field of renal stone surgery....Looking even further ahead to the development of non-invasive extracorporeal shock-wave stone disintegration or the possibility of stone disruption *in situ* by laser impulse it seems no exaggeration to say that in 5–10 years conventional renal surgery through the grossly traumatic loin incisions will be dead.' Thus, in order to remain in touch with international developments, he felt that an ESWL machine had to be purchased immediately. Objections of health authorities that the method had not yet been sufficently tested he found unacceptable.

Unlike private investment decisions, which are made according to the criterion of profitability, public institutions are responsible to the taxpayer. Their criterion for making decisions should be the practicality of an investment and its relative contribution to the improvement of medical care within limited resources. This means that every new type of technology should be evaluated prospectively, taking into account alternative possibilities for using the funds in relation to its efficiency. The problem is that the public decision makers are heavily dependent on the judgement of the very doctors who have a vested interest in acquiring the new technology. Understandable scepticism about these doctors' objectivity explains the tendency on the part of public authorities to delay decisions, with consequent tension between the clinician activists (in this case urologists) and the authorities.

However, the clinicians are themselves by no means united. Because of the high investment costs, only a few urologists could be sure of receiving the equipment; most had no chance from the start and therefore had little personal interest in the spread of ESWL. Those with a chance were competitors. Each had to try to be the first to receive a machine because with each machine installed somewhere else, the residual chance of receiving one worsened. Particularly urologists with a national reputation to lose wanted to be seen to be in possession of the latest equipment.

Here, the interests of individual urologists concur with those of the industry. Every attempt to slow down the diffusion process frustrates the sales interests of the manufacturers and gives competitors time to bring new models on the market. It is in manufacturers' interests to see that clinicians with influence on purchasing authorities receive and use the new equipment early. (This also explains why, at least in the first phase of the diffusion process, most of the machines were installed in university clinics. It is doubtful whether this decision was always the best one from the point of

view of medical care and the costs involved.) Both clinicians and the industry thus seek strategies to speed up the decision processes or circumvent them. The latter is difficult when capital costs are high.

The tactics of the health authorities, based largely on gaining time, tend to reduce the quality and content of the discussion with regard to the introduction of ESWL: for all parties concerned, the investment costs of the machines become the central problem. Health policy becomes restricted to the slower or faster availability of the requisite funds to purchase a machine.

The competition for access to the new technology is the *leitmotif* of the altercations concerning the first machine in each of the individual countries. The following three case studies describe the decision process concerning the investment of the first ESWL machine in The Netherlands, France and Denmark. The fourth case study, of Sweden, shows the extent to which even an alternative solution to the problem follows this model.

4.1 Who pays for the first machine?: The Netherlands

At the beginning of the 1980s, the Dutch government established a cost-containment policy for the health service. Any further increase in health costs was to be avoided, and new developments in health care were to be financed by compensating savings elsewhere in the health service. The purchase of the first ESWL machine in the Netherlands illustrates how new investment costs can be avoided.

In the summer of 1982, shortly after the first machine had been brought into routine clinical operation in Munich, the urologists in a few Dutch university clinics applied to the Kidney Foundation for purchase of an ESWL machine. The Foundation did not reject the application, but left the question open and concerned itself first with the question of location. No agreement could be reached with the urologists of the various universities, because everyone wanted the machine himself. The Kidney Foundation then asked the responsible ministries to come to a decision. The ministries handed the problem on to the Bureau of University Hospitals (mid-1983). The latter body (presumably advised by the same doctors the Kidney Foundation had already spoken to) said it was prepared to work out a recommendation on the location, recommending however that the Kidney Foundation should immediately order an ESWL, because of the long waiting list. The Kidney Foundation accepted this recommendation. This procedure involved the relevant ministries in the events and thereby made them in some way responsible.

Before a machine had even been ordered, and before it had been decided who should cover the investment costs and where the machine would be located, the urologists drew up a waiting list, implying that the patients on it would be treated by ESWL. The clinicians interested in the investment thus used the waiting list of patients to apply political pressure. What meaning could such a waiting list have had at that moment?

- At the end of 1983 only 800 patients had been treated in Munich and the second machine had only just been put into operation in Stuttgart. Patients were selected for the treatment by strict criteria.

- PCN was by then well established in Dutch university clinics, and patients whose case was urgent would have been treated endourologically. At the very least, some of those on the 'waiting list' must have been more suited to this form of treatment anyway.

Perhaps because this was well recognised, the ministries do not seem to have taken the waiting list very seriously; otherwise, they might have felt obliged to order the machine themselves or require the Kidney Foundation to do so. The country report stresses the readiness and the goodwill of the ministries, who, just like the insurance agencies, had a positive attitude towards the investment plans – admittedly without being willing to assume any responsibility as regards payment. The 'strong pressure group consisting of university urologists, the university hospital, the Kidney Foundation and the organisation of kidney patients' does not seem to have been all that strong if the ministries succeeded to a large extent in keeping out of the further development.

The financing of capital costs of medical equipment in university clinics had long been a matter of dispute. The legal responsibility lay with the Ministry of Education and Science. However, the latter distinguished, because of the scarcity of funds, between investments necessary for research and those intended exclusively for the care of patients, which would have to be met by the insurance agencies, as for non-university clinics. The insurance companies stubbornly refused to cover capital equipment costs of university clinics. It was scarcely to be expected that the dispute, which had raged for several years, would be solved solely in the case of ESWL.

Thus, the involvement of the Kidney Foundation was absolutely necessary for the university clinics, for two reasons.

- Speedier provision of funds than from the Science Ministry (even had these been granted) would avert the danger that non-university hospitals might acquire ESWL sooner because there was no argument there about who was responsible for the funding. If a few regional hospitals became equipped, the university clinics might have lost their right to a machine.
- Financing by the Kidney Foundation would mean that placement of the equipment in a university clinic would become acceptable to ministries and insurance agencies, since this independent financing would place no burden on either of them.

In October 1983, the Health Ministry decided on the installation of the first ESWL machine in a university clinic. The ministry allayed the fears of the organisations of health insurance funds and private insurance companies that ESWL might spread in an uncontrolled manner, by assuring them that both organisations would be involved in the decision-making process, that a 'certificate of need' would be used to keep the spread of ESWL under control, and that the installation of further machines would not be considered until the method had been evaluated medically and economically. As a result, the insurance companies indicated their approval of the 'procedure up to now'.

The university clinics had thus attained their preliminary goal. It had been

confirmed that at least one university hospital would become an ESWL location. Now they had gained sufficient time to solve the location problem. Negotiations on this point would clearly be difficult, insofar as each university hospital was in principle eligible. Taking a decision too early on the location of the university machine would have prevented common action by the university hospitals, since a clinic that was not going to get a machine would not have supported a common policy but would probably have attempted instead to obtain a machine itself. Now the same danger arose again.

The Bureau of the University Hospitals therefore published a list (January 1984) of four preferred academic hospital locations, corresponding to the maximum of four machines which had by then been calculated as required for The Netherlands. Of course, this excluded some university clinics from ESWL, but apparently this was acceptable to the universities because publication of the list established the claim of university clinics to be the sole justifiable locations for ESWL.

Neglecting the evaluation condition, the Bureau of the University Hospitals recommended (autumn 1984) that all four machines be purchased together in order to obtain a substantial bulk discount on a single order. This argument was expected to appeal to the health authorities, who seemed to be obsessed with the question of costs. However, they rejected the suggestion, on the grounds that the technology was still in rapid development.

This initiative came, remarkably, at a time when the financing of only the first machine had been secured, and the question of how three further machines at university clinics could be financed was still obscure. One can only assume that it was intended to bring the matter of financing to public attention again. Meanwhile, Rotterdam had been confirmed by the ministries and the insurance agencies as the location of the first ESWL machine.

At the beginning of 1985, a few weeks before the Rotterdam machine was supposed to be put into operation, the Kidney Foundation announced that it did not propose to cover the investment costs after all, but to provide a loan, to be paid back over the next few years. This in turn meant that the insurance agencies were to take on the servicing of the loan. The insurance agencies naturally refused to create a precedent here and stated that the Ministry of Education and Science was responsible. The latter repeated its refusal to cover investment costs for tasks related solely to health care and instructed the clinic not to operate the machine until the question of financing was settled.

The Kidney Foundation had appended to its annual appeal for donations that it intended to purchase an ESWL machine with the money collected. As the Rotterdam University Clinic had funded the necessary construction work prior to putting the machine into operation, it was no longer possible to install the lithotripter elsewhere. After more than 250 cases had been treated and an amicable agreement was still not in sight, the ministry put pressure on the Kidney Foundation to put its public announcement into effect and accept the investment costs. The Kidney Foundation had no choice but to present the machine to the Rotterdam University Clinic as a donation.

The policy of benevolent non-intervention had paid off for the health administration: the first ESWL machine had been installed without putting a

burden on the health budget. No decision had been made on how future machines would be paid for.

In the summer of 1985, for the first time the larger non-university hospitals put forward (in a parliamentary question) their claim to an ESWL machine. The Health Ministry replied (August 1985) that these hospitals were indeed eligible for consideration for ESWL, and the evaluation condition was now dropped, 'on the basis of the positive experience with ESWL in the FRG and the USA'. At the end of 1985, it was announced that the purchase of equipment for treatment in university clinics should follow the same principles as in other hospitals. This was the first time the financing of further ESWL machines in university clinics became certain.

4.2 Waiting for one's own machine: Denmark

(see also the country report for Denmark)

Denmark was one of the last three EC countries in which a lithotripter was installed (Table 2, above). In mid-December 1987, an ESWL machine was put into operation at the Bispebjerg Hospital in Copenhagen county; the Siemens firm had placed it at their disposal for a year, initially free of charge. This put an end to the policy of some leading urologists, who had recommended to their colleagues and to the national health administration that they do without the new method of treatment until they had succeeded in bringing their own considerably cheaper machine onto the market.

The consensus that existed at least for a time among urologists that they should agree to this procedure and delay the investment came about because centralisation of stone therapy, which was a consequence of the high cost of the machines, seemed undesirable to them. With five million inhabitants and only 1500–2500 stone patients per year, Denmark needed only two or three ESWL machines. But stone therapy was distributed among nine urology clinics and a larger number of departments of general surgery. Urology departments lacking the technology would suffer a loss of prestige and would have to refer their stone patients to the ESWL centres.

The suggestion that they should wait for a cheaper, Danish machine, and the chance of controlling the technology themselves, seemed worth considering. But it also involved the risk, for each urology department, that one of the others would not keep to this silent agreement but somehow or other obtain the funds for a machine and present the others with a *fait accompli*. As a result, the consensus was probably restricted to the three urology departments that had combined forces as early as 1981, under the leadership of the Copenhagen urologist H H Holm, who attempted to develop a machine themselves.

When, in 1983, the first commercial machines came on the market, this group had such respected status that it was invited to advise all Danish decision-making authorities, with the result that it was able to push through its policy. It had received financial support from various national research councils and private funds, and its work had proceeded to the point where the media were able to couple reports of first Munich treatment successes with references to the Danish ESWL project. When a private insurance company offered to donate a third of the purchase price of a Dornier lithotripter the

ministry rejected this offer after consultation with the research group. The health administration, which had not been confronted with the problem of ESWL, accepted these urologists as their expert partners in the discussion. Thus, other urology centres' chances of entering into the discussion were minimal from the start. At the local level where technology investments are politically decided, applications were rejected on the argument that the method was too expensive. The Medical Technology Assessment Committee, under the chairmanship of F Kamper-Jorgensen, also co-opted a urologist from this group as an adviser on the problem of kidney stone treatment and ESWL. Referring to the increasing spread of PCN as a valid alternative treatment, to the scarcity of public funds, and the unavoidable centralising effect referred to above, the committee advised in 1983 delaying purchase of ESWL.

In 1985, the ESWL research group and its commercial arm NITECH announced that a Danish machine would be in production by 1988. In March 1986 the EC workshop on kidney stone treatment clarified that ESWL was the treatment of choice in most cases and that others' second-generation machines, which were almost ready for marketing, would be considerably cheaper. The Danish Medical Technology Assessment Committee now decided that it would plan the spread of ESWL, especially since some Danish hospitals were considering purchase of a machine.

Soon afterwards, it became known that a hospital in Copenhagen (Bisbepjerg) had been offered the Siemens Lithostar for a year, free of cost, on trial. The urologists at Bispebjerg Hospital had at that time accepted the policy of waiting for the Danish machine, and this was explained to the mayor of Copenhagen who is responsible for hospital services in the city. The mayor, however, felt that one should not wait any longer and thus accepted the Siemens offer. This precipitated the decision as to where the first machine should be installed – which, however, took another year to come into operation.

4.3 Who is entitled to the first machine?: France and Belgium

Professor Cukier, a urologist at the Hôpital Necker in Paris, having heard of the experiments with ESWL at a conference in California, visited the Dornier group in Munich as early as 1980, and again at the beginning of 1982.[23] On his return he recommended urgent purchase by the Assistance Publique for the Hôpital Necker, with the object of making it a leading centre for the new treatment. He supported his recommendation with the information that several patients had already applied to have an ESWL treatment in Germany financed by the French social security, and provided CEDIT, a committee of the Assistance Publique for the evaluation of new technology, with copies of the scientific publications by the Munich urologists and an economic appraisal of it commissioned by the Dornier firm.

The Assistance Publique, the largest health care institution in France, operates 50 hospitals (more than 19,000 acute beds), mostly in or around Paris. CEDIT recommended purchase of the machine, but in order to avoid making one of the hospitals more attractive than others because of the

possession of prestigious equipment, stipulated that it should be used jointly by all ten urology departments of the Assistance Publique de Paris. The organisational problems of such a collaborative service were to be solved by a committee, which would also arrange medical and economic evaluation. The recommendation was accepted and the Assistance Publique ordered a Dornier machine in August 1983.

Other urologists now became involved, and claimed that the machine should not be installed in the prestigious Hôpital Necker, to the disadvantage of smaller urology departments, but in a 'neutral' therapy centre not associated with any existing urology department but centrally located in Paris for greatest convenience to patients. This was not acceptable to Cukier, who pointed out in press conferences that as he was responsible for bringing the technology to France, it should be placed in his hospital. The Assistance Publique was not enthusiastic about the doctors' recommendation either, and demanded a written assurance from them that this 'neutral' location would not entail risk to patients. Since most of the urologists were unwilling to put this in writing, the management of the Assistance Publique requested a different recommendation as to the location. The urologists were unable to agree, and the conflict over location of the first machine continued.[24]

In Belgium, similar problems arose. A commission convened by the government, made up of doctors and administration directors, had like the Paris urologists recommended (July 1985) a neutral location for the machine to prevent a monopoly by one of the seven medical faculties. A centrally placed military hospital was identified as having enough space and beds, as well as an emergency service capable of dealing with any serious anaesthetic or cardiac complications. The commission also warned against any sort of inauguration ceremony, again to prevent the impression of creating a monopoly (*ad hoc* commission note of 29 July 1985).

In a minority report Professor L Denis considered the installation of the machine on neutral territory unacceptable until the team carrying out the treatment was integrated into the hospital structure, so that the doctors could guarantee immediate and optimal intervention in any urological or cardiovascular crisis or resuscitation problems. 'Moreover, I am extremely astonished that greater significance is being accorded to the creation of an imaginary monopoly, which might increase the prestige of particular hospitals, than to patients' interests. Technology continues to develop. Will it be necessary in future for us to install the gallstone lithotripter, the linear accelerator or other new machines in a "neutral" location like the military hospital too?'

The government resolved the problem by deciding not to buy a machine until the cheaper second-generation machines became available; then, at the end of 1986, 11 machines were approved in quick succession and were installed during 1987 and 1988.

In France the problem of a neutral location was 'resolved' by installing the first machine in the Hôpital Necker, but making it available to all urologists by installing it separately from the urology department there in an independent inter-hospital administrative unit. Under the direction of three doctors, a urologist, a radiologist and an anaesthetist, the operation of the unit was organised in cooperation with a nursing sister and an administrator in such a

way that each of the ten urology departments of the Assistance Publique de Paris had access to the machine one day per fortnight.

Professor Cukier did not approve this either. The allocated treatment time was not enough for him. Like his Dutch colleagues he had made up a waiting list a year before the ESWL centre was opened. Once the machine was put into operation (November 1984) he demanded longer treatment times and more personnel, pointing to his list of almost 500 patients who urgently required treatment but who would have to wait for up to a year for it. Further, since the machine was located in his hospital, both patients and general practitioners gained the impression that he alone would be using it, which resulted in further applications. The management attempted to publicise the existence of much shorter lists held by other urologists, but it is not known what effect on patients this had. Cukier refused to share his waiting list or refer his patients. The Assistance Publique's 'neutral' solution to the problem of differential prestige was obviously unsuccessful, and cost much organisational effort which might have been more profitably spent. The problem remained unsolved until more Assistance Publique machines were put into operation in 1986.

The evaluation of ESWL planned as part of the operation encountered stiff resistance from most doctors. Some simply refused to forward details of treatments given. Others were deterred by the length of the questionnaire, and feared that the results would be used to compare performance of urology departments; perhaps to put in question the equal access which had been achieved with such effort; and almost certainly to attempt to question costs. This resistance was repeated in a higher key when the Assistance Publique wanted to make the acquisition of the second machine in Paris, an EDAP LT01, conditional on cooperation in an evaluation. Urologists reacted with incomprehension and open resistance: what would be the use, they asked, of an evaluation of a machine which had much lower capital and running costs than the Dornier, did not require anaesthesia, and had been used successfully in more than one private non-profit-making clinic?

4.4 Evaluation as a precondition for further diffusion: Sweden

The health authorities in The Netherlands and France made their decision to buy the first ESWL machine conditional on evaluation of the new technology, but the doctors concerned refused to provide data after the machine had gone into operation. Since the technology was convincing and the machine functioned safely and effectively they considered there was no need for further medical evaluation and they were not interested in the costs anyway. Moreover, they considered the treatment data as their own property which should be used to increase their own scientific reputation rather than assist in bureaucratic control.

The fact that the authorities provided no personnel or funds to perform a proper evaluation indicates that they were not really committed to it anyway. Authorities can also link provision of equipment to a binding agreement to give access to the data, the doctors retaining their legitimate intellectual property rights. Neither in Paris nor in Rotterdam did the scientific committee

which was to gather and evaluate data come into being.

The health authorities in Sweden were more consistent. Not only was ESWL to be evaluated, the opportunity was seized to set up a centre for medical technology assessment on the site where the machine was located (Linköping University Clinic) in order to make available in the future the experience and knowledge gained.

Urologists in Sweden became interested in ESWL very early in its development. Dr Tiselius in Linköping advised his clinic administration early in 1983 that despite the lack of experience with the technology it was imperative that they purchase a machine. The administration calculated the costs per treatment and the income the hospital might expect from patients referred to it from other counties and applied to the county council of Östergötland to finance the investment.

Östergötland is one of the most prosperous counties in Sweden, and the council would have had no difficulty in providing the necessary funds. However, the financial risk seemed to the politicians to be great enough to refer the question to the Federation of County Councils, as is required by a law passed in 1983 for highly specialised items of medical care affecting a catchment area larger than one region. The Federation plans national services offered by only one or two hospitals in the country with the National Board of Health; and in such cases the binding nature of the planning is ensured by a national referral list. Patients can only be referred (with reimbursement) to the location specified in the list.

After consultation with the National Board of Health the Federation agreed to support the purchase of the machine for Linköping, put the latter on the referral list, and advised the other counties to postpone their investment interests until a medical and economic evaluation in Linköping had been completed. The county council of Östergötland purchased the machine and in addition funded a Centre for Medical Technology Assessment at the university of Linköping to the tune of 7 million SwKr (just under 2 million DM).

It took less than eight months from the first application to the decision to buy it. This is presumably one of the reasons why no dispute arose as to the location of the machine. Before the other urologists had a chance to become involved, Linköping had already decided the matter in its own favour. Östergötland's decision to provide a generous sum for the foundation of the MTA institute was also a strong contributing factor. Finally, the advice of the Federation of County Councils to the other counties to delay their investment was also welcome to them and was clinched by the use of the national referral list.

'The purpose of the evaluation was to gain experience about costs and effectiveness of the new technology. It was assumed that other technologies such as percutaneous surgery ... could very well compete with ESWL in terms of effectiveness, costs and safety. The high investment costs and the dramatic change in management of patients with kidney stone disease that could be expected to follow the introduction of the new technology were other factors behind the decision to perform a careful assessment before further diffusion.'[16]

The investigation was threefold. First, the medical, economic and technical aspects of the ESWL were to be examined. Medically, the short-term treatment successes and complications, recurrence rate and long-term side-effects were to be documented. Secondly, the cost-effectiveness of ESWL and PCN were compared. The third study was to deal with the effects of the introduction of ESWL on the Swedish health care system, looking into both the economic consequences and the changes in patient management.

The first results were revealed at the beginning of 1987 and formed the basis for further planning decisions and developments (see Section 5.3).

5 THE DIFFUSION PROCESS

5.1 Effect of a policy of cost containment on diffusion: The Netherlands again

Jocham *et al*, speaking in 1986 at the EC workshop, stated:[9]'The introduction of ESWL into clinical routine has not only completely changed the treatment of kidney stone disease, but has considerably reduced operating costs. This is particularly true for the FRG as well as for the USA, which by the end of 1986 will have established an almost complete nation-wide network of lithotripters. The cost-benefit ratio has, as expected, developed even more favourably than was calculated in the cost-benefit analysis submitted from Dornier in 1982. . . .According to our own calculation, it can be assumed that, as a result of the application of ESWL in the FRG a saving of more than 100 million DM in national economic costs will be made annually.'

The claim that the application of the new technology is a contribution to the lowering of health expenditure has without doubt had a considerable effect on the acceptance, and therefore on the diffusion of the machines. The paradox that an investment of millions should lower costs has had the effect of increasing rather than decreasing the persuasiveness and media effect of the argument. In spite of considerable over-capacity and a marked rise in the costs of urological stone therapy in the FRG, every newly installed machine is welcomed in the West German media (eg *Oldenburger Volksblatt* 26 June 88, *Die Neue Ärztliche* 24 August 89, *Handelsblatt* 8 November 89) as a further 'contribution to the lowering of health expenditure'.

Before Dornier embarked on serial production of its machine, a testimonial written at the firm's behest[13] had identified three areas in which the new technology would decrease expenditure:

- With ESWL treatment, the amount of time spent in hospital is shortened from an average 16 days in hospital after an open stone operation to 2–5 days.
- The risk of a terminal kidney insufficiency after repeated stone operations is avoided, together with the considerable costs of subsequent dialysis treatment.
- The convalescence period of several weeks after open operation is avoided completely.

The most effective argument in media terms was without doubt the avoidance of dialysis cases. Despite the absence of reliable statistical data on the frequency of kidney failure as a result of repeated stone operations, one could cite 'medical progress' and 'cost containment' by reference to individual cases. Costly as the initial investment was, it avoided the painful and tedious life on a dialysis machine but each treatment with ESWL was actually cheaper. This was sufficient to convince the public that the rapid spread of ESWL was imperative.

As early as 1983, one finds the following claims in French newspapers, the first being in *Le Matin*, 17 January 1983:'By means of an extraordinary

machine, kidney stones are pulverised with shock waves: as a result of this revolutionary treatment, surgical operations can be avoided in future. . . .The new technology fulfils the dream of every doctor, to cure his patients without a surgical intervention, with all the risks involved in this invasive treatment. . . and apart from all this, all kidney damage can be avoided. This is important above all for those patients who perhaps have to undergo repeated operations, the kidney tissue being damaged each time. People who lose their only kidney are dependent on an artificial kidney for the rest of their days. This not only involves a great strain for the patient, but also considerable costs for the community.'

Three weeks later, by the famous Paris urologist Professor Cukier wrote in *Le Monde*:[24] 'The costs of ESWL treatment run to 8500FF. . . .And what does the loss of a kidney cost, after it has been operated on several times for stone recurrence? Finally, how should one rate it if someone has only one kidney left and loses it as a result of repeated operations? In any case, a haemodialysis costs 350,000FF per annum.'

The possibility of avoiding dialysis by use of ESWL inspired many doctors to make fantastic calculations of possible savings: according to the authors (doctors at the Katharinen Hospital in Stuttgart) of one such article[25], one hundred dialysis patients (5 per cent of all dialysis cases) per year in the FRG require dialysis treatment as a result of kidney damage following repeated stone surgery; if 70 per cent of these patients could be treated by ESWL, and if the average annual expenditure per dialysis patient is 75,000 DM per year for 15 years, the resultant cost saving would be 6176 DM per treatment!

Such calculations, published in serious medical journals, were eagerly greeted by the press and the other media. They created a climate of opinion in which the total investment cost was no longer important, since it would be offset by the savings within a very short time.

The only country that took such promises seriously and attempted to realise a decrease in costs, or at least tried to avoid a rise in expenditure as a result of the diffusion of ESWL, was The Netherlands. In 1983, the financing of hospitals was put onto a system of prospective budgeting and the government aimed at zero growth in health care costs. New services were to be financed through reallocation of resources. Against this background, the idea that ESWL would lower costs was particularly attractive. A study by de Waard *et al.* had concluded that 6 million Dfl per annum could be saved by substituting ESWL treatment for open stone surgery, despite the high investment costs.

There were two possible ways of handling the spread of ESWL. Either the government could, in accordance with Article 18 of the Hospital Provisions Act, put the machine on the list of the types of equipment that required official permission, and thereby, as in France, put the diffusion under explicit control and guidance. With this option, no Dutch hospital would then have been allowed to put a machine into operation without state permission, even if it were privately donated, but on the other hand the government would have had to agree to increased budgets of the relevant hospitals, in proportion to the capital costs and the increased number of treatments.

Or the government could make the purchase of machines a decision for the

hospitals. In this case the budget would be increased not automatically, but only if the hospital was wily enough to negotiate an increase; the health insurance funds would be the dominant actor in limiting both budget and diffusion. The Ministry took the second option.

The first machine had been donated to the University of Rotterdam in 1985. At that point the question of whether the government would regulate the spread of the new technology was left open. The health insurance funds had refused to meet capital costs, arguing that any investment expected to lower costs would have to finance itself. For this reason, and also because the government continually delayed its decision, no further machines were installed for the next two years. More and more tricks were invented by urologists, hospitals and politicians to make more machines available. It was suggested that Dutch patients had the right to seek ESWL treatment abroad. Finally, in February 1987, the Ministry decided to allow the purchase of machines, without any restriction but evidently in the belief that few hospitals would be able to finance the investment.

However, within a very short time, a number of hospitals succeeded in coming to an agreement on methods of financing and operation. By the end of 1988, a total of eight machines were bought. In each case, several hospitals (in one case as many as 17) were involved. Four of these machines are mobile; the stationary ones are used by several clinics in a rota system.

The discussion in The Netherlands was in many respects astonishing: although endourological methods were practised in 1985 not only in all university clinics but also in most peripheral departments, and open operations were therefore necessary only in rare cases, the argument centred exclusively on the substitution of open operations by ESWL. Although there is general agreement in the literature that the costs of ESWL treatment and PCN are virtually the same, with the endourological methods possibly cheaper, the cost comparisons at that time were generally made solely with the open operation. The length of hospital stay and degree of unfitness for work are also almost identical. A German text of 1987[5] states '[The] percutaneous operation technique [is also] a method which protects kidney functions and which can in principle be repeated as often as one likes, just like ESWL. Thus, the contact-free destruction of kidney stones offers no predictable financial advantages with regard to the reduction of dialysis cases.'

Anyone could have obtained this information as early as 1985. What led the people concerned – and by no means only in the Netherlands – to carry on a bogus discussion in order to expedite the diffusion of the machines?

The Netherlands country report ends with the pithy comment that the diffusion of ESWL has not reduced the total costs of the treatment of urinary calculus in The Netherlands. Although individual treatments are cheaper today than formerly, the rise in the number of cases and the frequency of repeat treatments have, on the whole, prevented a decrease in expenditure. Since, in the course of the spread of ESWL, no beds were done away with or personnel dismissed, as the organisation of insurance agencies had recommended, the capital costs were without doubt additional expenditure. The report does not explain how this expenditure was financed. The government had rejected the health insurance funds' request that the provision of urological

treatment be reduced on the grounds that it had no powers to impose a general cut in the hospital budgets or require a decrease in the number of urologists without the hospitals' agreement.

5.2 The planning procedure in France and the FRG
(see also the country report for France)

The structures of the French and German health care systems are remarkably similar. Both are financed primarily through a system of mandatory health insurance funds, under which almost the entire population is insured. In France, as in the FRG, there is strict separation between the care of out-patients in private doctors' practices and the hospital system, which is largely public.

In both countries, new regulations concerning the organisation and financing of in-patient care were issued at the beginning of the 1970s (Loi Hospitalière, 31 December 1970; Krankenhausfinanzierungsgesetz, 29 June 1972). The new regulations considerably increased state authority over control and planning over hospital and in-patient care, including the private, commercial sector. The existing property rights and the division of hospitals into public, private non-profit and private profit-making concerns were left untouched. It was the aim of both of these laws to organise health care more equitably over the regions and to put it on a sounder economic basis.

In France, with its centralised organisation, the planning authority and decision-making power are in the hands of the health ministry. In the FRG, with its federal system, they are divided up among the ministries of the individual states. The planning takes the form of the development of a long-term investment plan which regulates the desired degree of care in the individual regions. It determines the size and equipment of each department, and therefore, also the level of investment required in each case. This includes primarily the sort of care that is specialised and confined to a small number of centres, and which is supposed to cover the needs of a fairly large area. In France, this investment plan is called 'Carte Sanitaire', while in Germany they are the hospital requirement plans ('Krankenhausbedarfspläne') of the individual federal states.

Unlike in France, capital and revenue financing are kept strictly separate in the FRG. Capital investment is financed by the states entirely through taxation. The running costs and the cost of treatment are negotiated with the health insurance agencies on the basis of a lump sum for the treatment of each patient. This applies to all hospitals that are recognised in the hospital requirement plans of the states, whether they are run on a public or a private basis. In France the state provides only about 40 per cent of the funds required to cover the investment costs of the public and non-profit hospitals. The rest is provided largely by the social security system. Although the private hospitals are included in the state planning and require official permission before acquiring a large item of equipment, they nevertheless receive no capital subsidies.

The 'Carte Sanitaire' contains a list of the types of equipment that require official permission, and gives figures indicating the amount of care required at any given time.

In the FRG, the implementation of the law in the form of hospital requirement plans is left up to the states (Länder). However, a provision was added to the Hospital Financing Law in 1981, which contains two points:

- The acquisition of large pieces of equipment must be approved by the relevant authority in the state, with due regard to regional requirements in terms of medical care.
- If the equipment is acquired without official permission, the operating and treatment costs will not be met by the health insurance agencies.

A similar legal situation now obtains in France and the FRG as regards the spread of major equipment. The pressure groups involved in the planning are also largely identical. Medical associations, hospital federations and health insurance institutions are consulted, but the power of decision in both countries is in the hands of the relevant ministries.

Differences in the application of the legal provisions have a decisive influence, however, on the course of the diffusion process in the two countries. The centralised structure of France permits a more rigid policy than would be possible in the FRG, where the responsibility for planning is divided amongst eleven states. Although the state governments consult each other on essential aspects of hospital policy, there is no common plan for medical care. The individual states make their decisions autonomously within their own financial constraints. In the process, expensive high technology with a marked publicity effect can become part of the political competition. For example: although one of the health ministries had frequently stated publicly that there was an adequate supply of ESWL machines, shortly before the state elections, clinics in towns where the result of the election was important for the party in power mysteriously received a lithotripter. In the centralised French state, this attempt to create a political effect would at least be much more expensive.

On the other hand, in France, as in countries with a centrally organised National Health Service, wider national interests become more important. Fagnani *et al.*[26] have demonstrated, using the example of CT scanning, how protectionist interests influence the spread of high-level technology in favour of the national medical industry. Official permission and subsidies were held back until a French company was able to deliver relevant machines. The same process can be seen in operation in the case of ESWL.

The purchase of the first ESWL machine in France, a Dornier machine at the Hôpital Necker, Paris occurred early in 1984, shortly before the new technology was added to the 'Carte Sanitaire' list and thus required official permission (decree dated 5 April 1984). The second machine was installed in Lyon in May 1985. The urologist there, Professor Dubernard, had initiated a working group in 1982 with the purpose of developing their own ESWL machine – which later became the Technomed Sonolith 2000. At the same time, he tried to obtain a Dornier machine. At first, however, he failed to persuade the authorities of the need for this investment.

It was not until the beginning of 1983 that he managed to obtain the support of the local hospital administration. However, his efforts to obtain

a subsidy from the Ministry of Social Affairs were of no avail because, precisely at this time, the administration received expert advice that percutaneous stone removal was preferable to ESWL. Moreover, the same Ministry was already supporting another French development project, the ESWL project of the firm EDAP, and was therefore not very interested in the installation of other lithotripters. It was not until a year later, early in 1984, that Dubernard obtained a grant of 3 million FF from the Regional Council of Rhône-Alpes, somewhat more than 25 per cent of the cost. In the meantime, however, official permission had become necessary for the investment. This was reluctantly granted and the machine was eventually put into operation in May 1985. It was the first and last regularly approved Dornier machine in France. (The third Dornier machine is in a private clinic in Marseille and did not receive official approval until the end of 1986, when the first French machines came onto the market, by which time it had been in operation for a year and a half.)

For two years, the Health Ministry did not give official permission for any further ESWL machines. (It is not known whether any relevant applications were made during this period.) This *de facto* investment freeze was not lifted until 1986, when the French machines were ready for the market. At this point, there was a virtual flood of approved applications.

The French Health Ministry has two possibilities at its disposal when it comes to supporting such protectionist interests:

- It can delay approval of the investment and allocation of a subsidy. For example, the first 29 CT scanners were approved in 1976, but the funding was delayed for three years until the machines from the French firm CGR became available.
- It can make installation of an item of technology conditional on the purchase of the product of a given manufacturer.

Such protectionist provisions do not exist in the FRG. The only control is over the total amount of investment funds granted by the state at any particular time.

The first phase in the diffusion of ESWL in the FRG shows similar participants, but playing different roles. By the end of 1981, the medical testing of ESWL was sufficiently advanced for the Dornier firm to wish to field-test the equipment in a routine medical service. This required a different sort of financing. The firm would make the machine available free of charge, but an investment of 2 million DM was required to alter the university clinic building in Munich-Grosshadern. The Bavarian Ministry of State for Education and Culture, which was responsible for the financing of construction work, was unable to defray the costs at short notice. (It is not known how long it would have taken for the ministry to provide the funds.) The Dornier firm, and the urologists involved, wanted to avoid delay. Through the mediation of the local Bavarian health insurance funds, the parties involved persuaded the 'Kuratorium für Heimdialyse' (KfH), a non-profit organisation for the care of dialysis patients, to make a loan to finance the alterations. The health insurance funds in turn undertook to pay back this

loan by raising the treatment fee. The path was then clear for a type of introduction and diffusion of technology that is unique in the history of the FRG.

Fagnani *et al.*[26] state that the French system of health insurance is an 'accounting system for medical procedures ... devoted to reimbursement goals and ... not suitable for assessment of medical practice'; this is no less true of the German health insurance institutions, which are also primarily devoted to financial administration. Their competence in and commitment to the field of health policy is minimal. For this reason, it is amazing that the local health insurance funds made themselves the promoters of the diffusion of a new technology. It may always remain a mystery what the decisive factors were that led to this. Among other things, the personal thirst for distinction on the part of certain individuals seems to have been of some considerable significance.

According to the Dornier firm, the significance of the new method of treatment lay not only in its medical value but also in the reduction in costs. The local health insurance funds accepted these two arguments, and concluded that the faster enough machines became available for the treatment of all stone patients, the greater this effect would be. The requisite number of machines should, therefore, be installed as soon as possible.

In the FRG the health insurance funds are expressly forbidden to offer medical treatment in their own right, and would not have been able to buy the machines themselves. They therefore persuaded the non-profit organisation KfH to purchase the required number of machines, and agreed, as in the case of the Munich prototype, to pay a correspondingly higher fee for each medical treatment until the states were willing or able to cover the investment costs. The KfH ordered first twelve and then, a year later, eight more machines to complete a national supply of lithotripters. The planning and choice of location were carried out in consultation with the states. Over three years, twenty machines were installed. At the end of 1986, when the last of these machines was in operation, the second generation of machines came onto the market.

Two things about this process are remarkable:

- All the experts must have known already in 1982 that other firms were working on the development of ESWL. In the FRG alone, university centres working with the firm of R. Wolf, as well as with the Dornier firm, had received a subsidy from the Federal Ministry of Research and Technology. While Dornier had at first been able to charge monopolistic prices, the machines produced by other firms would of necessity be cheaper in order to become competitive.
- Furthermore, every expert must have been aware that the development of a complete nationwide network of supply would become problematical as soon as the second generation of machines came on the market. The options were either to allow a free market and a considerable degree of over-capacity or to prevent the spread of the new machines by strictly applying a requirement for official approval of new installations on criteria of need.

Astonishingly enough, it was not until early in 1987 that these considerations were first uttered in public. The first refusal of states to approve the installation of further machines led briefly to criticism of the entry of the local sickness funds into the diffusion process and the speed with which they had initiated this intervention. However, since most of the states were prepared to finance further machines gradually, this discussion quickly died down, especially as the regulation concerning the need for official approval of large machines is by no means as clear as at first appears.

Thus, if a hospital in the FRG installs high-technology equipment without the approval of the relevant ministry of the individual state, the sickness funds are not allowed to take the running costs and costs of treatment into account in working out the per patient allowance for that hospital. However, in contrast to France, where the sickness funds always pay directly the person who performs the service, German hospitals may buy services from a third party and subsequently send the bill to the sickness fund. For example, if a hospital does not have its own CT scanner, it can send its patient to a radiologist in private practice or to another hospital to be examined. The hospital which refers 'its' patient pays the bill, but is subsequently reimbursed by the sickness fund. The hospital is free to choose the provider of the service. It does not then matter whether the CT scanner or lithotripter has been approved within the framework of the service planning.

Thus, a machine that is installed in a hospital without the approval of the ministry can be *operated* economically if the hospital has a sufficiently large number of patients referred to it from other hospitals. However, the *capital* costs have to be met in some other way, since the state does not supply the funds. Here the industry uses its imagination. It offers the hospitals the option of paying in instalments or leasing the machine, in either case making the regular payments out of treatment income; or agreeing service contracts at exaggerated rates; or making agreements to buy other products of the firm in preference to those of competitors.

Thus whereas in France it seems possible to limit definitively the diffusion of costly technology following decisions of the ministry, the FRG government seems uninterested in maintaining its policy of cost containment in medical care when it conflicts with the policy of supporting the medical equipment industry. Interestingly, then, it has now become clear that the degree of political control over diffusion is very different in the two countries despite the initial impression that the two countries have more or less equivalent regulatory systems.

In March 1990 there were some 38 ESWL machines operating in France, in the FRG about 72. Even taking into account that the spread of ESWL in France – apart from the three Dornier machines – did not start till 1986, as opposed to 1983 in the FRG, it is difficult to avoid the conclusion that effective state control exists in France but not in the FRG.

5.3 Towards a national plan for ESWL: Denmark and Sweden

(See also the country report for Denmark)

The autonomy of the regional health authorities is a prominent feature of

these Scandinavian countries. It stems from the incorporation of health care into the area of competence of the County Councils (which otherwise embraces the planning and upkeep of schools and roads). As elected political bodies they are responsible primarily to their voters. Health care uses up 80–85 per cent of their budget in Sweden, 65 per cent in Denmark. The counties have the right to raise taxes and finance most of their expenditure from them; only when their means do not suffice are state subsidies granted – mainly to compensate for regional disparities or to support special projects.

Only the framework of health care is laid down by the Ministry of Health, which can, for example, oblige counties which do not wish to offer certain health services to arrange access and financial reimbursement to patients wishing to make use of such services in other counties. Because planning ideas such as choosing locations of major hospital equipment affect the interests of counties they cannot be imposed and are merely advisory in nature. Even in the case of inter-regional services the National Board of Health and its committees of experts can only make recommendations. When counties cannot or do not wish to act independently, the planning is taken over by the Federation of County Councils in Sweden, and thus remains basically decentralised. In Denmark the National Board of Health coordinates planning together with the Ministry of Health.

This system, in which the central authorities can be asked for advice but which leaves decision-making to decentralised health authorities, is described in Denmark as a 'dialogue-planning' system.

At first the introduction of ESWL presented both countries with the same problem: investment costs were high, populations were small and if machines were to be used to full capacity only a few were needed. This implied centralisation of stone therapy, contrary to common health care policy. This problem was to some extent common to all EC countries, since in each country the number of urology departments was much greater than the number of ESWL machines needed, and consequently a number of 'have not' departments were created. Administrators who decided on economic grounds not to put a machine into each urology department had to assume that physicians would be willing to refer their patients to clinics with ESWL. They made this assumption in the belief that all doctors were convinced of the merits of the new treatment and that patients were fully informed about and attracted to it.

In thinly populated countries like Denmark and Sweden, centralisation also leads to problems in medical education and training. In these countries the problem of centralisation took on considerable significance – especially in Denmark, where a powerful research group considered that it could within a few years produce a cheaper Danish machine which every county could afford to buy. Despite the basically identical decision-making structures in the two countries, therefore, the diffusion followed quite different pathways. In Sweden, an active urologist quickly reached agreement with his county council, ratified by the Federation of County Councils and the support of the National Board of Health to purchase a single machine, subsequent diffusion being conditional on formal evaluation (see Section 4.4). In Denmark, the advice from the central advisory committee (no doubt heavily influenced by

the relevant research group) that purchase of ESWL machines should await the advent of the Danish machine (to be made by NITECH) corresponded to the interests of the county councils in that it enabled them to postpone expenditure. When the appearance of the Danish machine was delayed more and more, however, county councils began to take independent action, which the central authorities tried to coordinate.

The problem of centralisation for the counties which would not acquire a machine are abundantly illustrated in the country report from Denmark. Briefly, those counties' urology service could not reduce costs greatly because of the need to keep up their expertise in endourology for those patients who did not wish to travel and for whom lithotripsy might not be the best treatment anyway; at the same time the county would have had to find the funds to reimburse the county where the machine *was* located. This problem is common to all countries where the sole or major source of funds is local taxation and where the costs cannot be passed on to third parties like sickness funds. The main block to diffusion in such cases hinges on the financing arrangements between counties and regional health authorities.

In 1984 the Medical Technology Assessment Committee felt that it was too early to perform a technology assessment, especially as there was no ESWL machine in Denmark at the time. However, a proposal of the EEC COMAC/HSR to mount a conference on new kidney stone treatment methods was accepted with alacrity, since it promised a better basis of information for future decisions.

At the workshop, ESWL not surprisingly clearly emerged as the method of choice for most cases. But did this result solve Denmark's problem? How great was the gap between ESWL and the 'second choice' endourological methods? Was it still permissible to wait for the Danish machine, imposing endourological treatment with a clear conscience meanwhile? The questions remained as to how soon it was necessary to purchase the new technology and how much was it worth paying.

The Danish firm NITECH announced that its machine would be on the market in 1½ years at most. Meanwhile it became known that some counties were considering purchasing a second-generation machine anyway. Shortly thereafter, Siemens offered such a machine free for a year to Copenhagen's Bispebjerg Hospital and a private foundation offered to donate one to a hospital in Aalborg. The MTA Committee persuaded the National Board of Health to set up a group to develop a national plan for ESWL treatment, and to report within a year. Did this mean there would be a new spur to investment? Three machines at most were required for the Danish population; two investments had virtually been decided upon already, and successful completion of the NITECH machine was not yet in sight.

Three parties evidently determined the course of events in Denmark: the NITECH group (researchers and manufacturers), which was involved in the development of the Danish machine and had the firm support of the central authorities; those urologists who were not integrated into the NITECH development programme and therefore wanted a machine as soon as possible, no matter who made it; and the counties, each of which was waiting for the promised cheap machine from NITECH but was under increasing pressure

from the urologists not associated with this firm.

Finally, the central authorities, in view of the tense situation of Danish national economy and a rather fixed health budget, tried to influence the development, believing that over-investment in ESWL would undermine other fields of health care. They set up groups and released statements but were unable to influence developments. They were still playing for time when things had long since developed in a different direction. They saw how the willingness to wait for the NITECH machine was steadily declining, because the cheaper second-generation machines were coming onto the market. They were not prepared to change their opinions and forget about NITECH and so became increasingly vulnerable to accusations of putting protectionism above the medical needs of the population. But what effect would a change of standpoint have had at that time? Not only would the NITECH group been offended; the counties were now also counting on the promises that every urology department would have a machine at its disposal.

And this was ultimately the recommendation of the planning group, reporting at the end of 1987. In view of the availability of less expensive second-generation machines it considered that there was justification for providing all nine urology departments in Denmark with one, even though this meant creating considerable over-capacity. This 'plan' had hardly anything to do with the sensible use of scarce resources; nevertheless the Planning and Referral Council passed it on to the National Board of Health and sent it to all relevant authorities, including the political hospital committees at county level. The foreword stated that the report was to be regarded solely as a professional evaluation, not a guideline containing standards and norms.

At the beginning of 1988, the National Board of Health attempted once more to intervene. In a memorandum it stated that two machines were sufficient for the Danish population, and the installation of further machines should await evaluation of the method. This time the recommendation met with vehement opposition from the Association of County Councils, which pointed out that decision-making was in their hands, and the state authorities retreated from the planning discussion. At the beginning of 1990, four imported machines were in operation.

The author of the Danish country report characterises the politics of ESWL diffusion in Denmark as 'planned delay' and considers that the political authorities were able to delay the diffusion of a new piece of technology by three to five years at most before pressure from hospitals and doctors made purchase inevitable. The yardstick of 'delay' remains unclear. There is no great difference in time of diffusion compared with, for example, Belgium or France. The comparison of the diffusion of a technology in different countries is often used as an instrument to accelerate diffusion, and represents a narrow view of the question. The yardstick has to be looked for by considering the investment costs of ESWL in relation to the whole range of investment needs of the health system. In this sense, planned delay characterises a tactical position which embraces all the difficulties which administrative and political decision-makers experience in obtaining adequate information and in implementing political decisions.

Although the first machine was installed in Sweden considerably earlier (1985 as opposed to 1987), diffusion thereafter was delayed by the condition that a medical and economic evaluation must precede further installations. The first evaluation report at the beginning of 1987 gave data on the estimated further requirements (30–35 treatments per 100,000 inhabitants) and the running costs – the latter in order to assist calculation of fair prices for treatment of patients from other counties. The go-ahead for purchase of machines for two other counties (Göteborg and Stockholm) was given, but it was mid-1988 before the hospitals in the counties could agree on their location and install them.

The national referral list in Sweden seems to have made it impossible for counties to ignore central policy. The ESWL was struck from this list in 1988 because, by the end of 1987, the total of three authorised machines had satisfied official planning requirements. Three of the six health care regions had come out empty-handed from the distribution. In 1988, two of them installed one machine each. This was contrary to the recommendations of the Technology Assessment Institute in Linköping, which had estimated the requirements of the whole of Sweden at three machines.

The cases of Sweden and Denmark therefore show that the diffusion of ESWL could be held back only as long as the counties or regions could be forced to find consensus. The moment the consensus was disrupted by a financing offer or a donation or by discarding the collective obligation to the national referral list, nobody felt bound by earlier limitations and planning efforts.

5.4 Financial constraints in the public sector and private investments: the UK, Italy and Spain

(see also the country report for UK)

In the Scandinavian countries the organisation and financing of medical care is entirely public. In Italy, and to a much lesser extent in the UK, the private sector plays an important role – not simply as a service for private patients (only 12 per cent of the UK population is privately insured) but in providing services which (especially in Italy but also in the UK) are used by NHS patients and paid for out of public funds.

Another important difference is that in Scandinavia the funding comes primarily from regional taxation, whereas in the UK and Italy the NHS is financed exclusively from central national taxes. However, the influence of the central government remains limited: in Italy because of the strong position of the regions which is embodied in the constitution, in England because Regional Health Authorities have been given progressively more autonomy, subject only to rights of monitoring as to progress towards policies and priorities specified by the relevant Secretary of State.

Despite very similar population figures (approx 57 million) the two countries differ greatly in the number of ESWL machines in operation on 1 January 1990: Italy 69, UK 15. With a ratio of machines to population of 1:800,000, Italy is one of the four European countries with the largest relative number, while the UK's ratio of 1:3.8 million puts it below the level of requirement estimated by some EC countries as a guideline. In both countries,

provision in the NHS is similar: in January 1989, seven of the 48 machines in Italy and eight of the 15 in the UK were installed in public hospitals. (Note that in 1986 Wickham and his colleagues had estimated that five ESWL machines would be sufficient for the British NHS.[27]) Thus the large difference between the countries is accounted for in the private sector.

In neither country has the ministry of health developed guidelines on the desirable number of ESWL machines. The Italian health ministry, apart from recommending at the beginning of 1986 that diffusion of ESWL (of which there had been seven installations up to the end of 1985) be delayed until more information was available concerning treatment risks and costs, made no further effort to influence it. The DHSS in London contributed partial costs for two machines in England, one for renal stone treatment and one for gallstone treatment, both subject to formal evaluation, in both cases funded by the DHSS. Otherwise, it was left to the regions to work out collaborative projects involving referral of patients across regional boundaries.

In both countries the NHS has been subject for some years to financial restriction. In Italy the state budget deficit has led to a strategy of deliberately underestimating the funding of the sector[28], while in the UK it is the explicit political aim of the Conservative government to reduce state involvement in the NHS in favour of private economic initiatives. Cash limits are enforced, and UK health authorities have to compensate for any increased expenditure by making savings in other areas. The capital investment in British NHS hospitals, which was comparatively low in any case, has declined further since the end of the 1970s. Here, as in Italy, the diffusion process of ESWL in the NHS is determined by the skill of local authorities and urologists in procuring the requisite funds through their own efforts.

For only four of the eight NHS machines in the UK, the relevant regional health authority met in full both the capital and the running costs and thus made the treatment part of their regular medical service. In other authorities, the capital was raised either as a loan or through a donation. This still leaves the running costs to be covered, and this is done by charging the relevant health authority for the treatment of patients coming from outside the district in which the machine is operated. It is left to the discretion of the district health authorities where patients reside whether a private clinic's costs or the (usually lower) NHS costs in another district will be paid – and as this decision is constrained by a basically tight budget this may explain why comparatively few ESWL machines have been purchased by private clinics in the UK.

The Italian NHS was established only in 1978. Medical care is by no means a near-monopoly of public institutions or state employees. Under the terms of a 'convention', private services are integrated into the total system, and in 1987 about 40 per cent of the total expenditure by the NHS was allotted to the private sector – though only about 15 per cent of *hospital* care is allocated this way.[29] Some but by no means all of the private clinics equipped with ESWL were 'conventionalised' from the start, and thus integrated into the public health system. Yet to be discerned is the effect of a judgement of the Italian Constitutional Court, which ruled in October 1988 that the NHS can meet the treatment costs in a non-conventionalised private clinic if public institutions

cannot provide the required treatment, either because the relevant service is not available or because of a long waiting list. This judgement might be applied to ESWL, at least as long as PCN is not regarded as equivalent treatment and/or is not available. NHS hospitals must have feared this because many subsequently developed initiatives to purchase ESWL machines – although it is not known how many machines purchased since the beginning of 1989 have been installed in public institutions.

The parallel existence of public and private services leads to a dilemma for the public institutions. Since private investors become involved only in those sectors and locations where it seems profitable, public authorities are confronted with the question of the extent to which parallel investments are justified or whether the limited funds should not be better employed at points where the private sector shows little or no interest. Furthermore, high technology like ESWL is not only attractive to patients but is also seen as a criterion of quality by a majority of the population, far beyond the catchment area of the individual machine. If the public health service does not equip its clinics with appropriate technology it runs the risk of depreciating their reputation.

The alternatives for the NHS are either to concentrate on filling gaps in medical care or to become involved, at least partly, in competition. In the first case it runs the risk of allowing the private sector a virtual monopoly in certain areas of medical care; and if this is not to lead to a two-tier system in which it is only the privately insured or richer citizens that can receive such services, it has to come to agreements with the private sector that will ensure that NHS patients have access to those services. In the second case, overcapacity will become inevitable in the long run. This seems to have happened in some cities in Italy and Spain (see Table 4, Chapter 2).

In Spain, the first ESWL machine was installed at a renowned private clinic in Barcelona in November 1984. The clinic is run by a private bank foundation, which is active not only in the health sector but more generally in the introduction of modern technology in various sectors. When the machine had been in operation for about a year, the Catalan Health Service, a regional organisation for the provision of health care with a structure very much like that of the NHS, felt obliged to sign a treatment contract with the hospital. Shortly thereafter, three more machines were installed in private clinics, so that at the end of 1987 Barcelona, the capital of a region with about six million inhabitants, had four machines available to private patients and those with social insurance. Throughout this period, doctors in the state clinics were urging the Catalan Health Service to purchase a machine, arguing that the money spent in fees for individual services in the private sector could be saved through their own investment and that the investment costs would have been covered long ago by the shortening of the patients' time in hospital. A report commissioned then by the Catalan Health Service concluded that Catalonia already had an adequate supply of machines with the four already installed, and that it would be more sensible to negotiate better terms with the private clinics. These recommendations were not taken up: in May 1988 the Catalan Health Service felt obliged to purchase a machine as well. A further machine, primarily for the treatment of gallstones, was purchased after that.

This example shows that private suppliers of services in the health sector react quickly to the technological developments that interest them (cf the reaction in Greece noted in Chapter 2). Speed of reaction is an essential factor in commercial success. Although health administrations are not necessarily slower to react, their task consists of guaranteeing medical care in the long term rather than engaging in an investment which may deny other areas much-needed funds. When the prestige of state doctors and hospitals is involved, however, competition may be forced on them – even though this stands in direct contradiction to any concept of medical care based on health policy.

6 TECHNOLOGY ASSESSMENT: MANY OPEN QUESTIONS, FEW STUDIES

Chaussy wrote in 1986: 'It is surprising that considering the number of stone removals no statistics have been compiled in the FRG either on a national or on a state level.'[3] Who, at that point, would have been interested in such statistics, and what use would they have been? While developments in the treatment of stones remained of interest only to urology departments, the numbers treated in a given population were of significance to no-one. With the arrival of ESWL, the number of expensive machines required became important.

What is really surprising is how little information was gathered *subsequently* either in Germany or in other countries, where there was no national interest in buying a German product and much interest in protecting the health care budget. The two Scandinavian countries perhaps apart, we still do not know how many stone patients are being subjected to open operation, whether these operations are necessary, or whether the considerable investment in ESWL equipment has brought about the desired improvement in medical care.

We can deduce from the available data in the FRG at least, that the number of stone treatments in urology departments which do not have ESWL has hardly decreased. Most of these departments use PCN, and seldom refer patients for ESWL. Centralisation of stone therapy to clinics with ESWL has therefore not taken place. Data on whether the development in other countries is similar is not available.

We do know from the country reports that as a rule, the number of treatments per patient in ESWL centres has definitely increased: where one operation previously sufficed, several ESWL sessions have been substituted, often with additional auxiliary operations. Whether several ESWL treatments represent a higher workload than a single open operation cannot be deduced from data on the number of treatments alone. There is however a distinct general impression in the country reports that stone treatment has become more expensive since the introduction of ESWL.

Not only the number of treatments but aso the number of patients treated seems to have increased considerably. Originally this was explained away as a backlog of patients whose condition had not been urgent enough for operation. This argument, never very convincing, can no longer hold water in any country. In some countries it is alleged that ESWL is being used preventively, that is to remove stones smaller than 0.5 cm in diameter and producing no symptoms, although a Consensus Conference in 1988 did not recommend it as universal practice.[30] Since the natural history of untreated small stones is unknown, we cannot say whether an intervention is medically advisable or harmful.

What is required is not only statistical surveys of the pattern of treatment and its cost since the spread of ESWL and PCN, but clinical epidemiological investigations of the quality of treatment. Such projects are difficult to realise: the article appearing[31] in March 1986 in the *British Medical Journal*, like the country report from the UK later in this volume, describes the vain attempt

to mount a systematic cost/benefit comparison between ESWL and PCN before ESWL had spread further. Although proposals commissioned by the Department of Health recommended a randomised control trial as the ideal investigational tool, this was rejected out of hand by the advisory committee of expert urologists, on the grounds that such an RCT was 'unethical', given the (to them) well-established superiority of ESWL.

Since in fact the chances of stone patients having access to the two machines then in the UK, with the second-generation machines more than a year away, were slight, the only difference randomisation would have had was to equalise the chances of ESWL treatment across the country, rather than having it depend on accidents of place of residence or possession of private means. Nevertheless, the RCT was abandoned.

In analysing the objections to RCT, Challah and Mays[31] write 'A randomised clinical trial implies that there is no preference for one treatment over others....The emotional adherence to new technology is one of the most important obstacles to evaluation and becomes insurmountable once it has spread to the general public.' And again, an RCT profoundly affects the doctor/patient relationship: 'RCT requires the clinician to suspend judgement in advising or choosing treatment.' Further, an RCT certainly delays the purchase of more machines, since all will agree that it is legitimate to refuse to make large investments until the results are available.

Because the collection of reliable statistical data was not put in hand, we still have a paucity of information on the stone recurrence rate and the long-term effects of ESWL and PCN. Without doubt, a proper evaluation can hinder or even prevent the diffusion of a questionable new technology, but it can also support the case of those who argue that it is unquestionably superior. Urologists who were so sure of their ground should actually have allowed the trial to proceed.

But were they so sure? It is significant that Professor Wickham's letter[32] responding to Challah and Mays' article was in no doubt that the patient suffering from renal calculus did not require a controlled trial to tell the difference 'between having a 12-inch loin incision – one of the most painful in surgery – two weeks in hospital and six weeks' convalescence versus two or three days in hospital with a virtually painless procedure followed by immediate return to activity. In either case the stone is removed, but the difference is provided by extracorporeal shock wave lithotripsy.' But he compared the effectiveness of ESWL only with open operation, with no mention of endourological methods – despite his having been the man who introduced PCN to the UK and induced its rapid spread there!

In July 1988 Mays *et al.*[33] published their comparison of the treatment results of ESWL and PCN. This 'raised doubts about the superiority of ESWL over alternative techniques for treating renal calculi'. One letter to the editor in response to the article is worth quoting in some detail: 'The patients who underwent lithotripsy were referred from many centres throughout the UK. They represent a group whose selection was biased by the referring surgeon....It would be a pity if the enormous contribution made by the St Thomas' urologists to the care of patients with renal stones were submerged in a wealth of unreliable statistics from an uncontrolled trial.' So an RCT

would have been appropriate after all!

However, it is doubtful if the reaction of the urologists would have been different even then. The letter continues: 'The overwhelming experience of centres throughout the world is that, even with the first generation lithotripters, the morbidity after lithotripsy is significantly less than after percutaneous surgery.' Precisely this 'overwhelming experience' could have been given statistical support: almost all EC countries are equipped with more than enough ESWL machines. Nevertheless, a large proportion of stone patients in the FRG are still treated, outside the ESWL centres, endourologically (it is scarcely credible that this is not true outside the FRG, but it is the only country from which we have reliable data). The capital costs of the machines are considerable; their capacity would suffice for the treatment of all patients for whom it is suitable. Is it the unwillingness of most urologists to refer patients, or is it their secret conviction that endourological methods are in fact equivalent?

On 16 December 1988, the German edition of the *Medical Tribune* published an article discussing the results of the investigation by Mays *et al.*, together with a commentary by Chaussy.[34] The latter states 'We are provided here with further proof that, if one accepts a higher degree of invasiveness, higher rates of freedom from stones can be attained more quickly, particularly in patients with larger stone masses. On the other hand, for kidney stones up to 2 cm in diameter ESWL alone – a non-invasive treatment which by now does not even require anaesthesia – is superior to other methods. It was initially a mistake to discuss these different therapies as if they were in competition; it becomes clear with more experience that the best results for each patient can be attained by sensible combination and mutual complementation.' By contrast, a consultant urologist in Nordrhein-Westfalen declares 'After ESWL has helped remove the large, complicated stones the great majority of concrements can be removed today without difficulty endourologically.' Centralisation has evidently led to directly opposing views, depending on whether the urologist has an ESWL machine at his disposition or not.

As described in Section 4.3, the problem of such centralisation and the accompanying prestigious monopoly played a major part in the discussions in France and Belgium, above all in the purchase of the first machine. The solution by the Assistance Publique de Paris of installing the machine in one hospital but to be used by ten urology departments in turn was examined in a study published in 1989.[35] The authors postulated that the availability of the machine to each urologist once a fortnight would lead to that urologist's wishing to use it to full capacity, and therefore a tendency to extend the criteria on the basis of which he would choose that form of treatment. Examination of the patient records from Paris and Lyon supported the hypothesis, though not to the expected extent. Among other factors, the early date for which the records were compared, 1986/87, meant that the criteria had not yet been clearly defined; furthermore, there were only two machines in France at the time.

However, this study's methodology is still interesting today. In some countries (The Netherlands, France, FRG) there are mobile machines which

are available to the relevant urology departments only on certain days. The question again arises as to whether this form of organisation influences the selection of patients. However, at present the hypothesis opposite to the one above seems to obtain: clinics with a stationary machine, especially if bought out of public funds, tend to employ it to the full, largely in order to justify the investment, and because of the machine's large treatment capacity this may lead to a broader set of indications for ESWL treatment and a less homogeneous patient workload. The hypothesis has not been tested rigorously.

In summary, ESWL has led to a considerable restructuring of renal stone therapy over the past seven years, the value and costs of which have not been properly investigated.

What conclusions can be drawn from the diffusion processes described above? How can one judge the 'success' or 'failure' of the diffusion, or of the health policy which has or has not determined it?

When Wickham[32] wrote, in 1986, 'We [the UK] currently have the lowest rate of lithotripsy per head in the West apart from Egypt', the statement was false – four European countries had the same or lower treatment capacity as the UK – but the importance of the statement is the implied basis of his judgement: the NHS in the UK remains behind the times as long as its urology departments are not at least as well equipped as those in other countries. But by what criteria does one judge the appropriateness of *their* equipping standards?

Similar reference to the state of the art in other countries occurs in other country reports, for example when a government waived the condition of a planned evaluation prior to the installation of a machine on the grounds that there has been a 'positive experience' with the method in the FRG and USA. In every case this expresses, on the level of health care policy, helplessness in relation to the judgement of the quality of the new method. In this respect, the individual doctor has an easier time of it. Everything that saves his patient risks or stress is qualitatively better. However, judging the quality of an innovation in relation to the individual is at best a precondition within the framework of planned medical care in the light of a health policy.

The Danish rapporteur speaks of 'planned delay', meaning a delay until the point where the new technology becomes cheap enough to be afforded – so that the total health budget was not spent on over-investment in ESWL machines. When PCN is widely available in a country, there may be an acceptable trade-off between a cautious investment policy and a non-optimal but still reasonable quality of care, when economic zero growth in the health sector is a reality.

When the introduction of lithotripsy in the FRG was first planned it was stated that 21 machines would provide a good level of medical care for the whole population. When one sees that 6 years later, 72 machines are in operation one must conclude that the FRG is indeed a rich country which can afford such luxury. Yet at the same time there is talk of a state of emergency in medical care – the FRG is fourteenth on the list of countries with respect to the number of hospital nursing staff per head of population. The question inevitably arises, where do the priorities lie in health policy and how are they implemented? It would seem that no-one raises questions as to the necessity

and value of a new form of technology *in the general context of medical care*. The segregation of care into separate, specialist areas does not seem to leave room for comprehensive considerations.

Against this background, demands for funds from all medical areas become equally important if they are presented with sufficient vehemence. As long as there is no criterion of selection, the only legitimate thing to do is to fulfil all demands on an equal basis. Since this touches on the problem of scarce resources, the diffusion of technical innovations like ESWL is almost exclusively treated as a financing problem. Investment decisions are made from case to case, with either positive or negative results depending on what funds are available at the time. However, this purely economic view of health policy neglects so many conditions that ultimately it cannot even realise its minimal programme of cost containment. Since no national health budget is infinitely upwardly mobile, commitment of funds in one direction must lead to a shortage in another. In the current discussions of health policy, these redistribution processes remain conspicuous by their absence, as do the concomitant problems of the safeguarding of quality.

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INTRODUCTION OF LITHOTRIPSY FOR KIDNEY STONE TREATMENT IN DENMARK

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DANISH HEALTH CARE SERVICES

Some general characteristics

The Danish health care services are publicly organised and financed. There is a very small private element. The public service is characterised by a high degree of decentralisation.

Three political-administrative levels exist, all with a right to levy taxes. The *state level* (Parliament and ministries) creates a framework of laws and incentives for decentralised health services management. In addition, the Danish state owns and runs the largest hospital in Denmark: Rigshospitalet (Copenhagen University Hospital). The responsibility for hospital services, general practitioners and practising specialists is delegated to 16 regions or *counties*, typically having 250–300,000 inhabitants. Local health and social services are run by *communities* of various sizes. Domiciliary health care is a local responsibility. Copenhagen and Frederiksberg Communities have community as well as county obligations.

Communities and counties are responsible for planning health services. Hospital planning mechanisms are described later. In general, the current Danish health planning system is a so-called 'dialogue planning system' – the dialogue taking place between counties and communities on the one hand, and counties and the central authorities at state level on the other.

Denmark has about five million inhabitants, 14 counties and about 275 communities. County hospital services are planned for populations of 250,000–300,000, specialised regional hospital services for 1 million and national hospital services for five million people.

The basic health care services (all hospital services and primary health care services) are provided free of charge for all residents. There is consequently very little private health insurance. There are co-payment arrangements for dental services for adults and for drugs.

About 65 per cent of all expenditure in each county is on health, so that health expenditures weigh heavily at the county level, hospital expenditure being the dominant feature. The amount and quality of hospital services is regulated by the county's total hospital budget. Poorer counties receive redistributed money from the state in order to minimise regional inequalities.

Tracing a kidney stone patient through the system

What follows is the scenario for a Group I (fully insured) national health service patient, ie 98 per cent of all Danes. (Group II have a co-payment arrangement.) Group I members have a free choice of general practitioner within a limited geographic area. The doctor may, however, be changed only once a year.

Suppose a Group I member suffers an acute bout of pain due to a kidney stone at night. The on-call general practitioner is called (no charge) and the physician decides that the case is so serious that the patient must be admitted to hospital (by ambulance, no charge), where the patient is treated with pain killers. Next day a diagnostic programme confirms the diagnosis of kidney stone. A few days later the patient is treated. In a few small hospitals the standard treatment in 1990 would be by open surgery, but most patients would be treated by Extracorporeal Shock Wave Lithotripsy (ESWL) or transurethral or percutaneous stone removal – if necessary after being referred within the county from a smaller hospital to a larger hospital with a department of urology. A growing number of patients would cross the county border to receive ESWL at one of the four ESWL centres existing in Denmark at the end of 1990. The patients pay nothing for this treatment, but if they cross a county border there is reimbursement between the counties.

Other patients with less severe pain may consult their general practitioner, who will refer them to the nearest hospital for confirmation of the diagnosis. An X-ray examination takes place (no charge), as a result of which the general practitioner decides that the patient needs treatment. A referral slip is sent to the hospital and the patient is given an appointment (perhaps after some delay) at the county department of urology – unless the county has contracted with one of the four ESWL treatment centres in Denmark. The patient is re-examined after treatment in the out-patient clinic of the department of urology before being discharged. Treatment has been completed at no cost to the patient, except for 50 per cent of the cost of any pain-killing drugs administered.

The general practitioner may decide to refer the patient to a 'practising specialist'. These specialists practise under a contract negotiated with the Danish National Health Insurance. Very few full-time specialists practise in urology, but about half of the Danish consultants (head of department of urology) have negotiated a contract to practise 4–6 hours per week under Danish National Health Insurance, providing a small privatised element in the public system. In Denmark all surgical interventions for kidney stone takes place in hospitals, and ESWL is also a purely hospital matter.

A few patients need home care following hospital treatment. A visiting home nurse can be ordered by the hospital or the general practitioner and if a home help is needed local authorities supply such services, paid for by the wealthier but gratis for old people and the less well off.

Danish hospital law and hospital planning system

The Danish parliament has adopted a hospital law for the entire country.[1] Basically this law places the responsibility for hospital services on the 14 counties and on Copenhagen and Frederiksberg Communities. The law states that the county must offer free hospital services to its residents.

The Minister of Health issues guidelines for the planning of hospital services, including guidelines for the planning of specialised regional and national services above county level.[2]

Every county without regional and national services has to contract for

[1] References p67.

such services with other counties and the state hospital. The diagnosis of kidney stone or stone in the urinary tract is considered a county responsibility, but according to a 22 November 1983 circular,[3] complex stone formations and hyperparathyroidism should be considered a regional or national matter, to be treated in one of six larger hospitals located in Copenhagen, Aarhus, Odense and Aalborg. Likewise, the diagnosis of hydronephrosis and stones associated with decreased kidney function should be considered regional and national matters.

A county may choose not to run a particular service but to contract with another county to do so on a fee-per-patient basis. This is currently the case for many counties regarding ESWL.

Every county must plan its hospital services, over an immediate 4-year programme period and a 12-year perspective plan period. From 1970 to about 1986 it was compulsory to obtain central approval of the 4-year plans by the Ministry of Health – having first discussed the plan with the Danish National Board of Health, a central advisory board. The ministry and the Danish National Board of Health analysed the plans from all counties and published a trend analysis as a kind of feedback to counties. The county plans were accompanied by standardised information on beds, manpower, activity level, etc. We present later an analysis of stone-related diagnoses derived from these figures.

Since the introduction of 'dialogue planning', counties no longer have to obtain central approval of their plans, although they are still obliged to discuss them with the Danish National Board of Health. More thematically orientated plans are to be substituted for the more general plans.

The Planning and Referral Council and its Medical Technology Assessment Committee

The Danish National Board of Health has established two committees as part of its national and local advisory role.

The *Planning and Referral Council* was established in 1978. Its role is to advise the Danish National Board of Health in order to establish a broader counselling of counties and of central authorities concerning definition, demarcation, organisation, and location of regional and national functions in the Danish hospital system. The county and state owners of hospitals, the Danish National Board of Health, and the universities were members of this council. It has published reports on, for example, the organisation of cancer treatment in Denmark, heart surgery, transplantations, etc. Its recommendations have often been implemented at county level and above.

In 1983 this planning and referral council extended its activities to include formal Medical Technology Assessment, and set up a separate MTA committee, both to introduce MTA into Denmark in general and to assist the Planning and Referral Council in its activities. The Planning and Referral Council now also included representatives from the Danish Medical Research Council and the Danish Hospital Institute – thereby co-ordinating better with research.

The National Health Policy Committee

Up to September 1987 the Ministry of Health was part of the Ministry of the Interior, but since its establishment as a separate ministry the National Health Policy Committee has been created in an attempt to coordinate policy between ministries of finance, social affairs and the interior, and also between the county and community councils, local social and health committees, the negotiating committee of the National Health Insurance and the communities of Copenhagen and Frederiksberg. The Planning and Referral Council has now been disbanded, but the MTA Committee has continued.

NATIONAL STATISTICS OF FREQUENCY AND TREATMENT OF KIDNEY STONES

The 1987 health survey by interview of the adult population established the point prevalence (ie 'having stone disease now') at 0.2 per cent, corresponding to about 8000 adult Danes.

The National Hospital Patient Register has been used three times for the description and analyses of patients treated in Danish hospitals. Stones of all locations in the kidney and in the ureter were included. From three careful studies[4,5,6] for 1980–84, 1981–86 and 1989 it seems that 5500–6000 patients per year (ie 78–88 per year per 100,000) were admitted to Danish hospitals with a stone diagnosis, about 4000 having a stone for the first time. 1350 patients were operated on for stones in 1986, when ESWL was not available in Denmark. The distribution of the 1350 patients over the counties was uneven. In the eastern part of Denmark the number was 580 patients, in the western part 770 patients. Since these studies made it possible to describe in detail the number of treatments, type of treatments, distribution over department, hospital and county, planning figures to estimate the need for and distribution of ESWL technology were easily available.

Table 1 shows a clear change in treatment technology. Open surgery has fallen drastically, but still represented 19 per cent of renal stone treatment in 1989, two years after the introduction of ESWL.

Table 1:
'Surgical interventions' for kidney and ureter stones, 1980–89
All Denmark, in-patients only

	1980	1983	1984	1986	1989
Open surgery	79%	74	59	40	19%
Percutaneous stone removal	–	2%	11	31	15%
Transurethral stone removal	21%	25	30	29	35%
Lithotripsy	–	–	–	–	30%
Total (%)	100	100	100	100	99
(number)	1589	1567	1634	1350	1827

Source: Danish National Patient Register.

When percutaneous stone removal was introduced into Denmark in 1983, almost all treatments took place at specialised urology departments. In 1986 about half of all percutaneous stone removals occurred outside specialised departments and about 20 per cent of them in surgical departments with no specialty in urology. ESWL clearly substituted for the percutaneous treatment method. Table 1 refers to in-patients only and therefore underestimates the number of ESWL treatments in Denmark. One ESWL centre estimates that about 60 per cent of ESWL treatments are ambulatory.

EARLY REACTIONS IN DENMARK TO ESWL DEVELOPMENTS ABROAD

The first knowledge of the German ESWL work came to Denmark about 1978 when an engineer on the 'postgraduate stone courses' reported this development.[7] Danish urologists were therefore interested in the field before 1980.

The first German patient was treated with ESWL in 1980 but it was not until 1983 that the first production model lithotripters were installed in the FRG. In Denmark it seems that knowledge of ESWL technology from Germany was first picked up at one or two academic urology departments in university hospitals. The first experiences with ESWL on patients was published in *The Lancet* in December 1980. This article brought about the formation of a Danish stone-research group, comprising urologists at Herlev, Gentofte, and Rigshospitalet (all in the Copenhagen area) and researchers from the Technical University and the Institute of Biomedical Engineering.

A competing Danish development

Their object quickly became the development of a Danish machine. Holm – the Danish project leader – writes[8]:

> 'In 1965 I tried – together with a technician – to destroy a kidney stone by means of strong ultrasound waves. We succeeded, but when we put beef in front of the stone, the beef coagulated while the stone was unharmed. The fault at that time was that we did not use focused waves. Together with a group in 1979 I tried to disintegrate stones of the ureter by means of shock waves conducted through a flexible ultrasound wire. However, these experiments did not lead to apparatus for clinical application.'

The early decision to develop a Danish machine, cheaper and easier to handle, was doubtless taken because one of the academic centres already had a long research tradition in the development of ultrasound machines. Other academic centres at that time were waiting for further publications on the experience with ESWL. The political-administrative authorities were not involved at this early stage, there being no mechanism for alerting them to the existence of emerging technologies. The mass media were likewise unaware of the new

technology, and the foreign industrial interest had not yet been developed.

The Danish stone-research group received financial support from various national research councils and from private funds. Thus the early Danish development was a matter of research and development.

Then, in 1983, the first production model ESWL was produced in the FRG and studies on patients were published in international scientific journals. The Danish mass media now ran articles on the new treatment methods, and referred to a Danish ESWL project.

In the same year the first stone removals via the percutaneous route took place in Denmark. This invasive technique was more appealing to traditionally surgically orientated urologists than the non-invasive ESWL.

Promotion of the new German machine also began in 1983, with the Dornier representative informing the Danish Minister of the Interior about the machine and asking for a grant to place one in a leading Danish hospital. A trade lawyer suggested to the minister that a special tax could be applied to this case and indicated that an insurance company would be willing to donate one-third of the total price, thus proposing a private model for in a purely public hospital service. The minister asked the National Board of Health for an opinion, and the Board in turn asked the leader of the Danish research project for advice.

The response concluded: 'The Board cannot recommend that the machine be bought at present. Instead, money should be raised for the final development of the Danish ESWL machine. The case will be further considered by the Planning and Referral Council and its Medical Technology Assessment Committee.'

At least two academic urology centres not involved with the stone research project in Copenhagen approached the local authorities for funds to buy a German machine. At one of the centres a group was formed late in 1983 to investigate the market situation and economic questions; at the other centre, the application was refused on the grounds that the machine was too expensive (a message thereafter repeated several times).

First discussion in the MTA Committee

In 1984, the central MTA Committee discussed kidney stone treatment and ESWL. A urology adviser to the Danish National Board of Health – also a member of the stone research group – had produced a memorandum for the MTA Committee discussion which argued that percutaneous stone removal was a great step forward and was such a reasonable alternative to open operation that introduction of the Dornier machine in Denmark was not necessary, especially in view of the capital costs (about 16 million Danish crowns) and the need for centralisation of treatment, etc. Despite the secretariat's recommendation that the field of kidney stone treatment be assessed, the committee decided to await further developments before beginning assessment.

First editorial in a Danish medical journal

When the first accounts of treatment of Danish patients by percutaneous stone removal appeared in 1984 there was an accompanying editorial by a leading Danish urologist.[9] He characterised the percutaneous method as effective, gentle and kind to patients, and recommended adoption by departments of urology. 'In the future, however, a different technique will probably be preferred', and the principle of ESWL was described. 'The development has been explosive, and experience with the new technique is limited to very few centres. It is therefore not possible at present to predict what will be the final distribution between the new treatment methods or whether they can be combined. However, the new extracorporeal technique is so effective and easy on the patient that the rather large initial investment in equipment is justified. Despite the limited possibility of obtaining the machine, we ought now to be discussing how the technique is to be introduced into Denmark.

'One machine will probably be sufficient to treat all stone patients in the entire country; centralisation will be a new event for a patient group of this size. Economic considerations aside, it would probably be more realistic to establish two centres. This will require consideration at central level.' No-one took action on this editorial.

Hvidt writes[7] in a letter in 1990, 'I believe that Danish urologists did have the guts and the will to deal with the planning issue in 1983 and 1984, even though the then chairman of the Danish Society of Urology did not take up my invitation.' It was in the department where Hvidt works that the first (German) ESWL machine in Denmark was installed.

Danish media took little notice of ESWL for some time. The first attempt to place a Dornier machine in Denmark had failed and no other machines seemed to be on the market. Percutaneous stone removal was rapidly diffusing to urology departments and the stone research group continued its research, sometimes delayed by lack of research funds.

1986: a year of intense activity

Late in 1984 the Medical Research Committee of the EEC adopted a proposal from the Health Services Research Committee to organise an EEC workshop on medical technology assessment related to kidney stone treatment, particularly ESWL. The workshop took place in Copenhagen in March 1986.[10] The Danish National Board of Health advised the Minister of Health to await presentation of the European experiences with ESWL before taking action on ESWL issues.

The research group analysing Danish data examined all hospital admittances with a stone diagnosis (either in the kidney or the ureter) for the years 1980–84 and observed the rapid introduction of percutaneous stone removal as well as the significant number of open operations carried out by small hospitals.[4] Some centralisation of treatment was felt to be desirable.

The EEC workshop clearly demonstrated ESWL to be the preferred treatment method in most cases. Danish sceptics accepted ESWL technology after the workshop, during which it became clear that a second generation of

ESWL machines was about to develop and that capital costs would be much lower.

The Danish ESWL project was also presented at the workshop.[11] This project aimed at avoiding some of the weaker elements of the first generation machine. Locating the stone by ultrasound was felt to be cheaper and more convenient than x-ray. A company (NITECH) had been formed in 1985 to make the new machine and test-develop it in the hospitals associated with the stone research group. Support came from the Industrial Research and Development Fund. It was planned to put a production model on the market in 1988. These plans were publicised in newspapers and television programmes. Many then argued: why not wait until then to install ESWL in Danish hospitals? Professional respect for the project was then high among physicians, with few sceptics.

The MTA Committee

In the second half of 1986 the MTA committee considered stone treatment and ESWL on the basis of results at the EEC workshop. A number of counties/hospitals were considering purchase of an ESWL machine. Therefore, the MTA committee felt that the time had come to attempt national planning of ESWL technology. It recommended[12] that a planning group produce within a year a report proposing a national plan for ESWL, to be sent from the Danish National Board of Health to all counties and hospitals. Its arguments were based on avoiding over-investment in ESWL technology when the total health budget was shrinking. Further arguments were the known geographical need, the fact that Danish patients were being sent to the FRG for ESWL treatment, and the development of the Danish machine. The MTA Committee pointed out that international journals were now reporting the use of ESWL for treatment of gallstones.

The free Siemens offer

Late in 1986 the Siemens company offered its newly developed machine free of charge for one year to the Copenhagen community. A working group was established very early to examine what kind of machine was appropriate for the Copenhagen Community (Bispebjerg Hospital). The group was not involved in the development of a Danish ESWL machine. Since the machine fulfilled a number of criteria laid down by the working group,[13] and since some members of the working group felt that one could no longer wait for the further development of the Danish ESWL machine, the offer was accepted. In 1988 it was finally decided to buy the machine (at a favourable price), after having had it free for a year.

A number of counties have developed contracts with Copenhagen Community on the treatment of patients with stones. A price per patient has been fixed. Medical experience with the treatment series seems to agree with experience from other countries.

The charitable donation in Aalborg

The second, privately donated, machine (a Wolf Piezolith 2300) was installed in Aalborg in November 1988. The urologists at this hospital report that they were not involved in the decision to donate the ESWL machine to the hospital. Therefore, they demanded a one-year preparatory period, since the treatment method was new to them, as was the market for machines. Actually, because of delayed decision processes, a delay of two years took place until a functioning machine was in place.

At the time that the Planning and Referral Council accepted its MTA Committee's recommendation to establish a group to draft a national ESWL plan, it was announced that a private foundation was about to donate a Dornier machine to a large hospital in Aalborg. Newspapers in western Denmark soon began to ask whether it was rational to place the ESWL machine there instead of in Aarhus, a university city with a medical faculty and with regional hospital obligations. Both politicians and urologists from Aarhus stated that this county – whatever happened in Aalborg – would buy its own machine, as they could not consider sending their patients up north and paying for them. As they expected income from referring counties when they provided the service the project would soon pay for itself. (Similar arguments are often used by all counties in their planning!)

Second editorial in a Danish medical journal

By late 1986, then, urologists had decided the time had come to get a machine, the public had become aware of ESWL through the mass media, and local politicians had become involved. Early in 1987, the Danish Medical Journal carried a second leading article[14] on modern stone treatment by a member of the stone research group.

> '... ESWL will soon be introduced in Denmark and reduce the need for endoscopic interventions in the upper parts of the urinary tract to perhaps 20–25 per cent of the present applications.... Some centralisation of kidney stone treatment is needed, but to more than two stone centres in Denmark, in view of Denmark's geography, the need for a spread of technologies for medical education, and the other urological functions of such a centre.'

ATTEMPTS AT NATIONAL PLANNING

The Planning and Referral Council's working group was established at the end of 1986. The group was asked:

- to study international developments as to kidney stone treatment, including new treatment methods and new machines and with particular interest the development of the Danish ESWL project;
- to advise the Danish National Board of Health and recommend on the future organisation of kidney stone treatment in the Danish hospital

system, in the short and long term;
– to include consideration of the treatment of gallstones;

and to report within a year. The Danish National Board of Health then informed all county councils that a national planning report would be produced. Some counties decided to wait for it. All Danish urology departments with regional responsibility participated in the work, and the Danish ESWL project was represented. The working group had a majority of urologists.

Hvidt feels[7] that 'the central authorities tackled this whole planning approach in a very strange way. Most urologists in the working group had contacts with the Danish NITECH project. In my opinion one should have involved the Danish Society of Urology on a broader basis.'

Report of the Planning and Referral Council's working group

The working group's 75-page report (late 1987)[15] concludes:

> 'ESWL treatment has so many advantages for patients – also compared with endoscopic methods – that it ought to be the method of first choice in most stone patients (kidney and ureter) and, therefore, soon ought to be introduced in Denmark. ESWL treatment should be introduced into specialised departments of urology which also use endoscopic methods. The working group is aware of the risk of overstocking with ESWL machines, but finds that the decreasing prices of machines and the lower running costs make such an organisation economically feasible as well.'

At that time there were nine urology departments in Denmark.

The report of the working group to the Planning and Referral Council was accompanied by a memorandum from the Danish National Board of Health, stating that from a capacity point of view only two or three machines were needed in Denmark, and only one in Copenhagen county/community.

The general economic policy which has evolved in recent years precludes the sending of service recommendations with heavy cost consequences from state authorities to decentralised authorities except when there is full agreement. The working group report was therefore sent to all relevant authorities with the caveat that it was to be considered solely a professional evaluation, not a guideline containing standards and norms. No decisions had been made on whether patient referral criteria might be recommended. The report also gave the impression that a tested production model of the Danish ESWL machine would soon be available. A factual status is presented in the report.

The report avoids discussion of the treatment of gallstones with ESWL, on the grounds that experience is too limited to date. Some newspapers commented 'patients suffer while committee talks'.

Meanwhile, practical preparations were being made to install and use an ESWL machine at two sites in Denmark. The Danish National Board of Health commented in its annual report for 1987 on the distortion of national

planning brought about by private donations, and emphasised the need for MTA.[16]

Consultation on the planning report

The Danish National Board of Health sent the report of the working group not only for information but with a request for comment from a number of interested parties.

The Danish Society of Urology agreed with the overall conclusions of the report. So did the Danish Society of Surgeons.

The report was also discussed by the political board of the Association of Danish County Councils. The board decided that the report should be sent to the county councils as a basis for the further planning. It was also decided that the question of the possible centralisation of ESWL treatment should be discussed in the National Health Policy Committee in connection with a general discussion of co-ordinating hospital planning and procedures for central recommendations to decentralised authorities.

Discussions in the National Health Policy Committee

Early in 1988 this committee asked the Danish National Board of Health for formal advice on the need for ESWL machines and their geographic siting. The Board recommended introducing ESWL treatment by first establishing two places where this treatment is offered.[17] An evaluation of whether this number should be increased should not take place earlier than two years thereafter. According to usual practice when dealing with regional/national specialities, one centre should be established in Aarhus and another in the Copenhagen area. Since all counties in eastern Denmark already have user contracts with the Rigshospitalet in Copenhagen, the eastern ESWL machine should be placed there. The Board also recommended that the establishment of ESWL treatment at these two centres should be followed by referral guidelines. It was mentioned that the Danish machine was expected to be ready for use in April 1988.

The Association of County Councils disagreed with the Board's recommendation.[18] It argued that each county would incur increased costs for treatment outside its boundaries without real compensating savings in its surgical departments. The Association recommended a larger number of ESWL centres. Other comments were provided by the Copenhagen Community, which had not yet decided whether they would buy the Siemens machine despite having had it free of charge for nine months; after expressing criticism of the Danish ESWL project they argued that four or five ESWL centres in Denmark seemed more reasonable than two. The National Board of Health defended its original view.[19]

The Minister of Health opened the discussion with a discussion of how to avoid inappropriate dispersal of medical specialties. The representatives of decentralised authorities maintained that the Committee had not been established for the purpose of increasing central guidance when competence for decision was established at the county level.

The Minister of Finance underlined the need for coordinating activities in order to keep costs down.[20] The chairman of the Association of County Councils agreed, but maintained that the state should not embark on detailed steering, when the counties respected negotiated economic frames for their total activity. Politicians representing decentralised authorities echoed this point of view: central steering was inappropriate in this case as the economics were too small-scale.[21]

The Minister of Health proposed four or five machines as an agreed total for Denmark. The role of private donations was also discussed. No definite conclusions were reached, but it was agreed that the Health Policy Committee was empowered to discuss cases where national coordination was needed and justified.[22] As of 1 February 1989 no further attempt has been made to establish a coordinating national plan for ESWL; decisions are left to the usual Danish health policy structures.

In December 1988 the Minister of Health decided to establish a working group to look at the dispersion versus concentration of specialty functions in hospitals.[23] The ESWL case has to some extent matured this decision. From the ministerial point of view the ESWL case was considered a test case.

STATUS OF ESWL TREATMENT IN DENMARK (OCTOBER 1990)

Four operational commercial machines

By October 1990 there were six ESWL machines in Denmark, five of them foreign. A new Danish NITECH model is being tested clinically. One of the foreign machines is used solely for experimental gallstone treatment. On the basis of 1989 national statistics one can estimate that about 50 per cent of Danish stone patients are treated with ESWL.

The Danish ESWL machine

The first patients were treated with the Danish machine in 1987. The agreement was that the hospitals involved in the development in the Copenhagen area should test the machine in 1988 and then use it routinely. It was further expected that one machine at the Rigshospitalet and one machine in Copenhagen county (Herlev) together with the machine in Copenhagen community would fully satisfy the need for stone treatments in eastern Denmark.

A test of the Danish machine in 1988 showed that improvements were needed before it went into production. Only one machine in eastern Denmark was therefore in operation. This machine treated patients from most parts of Denmark, although most were from greater Copenhagen.

Waiting for the Danish machine somehow paralysed the development. For example, consider the university department of urology in Aarhus with a

regional service obligation. The department had options with the Danish ESWL firm and should conduct scientific development work in the field. They finally lost confidence in progress with the Danish machine and bought a Siemens Lithostar, installed in September 1989.

However, new developments with respect to the Danish NITECH machine have taken place in late 1990. Since the Spring of 1990 a completely redesigned model has been produced and has been under clinical evaluation at the two university departments that have been involved in the project. The machine is based for about three weeks at one department for patient treatment and thereafter moved to the other. It is claimed to be functioning well, and seems ready for production as a series model. Leading urologists in Denmark feel, however, that the Danish market is close to saturation.

Regional planning considerations

During the autumn of 1988, a planning group covering a population of about 1–1.5 million inhabitants was established (relevant counties Fyn, Ribe, Sønderjylland, Ringkobing, Viborg, Vejle). The group was to review experience with ESWL treatment of kidney stones and gallstones and recommend an appropriate machine as well as the economics of various solutions. The group was also to make concrete proposals as to how 2–6 counties could use a single mobile machine. The initiator of this planning was a former professor of health economics who was also a member of the national MTA committee.

Five of the six counties decided to buy a Wolf Piezolith machine and develop it as a mobile machine to be transported between the hospitals according to a scheduled plan of need. A contract running from February 1990 to December 1992 regulates the arrangements.[24] The counties own and run the machine cooperatively. Agreements have been developed throughout Denmark between the ESWL centres and the user counties and price have been negotiated.

FURTHER DEBATE ON ESWL

Amongst doctors, lay people and politicians, and in the mass media there is no doubt: ESWL is the method of first choice. The debate on kidney stone treatment methods and ESWL technology has heightened awareness of economic, geographic, education and export factors in introducing medical technology.

The debate on ESWL is sometimes cited in the political debate in Denmark as proof of the inability of central authorities to influence practical health policy, and of the delay brought about by central authorities in acquiring appropriate patient care across the country. Some also consider that the case did not warrant central interest, not even worth a dialogue. Central authorities are accused of protecting a particular Danish group and a product development which had no chance on the market.

Others consider that the case was handled properly, although central authorities lack the necessary influence on new technology. Planned technology

delay allowed for a growing national awareness of this new technology. A dialogue was opened. National studies of patient statistics revealed that some patients were treated by old-fashioned methods and that the treatment organisation in general should be developed. Danish industry was given a chance to develop a new product. It was hinted that purchase of too many machines threatened the health economy and priorities.

No consensus on the case exists late in 1990. The end of the story has yet to be observed.

SOME KEY ISSUES AND CONCLUSIONS

Some key issues are shown below; more could be brought out.

1. The message that new technology has appeared on the international scene seems to spread rather quickly, being first recognised at academic medical departments.
2. The general economic situation precludes rapid acceptance and diffusion.
3. The existence of specific conditions (urology department with a research tradition and experience with other imaging modalities than X-rays) leads to the formation of an important axis between some leading urology and technical centres. The new technology message from abroad is transformed/redefined: develop a cheaper and more flexible Danish machine based on ultrasound.
4. Early attempts to create a new (and private) model for ESWL treatment fail when considered in relation to the public Danish hospital system. There is little willingness to accept the new models beside the existing system.
5. Competition between regional urological centres creates different attitudes and reactions. Some centres want their own foreign machine, others wait for a Danish one. As for planning, there is little communication between the regional centres.
6. Traditional treatment in urology being based on surgery meant that some urologists disregarded ESWL at first, adopting a modified surgical technique (percutaneous stone removal).
7. Formal regulatory and advisory mechanisms – central advisory bodies and decentralised planning mechanisms – have failed to move the country towards a national plan for ESWL at the right time. However, a number of regional treatment agreements have now been signed, including an arrangement in which five counties covering a population of about 1.5 million cooperate in the use of one mobile machine.
8. A formal committee for medical technology assessment working in relation to central advisory bodies and decision makers has played an active role in the discussions.
9. The National Hospital Patient Register has been very useful in the planning process.
10. The concept of *planned technology delay* may become a real planning tool, if it is considered appropriate to delay foreign technology for economic, industrial, or patient treatment reasons. It was used by the central authorities in this case in order:

- to avoid over-investment at a time when the total health budget was under strain;
- to try to develop a national plan for ESWL;
- to promote the development of a Danish machine.

However, planned technology delay seems to have a maximal time limit of 3–5 years in the Danish, decentralised hospital system. Sooner or later competition between regional centres creates a breakthrough.

11. From a patient's point of view, optimal treatment can be delayed by a public hospital system, but only for a few years.

12. The initial confidence among physicians, administrative, and political decision makers about the development of a Danish ESWL machine ebbed when timescales lengthened a number of times. Insufficient financial support explains some of the delay. New enthusiasm for a redesigned Danish model currently seems to exist at the Danish firm and amongst some Danish urologists.

13. The discussion in Denmark about the ESWL case has heightened awareness of organisational models which satisfy providers, consumers and economic considerations.

14. Contracts between counties do regulate the spread of ESWL to some extent. The market is almost saturated in Denmark.

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DEVELOPMENT OF EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY IN FRANCE

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THE ARRIVAL OF LITHOTRIPSY IN FRANCE

The first lithotripter at the Assistance Publique de Paris

When extracorporeal shock wave lithotripsy (ESWL) was introduced by the firm of Dornier in Germany, a urologist in Paris and one in Lyon urged their respective hospital managements to purchase Dornier machines.

In a 1988 article[1] we described how the first machine went into operation in the hospitals of the Assistance Publique-Hôpitaux de Paris (AP-HP) in November 1984, two and a half years after the first Parisian urologist had expressed interest in the technique. We emphasised the role of the AP-HP administration, which had purchased a lithotripter on the sole basis of the initial results published by the Munich team that had developed the technique. We related how urologists, radiologists and anaesthesiologists had been instrumental in convincing the AP-HP to create a single ESWL centre to be used in common by all the hospitals of the AP-HP with each of the ten urology departments having exclusive use of the centre one day every second week and with a urologist coordinating its activity.

Three factors explain the rapidity of the lithotripter's introduction:

- there was agreement on the part of all those immediately concerned: physicians, administrators and the City of Paris, which financed 50 per cent of the initial investment;
- the AP-HP, supplying 5.6 per cent of total French hospital capacity, enjoys a fair degree of independence *vis-à-vis* the Health Ministry[2]
- lithotripters were at that time not yet on the 'certification of need' list.

Purchase of a Dornier machine by the 'Hospices Civils' in Lyon

The second Dornier lithotripter was installed in the urology department of the Hôpital Edouard Herriot in Lyon in May 1985. A research project conducted by D Poulin of the Management Research Centre of the Ecole Polytechnique, under the direction of G de Pouvourville, compared the decision-making processes that led to the diffusion of lithotripsy in Paris and in Lyon.[3]

In Lyon, as in Paris, a urologist had advised hospital authorities early in 1982 of the impending arrival on the market of the Dornier machine. In spite of the opposition of his hospital management, the urologist campaigned for the introduction of the technique. His two arguments were, first,

[1] References p78.

patient need and second, the existence of an INSERM (National Institute for Health and Medical Research) project, under his direction, for the development of a French ESWL machine ('Technomed').

By April 1983 he had convinced his local hospital management to request a subsidy from the Health Ministry for the purchase of a Dornier machine. The ministry refused, on the basis of a report comparing the techniques of ESWL and percutaneous surgery and also because it was actively supporting the development of a competing lithotripter by the French firm EDAP in Paris.

In Spring 1984, the urologist from Lyon finally obtained from the Rhône-Alpes Regional Council a subsidy of 3 million FF for the purchase of a Dornier machine. Meanwhile, lithotripters had been placed on the ministerial 'certificate of need' list. The necessary purchase authorisation was obtained, but only with difficulty, because the comparable French machine was being developed. This was the last authorised purchase of a Dornier machine in France. Later, however, a third Dornier lithotripter was installed in a private hospital in Marseille, initially without authorisation.

D Poulin[3] compared the desiderata of urologists in Lyon and Paris, all of whom wanted shared use of the machine. However, the Lyon hospital management decided that the lithotripter should be installed in the department of the urologist who had been promoting the technique, and that he should perform ESWL for the patients of the other local urologist; in addition, urologists from the Grenoble Regional Hospital Centre were to have access to this lithotripter for their patients.

Negotiations with Dornier, who at that time had no competitors, were just as difficult in Lyon as they had been in Paris. The purchase contract was finally signed in January 1985 and the machine was installed in April of that year.

THE DEVELOPMENT OF FRENCH LITHOTRIPTERS

The Dornier monopoly

At first, Dornier enjoyed a monopoly position in France that made contract negotiations very difficult for French hospital managements: fixed prices quoted in DM, high prices for electrodes, expensive maintenance agreements, and so on. After 1985, with the development of French machines, this situation changed.

Furthermore, with the obligation to obtain a purchase authorisation from the Health Ministry came the same protectionist reaction that had arisen with CT scanners several years earlier: because of centralised planning of hospital equipment in France the purchase of foreign-made equipment was deferred in favour of French equipment that was under development and that was expected to be less expensive. It is in this context, and probably in favour of the public rather than the private sector, that the hospital in Marseille had been refused purchase authorisation.

The development of French lithotripters was, however, not without problems. As noted, two competing projects were being developed nearly simultaneously[3,4] – the EDAP project in Paris and the Technomed project in Lyon.

The EDAP lithotripter

EDAP, a company specialised in ultrasound technology, began developing a lithotripter in 1983. Stimulated by a Parisian urologist, the company developed a machine whose operating principle is different from that used by Dornier: ultrasonic waves rather than X-rays are used to locate calculi, and piezo-electric transducers generate the shock waves. Since this generator system makes it unnecessary to immerse the patient it was expected to be far less expensive in operation.

The Health Ministry immediately gave its support to this project, as did ANVAR, the French agency responsible for the evaluation of biomedical research.

In September 1985 a prototype was installed at the Hôpital Tenon (an AP-HP hospital) where the urologist in question practised. Because only two of the first nine patients were treated successfully, the AP-HP refused to finance the investment and the prototype was moved to a private non-profit hospital which participates in the national health service, although the machine remained under the scientific direction of the same physician. The result was that a private non-profit hospital helped to finance the final stages of development leading to ministerial approval.

In January 1986 a second prototype was installed in the same private hospital and the EDAP lithotripter (EDAP LT 01) obtained pre-market approval. In all, five EDAP LT 01s were authorised and installed in 1986, and nine in 1987. As of 6 January 1988, 58 of these machines had been sold world-wide, including 15 in France.

The Technomed lithotripter

The machine developed by Technomed, like the EDAP machine, obviated the need for a 'bathtub' (the generating system rather than the patient moves), and its locating system utilises ultrasound rather than X-radiation. Whereas the Health Ministry favoured the EDAP project, the Ministry of Research and Industry gave financial support to Technomed International, a company specifically created to develop a lithotripter using the INSERM invention.

The first clinical experiments were run in 1985 and the first Technomed machine, the Sonolith 2000, obtained pre-market approval in 1986, like the EDAP machine. Two Technomed machines were installed in 1986, one in Lyon and one in Poitiers; in 1987 four were installed, two in Paris and two mobile units. As of 6 January 1988, there were nine Technomed Sonolith machines installed in France and 25 more in the rest of the world.

ESWL IN FRANCE IN 1988

Equipment

It is difficult to arrive at a precise estimate of the number of lithotripters in operation. Some are authorised and installed; others are installed on temporary basis awaiting approval, either for renal stones or gallstones; and some are

still in a developmental phase.

Figure 1 shows the number of ESWL machines authorised and installed between 1984 and 1988, 28 in all: three Dornier, 17 EDAP and eight Technomed. Sixteen were installed in public hospitals, two in private non-profit hospitals and ten in private for-profit hospitals.

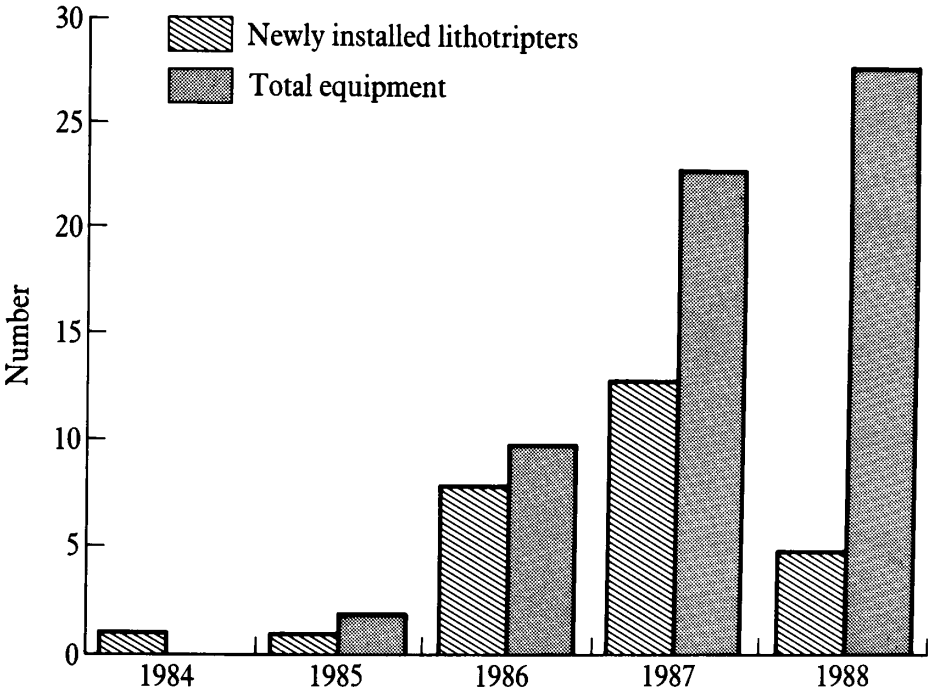

Figure 1
Diffusion of lithotripters in France, 1984–88

Figure 2 shows that some regions (Alsace, Lorraine, Burgundy, Central, and Limousin) remain under-equipped or altogether without ESWL machines.

Some sites remained problematic. The Strasbourg public hospital management decided to purchase a Siemens machine, which was not authorised by the Health Ministry. Grenoble and Saint-Denis de la Réunion had authorisations but had not purchased machines. Three new authorisations, for the public hospitals of Reims, Nancy and Tours, were under discussion for 1989.

In 1988, about 100 private non-profit hospitals with 133 urologists decided to use mobile Technomed machines, moving them from one location to another as the need arose. The Health Ministry at first refused to authorise mobile units but was later overruled by an administrative court. A decree dated 7 November 1988 authorised the use of four mobile ESWL units.

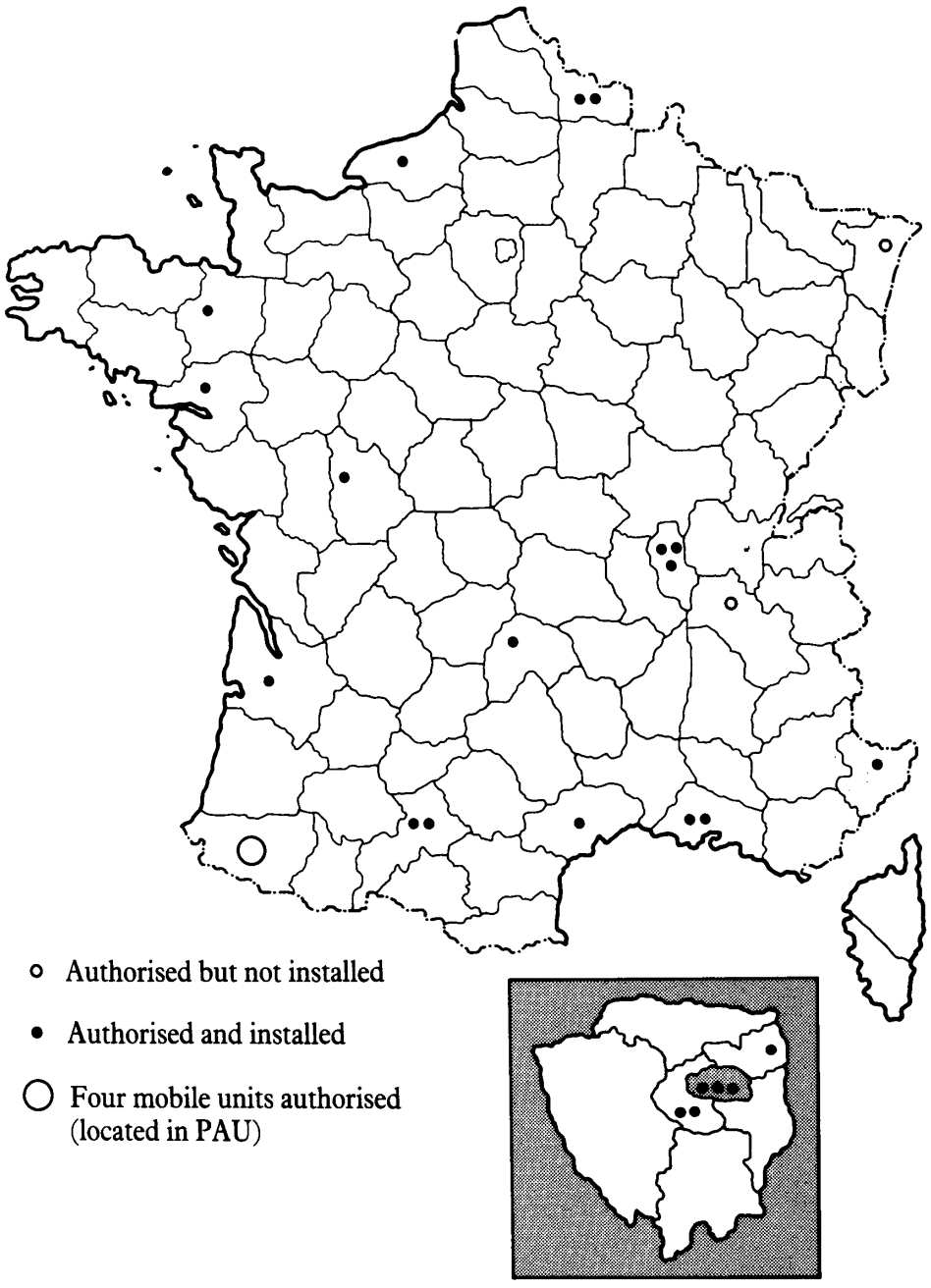

Figure 2
Lithotripter authorisations, 1988

The role of the authorities

Certification of need, equipment/population ratios and pre-market approval are the means by which the authorities control the number of ESWL machines, their type and installation site.

Since April 1984, ESWL lithotripters have been on the list of medical equipment requiring certification of need. This regulation applies to both public and private sectors.

In January 1985 lithotripters were added to the list of medical equipment requiring pre-market approval to be eligible for purchase by public sector hospitals.

The first equipment/population ratio was set (10 June 1986) at one machine per 2.8 million inhabitants and referred only to the treatment of renal stones. A second decree issued two years later established the equipment/population ratio at one machine per 1.5–2.8 million, without mention of the type of calculus – thereby tacitly including gallstones.

In 1988, most of the machines in use were installed in public hospitals and were of French manufacture.

Public and private hospitals maintain different fee structures. Public hospitals have a global budget and do not charge separately for each ESWL treatment. The fee that is reimbursed by the National Health Insurance to patients of private sector hospitals for ESWL was set at the level of the reimbursement for surgery, so that financial considerations would not influence the choice of therapy. In fact, the amount reimbursed has no relationship to the real cost of the treatment, which may vary greatly from one installation to another.

Evaluation and diffusion of the technology

A number of ESWL assessments have been published in France.[6,7,8,9,10] Results obtained in this country are similar to those elsewhere.

C Viens-Bitker *et al.*[10] studied the development of the use of the Dornier lithotripter in Paris between 1984 and 1986 and showed a change over this period: ever smaller calculi were being treated by ESWL and the use of the technique was extended to the treatment of ureteral stones. Thus study also compared the utilisation of a Dornier machine in Paris and one in Lyon and concluded that after a period of two years, indications for treatment became stable; furthermore, they had become the same in the two cities even though the initial therapeutic strategies had been very different.

J Ferror *et al.*[9] compared the results of treatment of 1000 patients on a mobile Sonolith 2000 unit with that of 500 patients on the same machine at a fixed site and concluded that the results were similar. However, a mobile unit is used on average only three days per year per site. It is obvious that with so little practice, urologists can hardly attain a satisfactory level of competence. In fact it is the technician attached to the mobile unit, rather than the non-mobile urologist, who performs the therapeutic act under the responsibility and supervision of a urologist.

Use of ESWL for gallstones in France

The first clinical experiments using ESWL for gallstones took place in the FRG. Since 1987 the technique has been applied in France, using French ESWL machines.[11,12]

The pre-market approval procedures for gallstone lithotripsy is (January 1989) in process at eight selected locations (Table 1). Several other clinical assessments are in progress, two of them in Paris: a group of AP-HP gastroenterologists at the Hôpital Saint-Louis (piezo-electric LT 01) and a group of surgeons[11] at the Hôpital Cochin (electro-hydraulic Sonolith 3000).

Table 1
Locations selected (February 1988) for evaluating equipment for gallstone lithotripsy (pre-market approval procedure)

Sonolith 3000 (Technomed)	LT 01 (EDAP)
Lyon: Hôpital Edouard Herriot et Clinique Saint-Louis	Bordeaux: CHR
Paris: Hôpital Cochin (AP-HP)	Nice: CHU
CMC Peupliers	Paris: CMC Porte de Choisy
Hôpital Saint-Joseph	Suresnes: CMC Foch

CHR, Centre Hospitalier Régional; CHU, Centre Hospitalo-Universitaire; CMC, Centre Médico-Chirurgical.

GENERAL OBSERVATIONS

Several points remain unclear concerning the use of ESWL:
- the place of lithotripsy in the treatment of biliary stones, which may be treated by various procedures including laparoscopy and percutaneous stone removal
- the number of machines required
- by whom the machines are to be used: urologists, gastroenterologists or both. This depends not only on the technical characteristics of the machines, but also on the availability of those currently in use.

A survey by the Health Ministry examined the utilisation rates of the 23 ESWL machines in operation in April 1988 in order to assess the validity of prevailing the equipment/population ratio. The findings were:
- An average of 10 months elapsed between the authorisation and the installation of an ESWL machine in the public sector, as against 1.5 months in the private sector.
- In 15 of the 23 cases (11/17 public, 4/6 private) there were nearby hospitals whose patients were also treated, often with a written agreement to that effect.
- In the public sector a machine was utilised on average 36 hours per week

and treated 65 patients per month; in the private sector, a machine was used on average 45 hours per week and treated 91 patients per month.
- 18 of the 23 machines were used for treatment of both urinary and biliary stones.

The development of ESWL is a good example of the influence exerted by central authorities, the role of physicians and the importance of national manufacture in the diffusion of a new health care technology in France.

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DIFFUSION OF LITHOTRIPSY INTO PRACTICE IN THE UNITED KINGDOM, 1983–89

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Note: *The current government Department of Health (DoH) in England was until the summer of 1988 part of the Department of Health and Social Security (DHSS). As far as the present subject is concerned the functions of the two differently designated Departments are identical; but they are correctly referred to in what follows according to the date of the decision or action. The DHSS, or currently DoH, implements ministerial policy for England only. Separate health departments develop policies for Wales, Scotland and Northern Ireland; these are usually, but not always, closely similar to those for England.*

DETAILED HISTORY OF EVENTS

The first lithotripter in the United Kingdom, a Dornier HM3, was installed in the Welbeck Clinic, an annexe of the private Devonshire Clinic in London, in 1983. This development came about on the initiative of Professor John Wickham of the Institute of Urology, University of London, an internationally known specialist in the treatment of kidney stone disease. Wickham had observed the early animal experiments with extracorporeal shock wave lithotripsy (ESWL) in West Germany performed by Professor Eisenberger in Munich and was convinced that ESWL was an essential tool for any urologist professing expertise in the management of renal calculi. As early as 1979, he had attempted to interest the Department of Health and Social Security (DHSS) in funding the purchase of machines, but civil servants were sceptical about the wisdom of investing in an experimental technology. A few years later, Wickham succeeded in persuading the private St Martin's Hospital Group that ESWL would be a highly marketable and attractive high-technology alternative to surgery, and the Group purchased the first UK lithotripter for use on private patients under his supervision.

While Wickham was negotiating with St Martin's, other urologists were also beginning to take an interest in ESWL. After seeing the HM3 in action in Germany Mr K Shuttleworth, a consultant urologist at St Thomas' Hospital, wrote to Ministers urging the acquisition of a machine for the National Health Service (NHS).

After visits to the German lithotripter centres in Munich and Stuttgart medical, scientific and technical experts in the DHSS concluded, on the basis that the Dornier successfully fragmented stones as claimed and was reliable and well engineered, that the HM3 was suitable for purchase and clinical use in the NHS. Any remaining ministerial reluctance to commit central government money to such a project was overcome by the proposition from St Thomas' that the establishment of a lithotripter centre should be a joint enterprise between the British United Provident Association (BUPA, a

References p 95.

non-profit, private health insurance and hospital operator), the Special Trustees of St Thomas's Hospital and the DHSS.

The mutual benefits of public-private collaboration in health care was a strong policy theme of the Conservative government at the time and the St Thomas' lithotripter centre was opened by the Minister of Health in March 1985 with considerable publicity. The capital costs of purchasing the Dornier HM3 were met by BUPA, the installation costs by the Special Trustees of St Thomas', and the running costs for a pilot three-year period (subsequently extended) by direct funding from the DHSS. Evaluation of ESWL was made a condition of DHSS revenue support and a grant was made to the then Department of Community Medicine in the Medical School at St Thomas' Hospital for this purpose.[1] The first results were published in July 1988. The St Thomas' lithotripter featured soon afterwards in television commercials supporting a BUPA campaign to increase its number of subscribers.

In May 1985, the DHSS Supraregional Services Advisory Group received an application from the English Regional Health Authorities (RHAs) that ESWL be considered for designation as a supra-regional specialty eligible for direct funding from DHSS. In January 1986 it was announced that this had been refused and that RHAs wishing to make provision for lithotripsy services should do so from their existing budgets and subject to existing Regional priorities. This has remained the position of the Department of Health (DoH) ever since.

No further lithotripters were purchased in 1985–86. However, the diffusion of ESWL took off abruptly once second generation machines became available. From April 1987 until the end of the year, five Wolf Piezolith machines and one Siemens Lithostar were installed in hospitals in the UK, reflecting the wide acceptance of ESWL by British urologists. Four of these were in NHS teaching hospitals and two in the private sector in London (Tables 1 and 2).

Table 1
UK lithotripters by year of acquisition

Year	New machines	Public	Private
1983	1	0	1
1984	0	0	0
1985	1	1*	0
1986	0	0	0
1987	5	3	2
1988	4	3	1
1989 (to July)	3	1	2**
Total	14	8	6
(operational)	(13)		(5)

* Public-private collaboration with 25 per cent of utilisation of machine for private patients.

** Includes one machine in private patients' wing of an NHS hospital.

One of the four NHS machines, at Sheffield, was purchased directly by DHSS in November 1987 to enable clinical trials of gallstone ESWL to be undertaken. A machine was purchased by the Scottish Home and Health Department and installed in Edinburgh to serve Scotland.

Table 2
Lithotripters in the UK, July 1989

Hospital	Type of hospital	Type of machine	Date in operation	Patients per year	Renal/ ureteric	Biliary
St Thomas' London	1*	Dornier	Mar 85	1200	›98%	‹1%
St Paul's (Inst of Urology) London	1	Wolf**	Nov 87	300–400	Mainly	
Deaconess Edinburgh	1	Wolf	1987		Mainly	
London Clinic London	2	Wolf	Jun 87	400	Mainly	
London Bridge Hosp, London	2	Wolf	Apr 87	650 renal 70-80 biliary (2–3/week)	90%	10%
Royal Hallamshire Sheffield	1	Wolf	Aug 87 (renal, Apr 88)	100 renal 100 biliary	50%	50%
Withington Manchester	1	Siemens Lithostar	Jun 87 (biliary, Aug 89)	1700	100% till Aug 89	
Southmead Bristol	1	Siemens Lithostar	Apr 88 (biliary, Mar 89)	500	Vast majority	Few
Harley St Clinic, London	2	Siemens Lithostar	mid-1988			
General Infirmary, Leeds	1	Wolf	1988	800	Mainly	
Royal Infirmary Manchester	1/2†	EDAP	1989			
Priory Hosp, Birmingham	2	Technomed Sonolith	1989			
St Thomas' London	1	Stortz	1989	Planned treatments		
				1000	500	500

1, NHS teaching hospital; 2, private hospital.
* but in collaboration with BUPA (insurance association).
** Wolf = Piezolith 2300 in all cases. Dornier, Wolf and Siemens machines are German, EDAP and Technomed French and Stortz, Swiss. There are no British lithotripters.
† in private wing of NHS teaching hospital.

The running costs of the Sheffield machine are currently met jointly by the DoH and the local RHA, while DoH provides funds for the research costs of the biliary ESWL trials. As second-generation machines began to be taken up in the UK, the Procurement Division of DHSS published in *Health Equipment Information* No. 172 (August 1987) a short technical assessment of the range of machines which were then available, to assist potential purchasers. This HEI bulletin covered constructional features, anaesthesia requirements and contractual aspects of equipment purchase. The HEI bulletin noted that 'ESWL is now widely accepted as the preferred method of treating kidney stones and the technique is now being extending to the treatment of gallstones'. While the DHSS' approach thus appeared implicitly to support the diffusion of second generation machines into practice, there was no explicit requirement for RHAs to invest. No specific policy guidance was issued on ESWL by DHSS.

In 1988, a further three lithotripters came into use in the UK, two in NHS teaching hospitals and one in the private sector. Two of these machines were Siemens Lithostars, the development of which had lagged behind the Wolf Piezolith.

Both of the machines installed in NHS hospitals in 1988 were bought with charitable funds. The Bristol machine was purchased by a charitable trust endowed by a local businessman-philanthropist, and in Leeds the purchase cost was met one-third by the Trustees of Leeds General Infirmary, one-third by the Yorkshire RHA and one-third by public subscription. The Leeds centre is entirely self-financing on the revenue side, charging other health authorities on the basis of a price either per treatment or per course of treatments. The Bristol centre receives a block allocation from the South Western RHA to treat RHA residents and charges out-of-Region patients along lines similar to the Leeds centre. Lithotripsy is a designated Regional specialty in the South Western Region.

At the time of writing (July 1989), three further machines have entered the UK. St Thomas' Hospital is about to acquire a 'third-generation' Stortz lithotripter for preliminary technical and clinical assessment. Manchester Royal Infirmary has invested in an EDAP machine which has been installed in the private patients' wing at the hospital, and a private hospital in Birmingham has bought a Technomed Sonolith lithotripter.

In all, there are currently 13 machines operational in the UK: one first-generation Dornier HM3, six second-generation Wolf Piezolith, three second-generation Siemens Lithostar, one second-generation Technomed Sonolith, one second-generation EDAP, and a so-called third-generation Stortz machine (Table 2). The machines are concentrated in the southern half of England, particularly in central London, with a single machine in Scotland and none in Northern Ireland or Wales. The NHS machines are all located in teaching hospitals.

There has been substantial private sector investment in lithotripters, with five in independent private acute hospitals and one in the private patients' wing of a major NHS teaching hospital. At present, only two machines, at Sheffield and the London Bridge Hospital (both Wolf Piezoliths) are being used to treat appreciable numbers of cases of biliary tract stones. The main

activity of the UK centres lies in the treatment of renal stones. Observations made at a number of these centres suggest that the diffusion of machines has resulted in a marked increase in the overall rate of treatment of renal stones, since all the NHS centres have waiting lists and percutaneous surgery is also available at a wide range of urological centres.

The dominance of Wolf machines in the UK market, in contrast to most other European countries, appears to be due to the fact that Wolf was already well established in the health sector in the UK through a subsidiary with a long-standing reputation for the provision of surgical equipment, and because the Wolf machine was both cheap to install and used ultrasound rather than X-ray to visualise stones.

THE ROLE OF DIFFERENT FACTORS IN THE DIFFUSION PROCESS

The role of Central Government

There is no specific legislation governing the purchase and use of medical devices in the UK. The DoH devolves responsibility for decisions about new medical technologies to health authorities. In general, RHAs and District Health Authorities (DHAs) must fund new technologies from their main financial allocations.[2] Small sums of money are available from central government for demonstration projects, and Special Medical Development (SMD) grants are given to a selected range of services to facilitate their transition from research-based experiments to service provision (eg SMD grants have been made to a number of gene centres to develop the clinical application of DNA genetic probes).

A highly restricted range of services covering programmes of heart transplantation, liver transplantation, spinal injuries, etc are designated Supra-regional Services and funded directly at central government level. The DoH through its Research Management Division provides funds for evaluative studies of certain technologies (eg the randomised controlled trial of second-generation biliary ESWL at Sheffield[3] and the descriptive study[1] of first-generation ESWL at St Thomas', London). Money is also channelled through the Procurement Directorate of the DoH to support research and development in the domestic medical technology industry, equipment evaluations and 'pump-priming' to support particular product developments.

The main role of the DoH in relation to new medical devices is to provide information and, to a lesser extent, advice about the technical qualities, reliability, safety and costs of devices through the Supplies Technology Division of the Procurement Directorate. The Supplies Technology Division focuses on the non-clinical aspects of technologies while the Standing Medical Advisory Committee (SMAC) and its ad hoc sub-committees, in association with the medical divisions of the DoH, provide advice on clinical applications which is based on the balance of opinion among leading clinicians in each field. In this way the policy-makers in the DoH have ready access to medical advice. As a result the system tends to reinforce deference to the prevailing view in the medical profession.

In 1988 a Health Technology Assessment Group was established within the DoH under the auspices of the Chief Scientist and serviced by officials in the Research Management Division. The Group embodies a new positive commitment by the DoH to the early and timely assessment of kinds of medical technology which have significant revenue consequences and to the early investigation of a range of potentially important new clinical procedures and techniques. The role of the Group is to encourage the mounting of trials at an early stage before new techniques have diffused widely and before public and clinical popularity makes trials difficult to mount. It is too soon to know whether the Group's activities will significantly alter the policy of central government and the DoH towards high technology medicine.

Although there were no specific policy statements about the acquisition or use of ESWL, and ESWL was not designated a supraregional specialty receiving subsidy directly from DoH level, the advent of ESWL was clearly too important and too visible to be ignored. Hence, DoH invested directly in two centres: the St Thomas' first general Dornier machine for renal stones and the Sheffield, second-generation Wolf machine, primarily for gallstones. In both cases DoH's financial involvement occurred at an early stage in the clinical application of the technology, for a fixed period of time, and was associated with an evaluative study commissioned from one of its own health services research units.

However, at St Thomas' the original initiative came from the clinicians, whereas in Sheffield the initiative came from DoH, which was seeking the expertise to undertake an evaluation of biliary ESWL. In the context of biliary ESWL, it was possible to obtain clinical commitment to a randomised controlled trial (RCT) design since most gastroenterologists consider that the efficacy of biliary ESWL is far from certain. The DoH's current position is to encourage RHAs interested in biliary ESWL to await the results of the Sheffield RCT.

For renal ESWL, British urologists believed far more strongly in the superiority of ESWL over alternative techniques, no RCT has taken place and DoH has adopted a more responsive role. The DoH accepted clinicians' reluctance to undertake an RCT of ESWL vs. alternative treatment, against the advice of its health services researchers.[4] However, for renal ESWL, the DoH refused to fund directly more than one machine. Its cautious approach was conveyed to RHAs which refrained from buying their own Dornier machines in 1985 and 1986. The DoH advised a wait-and-see policy in the knowledge that a number of manufacturers were developing less cumbersome and less painful machines. At no stage, however, were RHAs positively prevented from buying Dorniers. Equally, when the second generation machines became available there was an upsurge in acquisitions, but without the need for an explicit policy of encouragement from DoH. There have been neither national plans for lithotripsy nor published projections of the numbers needed and their optimal siting. The DoH has thus been successful in pursuing a devolved policy which implicitly allows the enthusiasms of clinicians to be expressed, yet which places the onus for acquisition and use on RHAs, DHAs and individual NHS hospitals, operating within existing financial constraints, and which has committed central government to only a

relatively modest level of direct financial involvement in two ad hoc demonstration projects.

The private sector has made a substantial investment in lithotripters. Private operators have made extensive use of the information and advice available from the technical specialists in the DoH Supplies Technology Division. In addition, since 1979 ministers have been ideologically supportive of a flourishing private sector and were directly involved in ensuring the successful launch of the St Thomas' private–public collaboration. Health authorities are increasingly encouraged to send their patients for treatment in the private sector if a better service or one which is unavailable in the NHS can be obtained. This helped to create a climate in which private operators felt sufficiently confident to purchase such expensive devices.

The role of financial incentives

In the National Health Service

In a system of health care based on global budgeting at each level of administration and with salaried hospital doctors there are no direct financial incentives for hospitals or physicians to acquire expensive new medical technologies. Commentators have pointed to the generally slow pace and modest extent of technology diffusion in the UK NHS.[5] However, several recent developments in the financing of the NHS may have made the acquisition of lithotripters more attractive to hospitals.

Specialised services may now be funded by means of cross-charging arrangements between health authorities. Under cross-charging, revenue can be generated by providing services which attract patients from other areas. The favourable publicity given to lithotripsy, the degree of clinical support and charitable purchase of a few machines have enabled some NHS lithotripter centres to become partly or wholly self-financing through providing treatments or complete courses of treatment in return for pre-set fees. To date, 'sending' health authorities appear to be content to make special payment for ESWL treatment of their patients outside the district rather than surgical treatment locally provided and funded from mainline budgets.

As more and more types of treatment come to be covered by cross-charging arrangements, this liberality may change. The presence of a lithotripter is not only perceived by an NHS hospital as a potential source of revenue from other parts of the NHS but also as a means of attracting private patients and of thereby increasing revenue. Thus, the recent Manchester Royal Infirmary scheme to install a lithotripter in its private patients' wing was part of a hospital strategy to maximise private income.

The changes to the NHS proposed in 1989 in a Government White Paper *Working for Patients*, and now embodied in an Act of Parliament (June 1990), which envisages a blurring of the boundaries between public and private sectors, may further encourage NHS hospitals to consider methods of attracting patients from the private sector. For individual consultants there are straightforward financial incentives in being able to offer ESWL to private patients in situations where they can charge private physicians' fees.

In the private sector

The purchase of the Dornier machine at St Thomas' Hospital in 1985 was the largest single capital investment which BUPA had made in collaboration with the NHS up to that time. It served a variety of purposes for BUPA: it demonstrated BUPA's involvement in the provision of the very latest in prestigious, expensive, high technology medicine; it associated BUPA with a well-known NHS teaching hospital; it fostered the belief that public and private sectors could work together to their mutual advantage; it formed the basis of an advertising campaign to increase subscribers; and it gave BUPA access to 25 per cent of the treatment time on the new machine for its patients. Whether these benefits justified the investment at St Thomas', only BUPA management are in a position to judge. The St Martin's Hospital Group had preceded BUPA in purchasing a Dornier machine. The St Martin's Group could be confident of attracting a substantial throughput of patients since their lithotripter centre was directed by John Wickham, the leading specialist in renal stone management in England, who commanded an extensive referral network.

In general, the other private hospitals which have purchased machines have invested in ESWL for similar, unsurprising reasons: to attract patients and increase their incomes. In the private sector, patients' preferences may be given greater weight than in the NHS and this may, in part, explain the appeal of ESWL to the private sector since ESWL has always been marketed on the basis of its greater patient acceptability. In addition, the high level of visibility of lithotripters may have been important during a period when private hospitals were concerned to establish reputations in fields other than routine elective surgery. There are currently three private machines in central London in addition to the part-private, St Thomas' BUPA machine. Thus, there is likely to be some spare capacity in the private sector in London, but no evidence that private insurers have taken advantage of this situation to drive down charges.

The role of clinicians

In most of the decisions to invest in lithotripters in the UK, hospital clinicians have played a key role both in advancing the initial idea and in pursuing its implementation. Led by Professor Wickham, urologists were quick to support the diffusion of further lithotripters after the first machine became available to the NHS at St Thomas' in 1985. There was a high degree of agreement at an early stage among the fairly small number of consultant urologists in the country that ESWL was superior not only to conventional open surgery but also to percutaneous nephrolithotomy (PCN) for 80–90 per cent of renal stones. As both a product champion and an opinion leader, Wickham argued that the NHS would cease to be a leading medical system unless it could make therapies such as ESWL widely available. Comparisons were made between the technological dynamism of USA and West Germany and the stodgy indifference of the laggardly UK system.[6]

Hence, there was strong resistance from an expert committee of urologists

convened by DHSS to the proposal from health service evaluators to undertake a randomised controlled trial of ESWL versus PCN at St Thomas'. This was interpreted as unethical, unnecessary and playing into the hands of DHSS and health authorities who would then have a pretext for deferring the purchase of further machines. RCTs of clinical techniques were unfamiliar methods in the field of urology and were viewed with suspicion. It was not surprising that an expert committee of urologists should have taken a favourable view of the advantages of ESWL since the advent of the technology had given the specialty supportive publicity and a high-technology tool when PCN was diffusing only slowly into clinical practice in the UK. However, it was highly unlikely that every consultant urologist would be able to have his own machine in the foreseeable future. As a result, the benefits for individual consultants were distributed unevenly, as NHS stone centres were established at teaching hospitals rather than district general hospitals.

The nature of the technology

Several features and perceived features of ESWL have affected its diffusion. The characteristics of the technology inevitably interact with the interests of clinicians and health care providers to shape the diffusion process. The *high capital costs* associated with both first- and second-generation ESWL have inhibited the diffusion of machines in large numbers in the UK despite substantial charitable and private sector investment. In this respect, ESWL is little different from other costly medical devices such as NMR imaging, where high start-up costs have led to a relatively slow diffusion of machines into the NHS compared with the health care systems such as West Germany or the USA with more open-ended budgetary processes. Related to this, health authority planners and managers were inhibited from rapid purchase of first-generation machines by the likelihood, based on their experience of other innovations, that the first wave of machines would soon be rendered obsolescent by cheaper and/or more effective variants. They were reinforced in this perception by the cautious stance of the DoH, and subsequent developments have vindicated their wait-and-see policy.

By contrast, *all the other features* of the technology appear to have encouraged its diffusion. ESWL was compatible with the value systems of urologists (for example, it did nothing to replace the traditional curative, individualistic approach to the management of renal stone disease by an approach geared to prevention of stone). It was a dramatic, highly visible change of curative method, but based on simple principles – thus, easy to popularise and straightforward to undertake (unlike the skilled surgical technique of PCN). It was a method with a very low risk of mortality and less invasive than the alternatives and therefore assumed to be more acceptable to patients. Despite the high purchase cost, it was possible to argue that the non-invasive nature of the procedure would reduce hospital stays and thereby reduce costs. This was attractive reasoning in a tightly cash-limited public health service.

When second-generation machines came into production which were far easier to install, cheaper to buy and maintain, required little or no anaesthesia

and could operate on an out-patient basis, the perceived advantages over previous methods were sharpened still further.

Since machines of whatever generation are still relatively costly, there is a strong incentive to centralise ESWL provision in a small number of hospitals in order to ensure a large throughput of patients. This creates 'haves' and 'have nots' among urology departments. In the NHS, with its tradition of hierarchical regionalism and strict rationing of expensive new technologies, this exclusivity means on the one hand that hospitals and specialists with machines are able to enhance their standing and, on the other, that those specialists without their own machines become dependent on lithotripter centres if they wish to offer their patients 'state-of-the-art' treatment. Urologists without machines in their hospitals appear to be willing to refer their patients to lithotripter centres as long as this does not undermine their capacity to perform sufficient numbers of percutaneous procedures to maintain their competence.

Assumptions about *patient preference for the non-invasive modality* of ESWL have played a large part in the case for its diffusion. Lithotripsy has long been claimed to be the first choice of patients keen to avoid an operation, but there have been no systematic comparisons of patients' views about the relative acceptability of open surgery, percutaneous methods and lithotripsy. Few patients, if any, will have been given sufficient data in the normal course of events on the costs and benefits of the different modes of treatment to have reached an informed view, for example, about the potential trade-off between a non-invasive, usually anaesthesia-free, technique requiring several out-patient visits to hospital with a lower stone-free rate and the increased possibility of requiring further treatments in the future; as against a percutaneous technique usually performed under general anaesthetic, requiring a short hospital in-patient stay, but with a higher stone-free rate and lower likelihood of the need for re-treatment.

Patients and their relatives might also wish to weigh up the attractions of travelling to one of the few lithotripter centres against receiving percutaneous surgery nearer to home. There are other considerations: 15–20 per cent of ESWL patients will in fact still receive a general anaesthetic since it is usual to insert a ureteric catheter under general anaesthetic in patients with stones over 1.5 cm in diameter, to ease the passage of fragments after treatment. Trade-offs in terms of patient acceptability are theoretically more complex than the proponents of ESWL have admitted. Criteria for patient acceptability of a non-invasive method of treatment may have influenced the private sector to take a particular interest in lithotripsy.

The role of manufacturers and the choice of machine

In most European countries, Dornier and Siemens machines have taken the largest share of the lithotripter market. However, in the UK, the small firm of Wolf is the market leader with half the installations. A fifth of all the Wolf machines in use in the EC and Sweden are in the UK. Why have the Wolf Piezolith 2200 and 2300 found such favour in UK? The DoH recommends that prospective purchasers should talk to manufacturers and users of all the

machines which are currently available. The success of Wolf in the UK appears to be due to a combination of the firm's long-established position in the UK as a supplier of medical equipment, its extensive after-sales support network in the UK and its good reputation with clinicians for making reliable surgical tools such as endoscopes and cystoscopes. Faced with these in-built advantages EDAP and Technomed have faced an uphill struggle.

In addition, the machine characteristics that have been influential are the availability of real-time continuous imaging by ultrasound, which avoids X-ray dosage; the long life of the piezo-electric system used to generate the shock waves, with no need to replace expensive electrodes; and the ease with which the Piezolith can be made to treat either kidney or gallstones.

The choice of machine may also have been influenced in some instances by the siting of the prospective machine and the availability of staff to carry out the treatments. Thus in Bristol, the lithotripter was placed in a redundant X-ray room. There was at first no additional funding for staff to operate it. As a result, the centre has been run by radiographers under the supervision of urologists. Because radiographers are equally familiar with ultrasound and X-ray imaging, the choice of a Siemens Lithostar which requires X-ray skills presented no obstacles. In centres which expected to treat significant numbers of biliary stone cases, there was a strong argument in favour of the Wolf machine, especially if it was planned to use nurses to operate the machine.

In the absence of reliable information on the relative effectiveness of ESWL and alternatives when interest in acquiring second-generation machines was rising, potential purchasers had to rely on the experiences of other urological centres and the information issued by rival manufacturers on technical specifications, maintenance requirements, cost, clinical applications, etc. Manufacturers were and still are in a crucial position to influence the choice of machine, particularly when their representatives are able to be in close contact with the clinician groups contemplating purchase.

The presumption that new is always better still appears to dominate the debate, and manufacturers are able to capitalise on this by offering inducements to centres to become early adopters of new versions of a technology. The latest example of this in lithotripsy in the UK concerns the acquisition of a 'third-generation' Stortz lithotripter by the centre at St Thomas's, where the first NHS Dornier was installed in 1985.

Stortz has agreed to give St Thomas' a prototype of its new machine for a 12-month experimental trial free of charge together with three years' maintenance, on condition that St Thomas' buys the first production model Stortz lithotripter. The lithotripter centre has approached the Special Trustees of the hospital for the capital costs of the new machine and intends to cover all the additional revenue costs by charging health authorities for both biliary and renal ESWL on the machine according to some system of prospective payment. Whether the St Thomas' scheme emerges in this form or not, the example demonstrates the importance which manufacturers place on being able to associate their products with well-known 'centres of excellence'.

The influence of the regulatory framework at Regional level

Regional Health Authorities (RHAs) frequently play an important role in the purchase of equipment such as lithotripters where high capital costs in relation to likely patient numbers encourage centralisation of services. In line with the DoH's devolutionary approach to the development of most new medical technologies, RHAs have been expected to reach their own decisions as to whether to invest in a lithotripter and/or provide revenue funding for patients within their Region to receive ESWL. No funding has been set aside centrally for lithotripsy except in the case of the two centres where renal and biliary ESWL are the subject of DoH-sponsored evaluative studies.

In certain Regions, for example South Western and North East Thames, the NHS lithotripter service is formally recognised as a Regional Specialty and each unit receives a specific revenue allocation to treat the residents of the Region. In N E Thames the RHA also contributed to the costs of installing the machine and setting up the centre. Patients from other Regions are treated on condition that there is spare capacity and that the referring District is prepared to pay either for a treatment session or a complete course of treatment. This is normally a fixed sum set in advance, irrespective of the actual length of stay or procedure required. Charges tend to be set by reference to the charges levied by other similar units in the NHS rather than on the basis of competitive pricing policies.

The Regional involvement in the lithotripter centre at the University Hospital of South Manchester took a different form: the RHA response to urological interest in establishing a centre was to provide a loan so that the DHA could purchase a Siemens Lithostar. The loan is to be repaid by the DHA over four years. A further small revenue sum was provided by the RHA to help the centre become operational, but otherwise the centre is expected to be self-financing by charging all out-of-District users. The specific contribution of the hospital management took the form of making available a dedicated 14-bedded ward.

Other NHS units which have arisen from similar clinical initiatives have been established without either official designation as regional specialties or special allocations from the RHA. For example, it is claimed that the Leeds lithotripter is entirely self-financing without even a subsidy from its local DHA. The Leeds machine was purchased by a combination of resources from the DHA, the Trustees of the Leeds General Infirmary and a public fund-raising appeal. The running costs of the unit are met by charging the DHAs of patients who are referred from outside the local district. All the DHAs in Yorkshire Region have agreed to pay for ESWL at Leeds. Patients from the 'home' district are treated free of charge. Again, the charges are modelled on more detailed empirical costings carried out by another lithotripter centre, adjusted for subsequent health care cost inflation. Private patients are charged a third more than NHS patients to generate income to the unit.

In summary, there is considerable diversity in the revenue and capital funding and the official status of lithotripter units in the NHS. This diversity reflects both the autonomy of RHAs and to an extent of DHAs to decide whether to encourage, discourage or adopt a neutral but permissive policy

towards ESWL diffusion, and the fact that the vast majority of public and private schemes have been initiated by entrepreneurial clinicians (usually with a special interest in stone management) who wished to provide the service, rather than planners or managers aiming to develop the most up-to-date or the most profitable new services.

The impact of research studies and evaluations

The results of formal studies into the relative effectiveness and cost of ESWL *vs.* alternative treatments have played little or no part in influencing the diffusion of renal lithotripsy in the UK. The diffusion process for biliary lithotripsy may turn out to be different in this respect. Enthusiastic clinical opinion and observation of renal ESWL in action, combined with data from uncontrolled West German case series, have been far more important than careful evaluations in affecting clinicians and managers. Indeed, the plans for lithotripter acquisitions which resulted in the flurry of new machines in 1987 were mostly laid before any comparative studies had been published.

The first contemporaneous comparative study of PCN and ESWL was published as late as mid-1987.[7] In this respect, ESWL has not differed from many new medical technologies in being introduced quite widely into clinical practice without previous clinical trials.[8] When the first Dornier machine was about to be installed into an NHS teaching hospital, proposals for RCTs of open surgery, PCN and ESWL were swiftly rejected by a DoH expert committee of urologists as unethical, on the grounds that ESWL was self-evidently superior. As a consequence of clinical opposition to the RCT design, a descriptive comparative study was undertaken.[4] This was the first study of ESWL versus any alternative therapy in similar groups of patients to be undertaken in Europe. The interim report of this study (summer 1988) failed to provide unequivocal support to the prevailing orthodoxy that ESWL was more cost-effective than alternative treatment methods. The study method has since been criticised for failing to embody strict scientific criteria, which could only have been applied by performing an RCT!

No other comparative studies of renal ESWL and percutaneous surgery have been mounted in the UK despite the fact that urologists remain uncertain about the most appropriate treatment regime for patients with a mid-range stone burden, which appears to be suitable for PCN or a combination of PCN and ESWL. The precise limits of this group are differently defined by different urologists, but might cover, for example, single stones 2–3cm in diameter or more than 3 stones up to 1cm in diameter. The Medical Research Council has recently discussed with interested parties the possibility of undertaking a RCT of PCN vs. ESWL in patients falling into this category. However, no definite plans have emerged and urologists remain at best lukewarm about controlled trials in this field. The one exception concerns the advisability of prophylactic treatment of asymptomatic renal stones despite our ignorance about the natural history of untreated stones. Several centres have noted the increase in the rate of referral for ESWL treatment of asymptomatic patients within an overall marked increase in renal stone treatment rates occasioned by the diffusion of ESWL. Questions

have arisen about whether this is an appropriate use of resources and about what would happen to such stones if left untreated. The possibility of undertaking an RCT of ESWL *vs.* no treatment in asymptomatic patients is currently under review in one lithotripter centre.

There is considerably more interest, but again no action, in establishing routine comparisons of the outcome of the treatment regimes offered at different centres. There have been no systematic studies of the relative cost-effectiveness of any of the different second-generation machines which have been installed in UK, or for that matter elsewhere in the world. Thus, it has not been possible to take purchasing decisions with reference to any comparative data on clinical as opposed to technical dimensions of performance. Tentative discussions are under way between centres to explore the possibility of their participation in a national lithotripsy case register which would, among other objectives, provide machine comparisons and some evidence about the relative effectiveness of the different patterns of patient management which exist between centres.[9]

Biliary ESWL

The diffusion of biliary ESWL in the UK appears so far to have been far more closely related to the collection of rigorous research data than has been the case for renal ESWL, probably because of the greater degree of scepticism and uncertainty among general surgeons and gastroenterologists as to the potential of biliary lithotripsy as an alternative to cholecystectomy. The intense pressure to acquire machines for routine clinical use has not built up for biliary as it did for renal ESWL. The two machines which are used for significant numbers of biliary stone cases, at Sheffield and at the private London Bridge Hospital, operate primarily on an experimental basis for biliary ESWL.

Instead of following the normal pattern of a bottom-up, clinically-led project, the Sheffield lithotripter was purchased as a direct result of a DoH initiative to obtain an early and scientific evaluation of the merits of this new application of ESWL to gallstones. Sheffield was selected because of the high degree of biliary surgical expertise in the main teaching hospital and the presence of the DoH-funded Medical Care Research Unit within the Medical School, with the experience to undertake the proposed RCT. The ability to mount a biliary ESWL RCT at Sheffield in contrast to the purely descriptive study at St Thomas' for renal ESWL evaluation has been brought about partly because of the clinical uncertainty about the advantages of ESWL for gallstones but also because of a greater determination on the part of DoH to link its investment in new technology to what is widely regarded as the most scientifically rigorous form of evaluation, an RCT.

FUTURE TRENDS

It is fair to assume that there has been at least some discussion in almost every large acute hospital in the UK about the possibility of acquiring a lithotripter. Lithotripters are generally regarded as attractive, high-status and useful

clinical devices. There are plans at various degrees of detail and with different probability of implementation for machines in Cardiff, Cambridge, and Newcastle. There may be others. St Thomas' is about to start using a prototype third-generation machine on a trial basis. It is claimed that this machine will incorporate the power of the first-generation Dornier in breaking stones, together with the ability to be used to offer anaesthesia-free treatment similar to second-generation machines as required. The machine can be used for renal or biliary stones since imaging is by x-ray or ultrasound. At present, the interest is in obtaining machines primarily for renal and ureteric applications.

There appears to be far less pressure on RHAs and hospital managements to invest in machines for biliary work. There seems to be a consensus that developments should await the results of trials in progress in the UK and elsewhere into biliary ESWL as compared with conventional medical and surgical regimens.

In renal ESWL, there are at least two planning issues which can be identified (though this does not mean that anyone is actively tackling them):

- Are there sufficient public and private lithotripters in the UK to meet needs for renal stone treatment, and is the current distribution of lithotripter centres adequate to ensure equal accessibility in relation to need in all parts of the UK?
- As machines become cheaper, should the long-term objective be to provide lithotripters in every DHA or should stone treatment be concentrated exclusively in specialised centres?

On the question of devolution versus concentration of expertise, a leading urologist has argued that every District urologist should eventually have access to his own machine so that the 80 per cent of stones that are small and simple could be treated and followed up locally, with the remaining 20 per cent being dealt with at a few specialised stone centres equipped and staffed to carry out the full range of percutaneous, endoscopic, open and other techniques (Wickham JEA, personal communication). Others have taken the view that pressure for machines in non-specialised settings should be resisted since it is not always easy to predict when complications are going to arise and further, that both straightforward and more complex cases are better and more economically managed by units with a large patient throughput. For financial reasons, if for no other, ESWL is likely to remain a fairly centralised service, with NHS centres for each Region becoming the norm.

Turning to the number and distribution of machines, there still appears to be excess demand (waiting lists) in the public sector for renal ESWL despite the increased number of machines and the continuing PCN activity. The impression of urologists is that the advent of renal ESWL has led to a substantial increase in overall treatment rates (Feneley R, personal communication). This demand may level out and begin to decline as the backlog of current need among patients unsuitable for surgery passes through the centres. However, treatment thresholds also appear to have shifted. At this point, demand for ESWL may be substantially replenished if biliary ESWL proves to be an effective alternative to surgery.

It is thus a difficult time to attempt to predict the likely growth of ESWL provision when the technology, indications for appropriate use and definitions of successful outcome are all in a state of flux. With the growth of systems of cross-charging between health authorities and the Government proposals for a market in publicly funded health care, the question of the geographical distribution of centres has changed. Although Wales and Northern Ireland have no machine this may not necessarily (particularly in the case of Wales) be a major obstacle to the treatment of their patients by ESWL. Certainly, a number of English RHAs and DHAs have chosen not to acquire their own machines but to participate in cross-charging arrangements to ensure that their patients can easily be referred and treated at centres outside their boundaries. A final issue for the future relates to the division of labour in lithotripter centres. Although centres vary considerably in the allocation of responsibilities to different types of staff, there is a marked trend for the machine to be operated by non-medical staff, usually either nurses or radiographers, under medical supervision. The referral and assessment of the patients remains firmly with medically-trained staff while the new technology has considerably broadened the range of staff competent to carry out the ESWL treatment. Such a trend is likely to be reflected in the staffing required to run new lithotripter centres.

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FACTORS AFFECTING THE DIFFUSION OF THREE KINDS OF INNOVATIVE MEDICAL TECHNOLOGY IN EUROPEAN COMMUNITY COUNTRIES AND SWEDEN

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97

CONTENTS

1 INTRODUCTION

The three technologies whose diffusion is considered in this study are very different in nature.

One, lithotripsy, involves heavy capital investment in a single piece of equipment which can serve a large population; another, heart transplantation, requires considerable surgical and scientific skills, sophisticated information and transport arrangements, and resolution of ethical issues, but no massive new equipment; and the third, prenatal screening, requires relatively simple procedures but a well-organised infrastructure of specialised centres liaising with obstetricians, as well as another kind of ethical consideration which demands the sympathetic consensus of religious bodies, the public and State laws.

By taking three rather different technologies we hoped to identify the similarities and differences in their uptake and use. Box 1 defines the technologies in more detail.

BOX 1

Prenatal Screening

Four tests were considered under this head, two of which are in fact diagnostic rather than screening (amniocentesis and chorionic villus sampling), one which can be used for both screening and diagnostic purposes (ultrasonography), and one which is truly a screening procedure, maternal serum alpha-fetoprotein assay.

The four tests are:

amniocentesis: a procedure usually performed at around 17 weeks of pregnancy, in which a small quantity of the amniotic fluid surrounding the fetus is withdrawn through a needle inserted through the abdomen and uterine wall. The fluid and the fetal cells it contains may be tested by chromosomal analysis for different disorders in the fetus.

chorionic villus sampling (CVS): a procedure by which a small quantity of the chorionic villi on the surface of the placenta is withdrawn for DNA analysis. CVS can be performed at any stage of pregnancy from about 8 weeks of gestation.

maternal serum alpha-fetoprotein (MS-AFP) screening: AFP is a protein derived from the fetus, present in the amniotic fluid and also circulating in traces in the maternal bloodstream. The concentration of AFP in maternal blood serum can be used to screen for neural tube defects in the fetus and, it has been claimed more recently, for Down's syndrome too.

ultrasonography: a process using high-frequency low-energy sound waves that can be focused and used to produce images of tissues, organs or structures within the body. Physical malformations can be detected with greater or lesser certainty depending on the quality of the equipment and skill of the operator. Periodic ultrasonography can detect fetal growth retardation.

BOX 1 continued

Stone Treatment
Kidney stones were traditionally removed using open surgery. In the 1970s two alternative technologies were developed: extracorporeal shock wave lithotripsy (ESWL) and percutaneous nephrolithotomy (PCN).

Lithotripsy uses a source of shock waves outside the body. These waves are focused on the stone and cause it to disintegrate. The particles are then passed out through the body in urine.

PCN involves endoscopic removal of stones. Direct access to the stone(s) is made through surgical incision into the body. Miniaturised endoscopic equipment is used to locate and remove the stone.

Endoscopic treatment and the use of lithotripters are also being developed for gallstones.

Organ Procurement and Transplantation
Both these terms are self-explanatory, but it should be noted that the study focused particularly on heart and liver transplantation, with some reference to the earlier introduction of kidney transplantation.

The second strand to the analysis concerned comparison among the EC community countries and Sweden. Among them these countries have a considerable range of cultural diversity as well as various types of health systems, and it was important to discover whether this resulted in differences in how new medical technologies are introduced and spread. A previous study[1] looked at the formal regulatory processes, but policy makers and individuals within health systems recognise that these are only one of the influences on the diffusion process. We were interested in learning whether the influence exerted by the various actors involved in the diffusion process was similar across the different health systems and regulatory mechanisms, and whether different factors were important in different countries.

If governments are serious about controlling and deploying their health expenditure to best effect, one recommendation emerges very clearly from this study. They need to improve their data collection about the existence and use of medical technologies. We expected from the start that country rapporteurs would have to seek hard for evidence about what influenced the diffusion of technologies, but it was surprising how much difficulty rapporteurs had in obtaining straightforward facts such as the number of items of equipment or procedures undertaken. When the technology involved large, expensive items of equipment like the lithotripter, the data were somewhat more readily available. It was less easy for procedures such as amniocentesis. However, even with lithotripsy there is a need to know how many stone treatments were performed prior to its introduction and how many open or

endourological procedures take place now. Both pieces of information are in very short supply, if not unobtainable.

Some countries have better data than others. It might be expected that nationalised health systems would have uniform full-coverage data. However, this was not the case for the three technologies in this study. On the contrary, countries where reimbursement mechanisms are used may in fact have better information, especially on procedures. On the whole though, central records on the technologies and procedures were not generally available and each technology required considerable investigation. Transplantation data were the most readily available because of the national and international networks for organ matching that are in operation (e.g. Eurotransplant and Scandia Transplant).

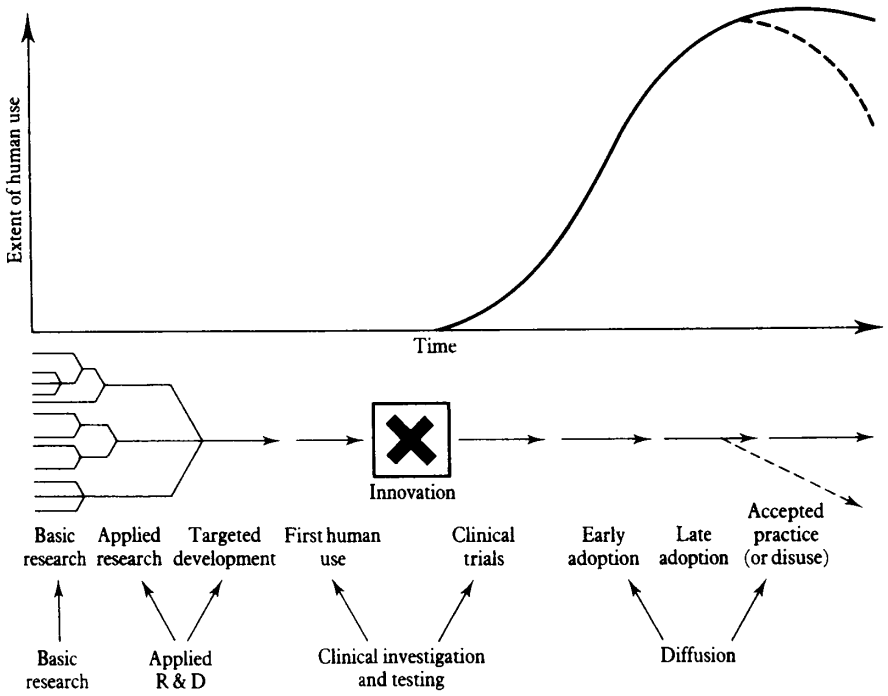
In this overview the introduction and diffusion of the three technologies are examined and then the factors which influenced the speed and extent of this diffusion – this includes the nature of the technologies themselves, social and economic characteristics of the countries, and finally the more specific influences on their diffusion. Some surprisingly clear patterns emerge which do lead to a common agenda across Europe even if this needs to be implemented in country-specific ways.

2 THE DIFFUSION OF THREE MEDICAL TECHNOLOGIES IN EC COUNTRIES AND SWEDEN

The diffusion process

Many people do not realise that there is a common pattern to the way new ideas diffuse.[2] Medical technologies fit this overall pattern, illustrated in Figure 1.

Figure 1
Stages in the development and diffusion of medical technologies



First the innovation has to be developed; it may go through a number of false starts before it reaches a definable product, regardless of whether it is a clinical procedure or a product which can be sold on the market, such as drugs or equipment.

Once the innovation is in prototype form it has to be adopted by some of the key people in the relevant professional or societal group. It is then that there are sometimes differences between medical equipment and procedures. Equipment developed in industrial laboratories will have to be tested out in clinical settings, so that relevant clinical departments may have to be persuaded of the innovation's potential usefulness. This will be less of an issue if the basic ideas were developed in a hospital or university research laboratory, or if there have been links between industry and the health system throughout.

Clinical procedures will have been developed by clinicians themselves, though perhaps in collaboration with others.

The first people to try something are often seen as mavericks and it is only when respected opinion leaders begin to take up the technology that more general acceptance becomes possible. There are inevitably a few 'laggards' who may never accept the idea.

Of course, this overall pattern tells us little about the time scales involved, the rate of adoption, or the ultimate saturation point. For example, for a number of expensive technologies saturation is likely to mean that all the specialist centres have taken them up, not that every hospital in the country has the technology. Also, some technologies may be starting to diffuse when they are superseded in whole or in part. Other factors may intervene, such as a change in government policy or in reimbursement criteria. So the diffusion curve provides the underlying skeleton, but there is much more to understand about what actually takes place.

Perhaps the most interesting difference of medical technology from the diffusion of innovations described in the classic literature is that the adopters are often not individuals who can independently decide to adopt or reject, but are part of large complex systems. The innovation itself may require the commitment of a number of people from different professional backgrounds. The negotiations required for acceptance are at least as interesting as the speed and extent of diffusion – hence the analysis undertaken in this study.

Innovation development

The developmental histories of the three technologies in this study provide a rich account of the trials and tribulations of innovation development. New medical technologies do not suddenly appear from nowhere. A number of scientific breakthroughs is often required, sometimes from quite different fields. Organ transplantation illustrates the length of time innovations may take. It was more than 50 years before animal experimentation on kidney transplantation in 1901 led to clinical reality in humans. There were technical surgical issues to be overcome, but the real key to success was the understanding of the immune system and the development of drugs to suppress the immune reactions to the transplanted organ. The first successful transplants using genetically related donors took place in 1954 in the US and UK. Diffusion really only got started after the first successful kidney transplant using a cadaveric donor in 1962 and after the development of matching for histo-compatibility. When immunosuppression made non-related donor transplantation much more successful there were teams in readiness in a number of countries skilled in using living related donors for transplantation. Thus, the essential infrastructure for the innovation to diffuse was in place in skeletal form.

Heart transplantation in humans began rather later, but had a false start. The first transplant was done in South Africa by Dr Barnard in 1967. To reach that point a number of breakthroughs were required including, in 1953, the development of the extracorporeal circulation pump. What had not been overcome though in 1967 was the rejection problem. Although a number of countries then began transplantation, by 1970 all but five centres had stopped. In

Stanford, USA, the work continued, but it took a further ten years for survival results to improve significantly. By that time cyclosporin had become available. It was first tested in clinical transplantation by Calne in the UK, in kidney transplantation in 1978, and shortly afterwards heart transplantation started in earnest. Liver transplantation also had to await cyclosporin before taking off. However, as shown below, its diffusion is still considerably slower than with heart transplantation.

Prenatal screening development was also a slow process but perhaps without the dramatic ups and downs of transplantation. Amniocentesis was the first test to be developed and this required a number of scientific and methodological developments: the understanding of human chromosomes, identification of the genetic defects associated with Down's syndrome, the ability to culture amniotic cells for chromosome analysis and the equipment and skill development to obtain amniotic fluid transabdominally with safety. In the 1960s a number of European countries experimented simultaneously with amniocentesis, including some countries where the abortion laws at that time meant that the purpose could only be investigative. The drawbacks to mid-trimester diagnosis led to a search for a test which could be done earlier in pregnancy. First-trimester sampling of placental tissue was tried in 1968, and unsuccessfully a number of times throughout the 1970s. It took until the early 1980s until chorionic villus sampling developed fully. This required the combination of the development of a fine cannula with the use of ultrasound so that the villi could be located and the procedure performed safely.

Ultrasonography is both a screening and a diagnostic technique and a support to the other technologies. It emerged from a different setting, naval warfare. The potential for clinical application was recognised in the 1920s and 30s. Obstetric ultrasonography was pioneered by Donald in Glasgow and the first papers were published in the late 1950s. This was only the beginning: the image produced had to improve significantly for clinical use and it was only in the 1980s that real time ultrasonography was widely introduced.

Finally, MS-AFP assay again had different origins. AFP was recognised as a fetal product in 1956. In 1972, reports came out of Japan that MS-AFP concentration was higher than normal in an anencephalic pregnancy and, from the UK, that amniotic fluid AFP was higher in the presence of fetal open spina bifida or anencephaly. Thereafter screening began, with a large-scale collaborative study in the UK in 1975, and in Denmark, FRG, The Netherlands and Sweden at the same time.

Though both are used in renal stone treatment the two techniques of PCN and lithotripsy came about through rather different routes. PCN is based on endoscopy and over a period of time the users (surgeons) were working closely with manufacturers to design the requisite ever smaller instruments. Lithotripsy was one of the medical innovations which developed from research in another sector, in this case defence (like ultrasound). The German firm Dornier had a research grant from the Ministry of Defence to study the interaction between shock waves and tissues in animals. The relevance to medical care, specifically kidney stone treatment, was noted but this required a means to reach stones without destroying the intermediate tissue. Once the idea of focusing the shock waves was developed, a prototype was possible.

Because of the links during the developmental phase, the prototype went into the Munich University Hospital in 1982, around the same time that PCN was reaching maturity as a procedure.

The technologies in the study illustrate then both technology-push and the need-pull developments. Transplantation and PCN were very much driven by the perceived need of doctors and scientists for their development. Lithotripsy came much more 'out of the blue' from work in another area, just as CT scanning came out of the entertainment industry.

Early adoption

It is already clear from innovation development that the same countries appear repeatedly. The country of origin of the innovation may vary, but the group of countries who are either the innovators or the early adopters is fairly constant. These are mainly the northern European and Scandinavian countries – with, of course, the USA also in the forefront.

Tables 1 and 2 show the start of heart and liver transplantation respectively. Most surprising is that Denmark did not start heart or liver transplantation until 1990. Why this delay occurred is discussed in a later section. Table 3 shows the dates of introduction of lithotripsy. Data on the spread of PCN across countries is not available although Sweden, Germany and the UK were among the first countries to report use.

Table 1
The start of heart transplantation in EC countries

Category	Country	Year of start
Innovators (1967–1970)	(South Africa)	1967
	USA	1968
	France	1968
	UK	1969) stopped
	FRG	1969) 1970
Early adopters (1973–1984)	UK	1973
	FRG	1981
	Belgium	1982
	Sweden	1984
	Netherlands	1984
	Spain	1984
Late adopters (1985–1990)	Italy	1985
	Ireland	1985
	Portugal	1986
	Denmark	1990
	Greece	1990
Not yet started	Luxembourg	

Table 2
The start of liver transplantation in EC countries

Category	Country	Year of start
Innovators	(USA)	1963
(1963–1970)	FRG	1968
	France	1968
	UK	1968
	Belgium	1969
Early adopters	Netherlands	1977
(1975–1983)	Italy	1981
Late adopters	Spain	1984
(1983–1990)	Sweden	1984
	Ireland	1985
	Portugal	1987
	Denmark	1990
	Greece	1990
Not yet started	Luxembourg	

Table 3
Uptake of lithotripters in EC countries

Category	Country	Year of start
Innovator	FRG	1982
Early adopters	UK	1983
	France	1984
	Italy	1984
	Spain	1984
Late adopters	Netherlands	1985
	Sweden	1985
	Belgium	1986
	Greece	1986
	Ireland	1987
	Denmark	1987
	Portugal	1987

Finally, Table 4 shows the introduction of the three prenatal screening technologies. Here it is interesting to note that amniocentesis was introduced fairly slowly over about seven years. The reasons seem to be that the procedure required the establishment of an infrastructure of clinical genetics services which most EC countries did not have at that time. In contrast, CVS was introduced rapidly primarily because that infrastructure was now in place. A change in abortion laws also seems to have been necessary for amniocentesis to be taken up. That factor was probably even more influential in the spread of diffusion within a country than in the first attempts with the technique by innovators. Much less information on MS-AFP testing was given by the country rapporteurs, perhaps because many countries do not have a programme.

Table 4
Introduction of prenatal screening technologies in the EC and Sweden

Amniocentesis		CVS		MS-AFP	
UK	1969	UK	1982	UK	1974
Denmark	1970	France	1982	Denmark	1974
FRG	1970			FRG	1974
Netherlands	1970	Belgium	1983	Netherlands	1974
Spain	1970	Greece	1983	Sweden	1974
Belgium	1971	Spain	1983	Belgium	1975
Portugal	1972	Denmark	1983	Greece – date unknown, no screening, but some amniotic AFP measurement	
France	1973				
Italy	1975	FRG	1984		
Greece	1976	Netherlands	1984		
Sweden	1970–1	Portugal	1984	Portugal	no information
		Spain	1984	Spain	no information
				Italy	no information
Ireland – no organised screening programme				France – no national programme but some undertaken	
Luxembourg – none undertaken within country, counselling and screening tests referred to other countries.					

Innovation diffusion

In the stories of the development of the three technologies many of the same countries reappear as being at the forefront of scientific and medical development. It does not necessarily follow that the innovations diffuse quickly in these same countries. In this respect the UK stands out as unusual in often being an early adopter but then lagging behind in the later diffusion.

Table 5 shows the number of lithotripters installed each year. The equipment was developed in the FRG so it is not surprising that diffusion took place there first and that that country was still in the lead per head of population in 1990. Many countries have more machines than national plans suggested was necessary. The drawbacks for urology departments in not having their own machine were such that many of them went ahead anyway, outside national planning agreements, eg in Sweden. Contrast this with the UK: it purchased a lithotripter very early on but diffusion has been very slow, with UK and Portugal at the bottom of the table per head of population by 1990. Even having been the country of origin of the innovation does not mean that the UK keeps up in the diffusion process. This is well demonstrated by the figure for CT scanners: the British firm EMI developed the first CT scanner in the

Table 5
New installations of ESWL by year

Country	1982	83	84	85	86	87	88	89	Total
FRG	1	3	8	7	5	12	16	20	72
UK		1		1		6	3	4	15
Italy			1	6	3	11	27	21	69(74?)
Spain			1	7	1	11	14	16	50
France			1	2	7	16	3	7	36
Netherlands				1		2	5	3	11
Sweden				1			3	2	6
Belgium					1	3	7	1	12
Greece					1	2	3	4	10
Denmark						1	1	1	3
Ireland						2			2
Portugal						2	1	1	4
Europe	1	4	11	25	18	68	83	80	290

The numbers shown do not correspond to the present number in operation, a few of the first-generation machines having already been taken out of service. Danish-made NITECH machines are not included: two were being installed by the end of 1989. A further five Siemens machines are believed (according to information from the manufacturer) to be in operation in Italy, but since their location could not be ascertained they are not included. A few of these lithotripters are used exclusively or primarily for gallstone treatment (although gallstone lithotripters are capable of disintegrating kidney stones provided these are detected by ultrasound), so that the number at the disposal of kidney patients is somewhat lower than that shown.

UK in 1973, but by 1986 the UK was well down the European table.[1] Similarly, the UK was an early developer of kidney dialysis and transplantation but there have been repeated concerns over the years that it is not keeping up with its European neighbours.

In part this may be explained by the funding constraints on the NHS in Britain. Compared to the other northern European and Scandinavian countries with similar scientific and medical development, it is both a less wealthy country and spends less of its GNP on health (around 6 per cent over the last few years). This cannot, however, be the only reason. After all, Table 5 shows how quickly Greece, and, particularly, Italy, were able to catch up – both countries with relatively poor health services compared to northern Europe. There is clearly something about the way the capped budgetary system operates in the UK which is unusual. It probably has to do with a sense of competing needs at local level within a local budget, and also the difficulties in acquiring large capital sums for equipment purchase. Certainly those technologies requiring significant capital investment such as CT, MRI scanners and lithotripters have been slow in diffusing in the UK.

Returning to the lithotripter, Table 5 illustrates clearly the problems of a monopoly supplier. Diffusion was slowed by Dornier's capability to deliver, its capacity being about 15 per year in 1986. The diffusion was also slowed by governments' and funding bodies' adoption of a wait-and-see policy, especially as cheaper machines were known to be in development. The innovation took off when in 1986 a number of these machines from other companies became available and when some countries, e.g. Belgium, removed some of the controls on purchase (towards the end of that year).

Another feature of innovation diffusion can be seen in Table 5: the north–south Europe divide. The northern European countries developed and took up the innovation early on. Southern European countries, though, while

Table 6
Date of introduction of amniocentesis into EC countries and Sweden

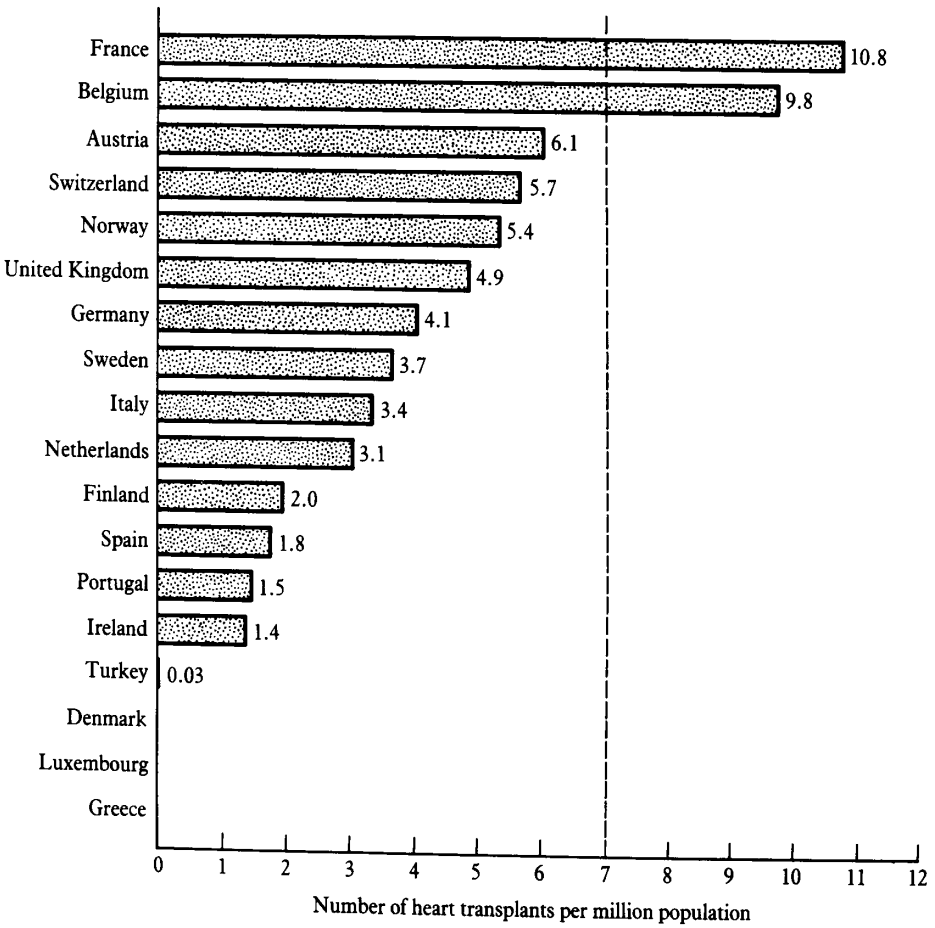
Country	Year
UK	1969
Denmark	1970
FRG	1970
Netherlands	1970
Spain	1970
Belgium	1972
Portugal	1972
France	1973
Italy	1975
Greece	1976
Sweden	1970–71

Source: Country reports

starting late, may leapfrog a stage and catch up fast. It is in the diffusion of prenatal screening technologies that this feature appears perhaps most clearly (Table 6). Reid, in her overview of these technologies, puts forward a number of possible explanations. These include having the scientific intrastructure and the research funds for clinicians and scientists to travel to international meetings, but also to start new tests on their return. Sources of research funds include those in industry, again more likely in the more industrialised countries. Such private backing was crucial in a number of countries in getting the innovation started.

These economic features are the general background to the diffusion of many medical technologies, but particular influences on prenatal screening were cultural and religious differences. Reid points out that attitudes to screening are closely related to those on abortion, and the southern European

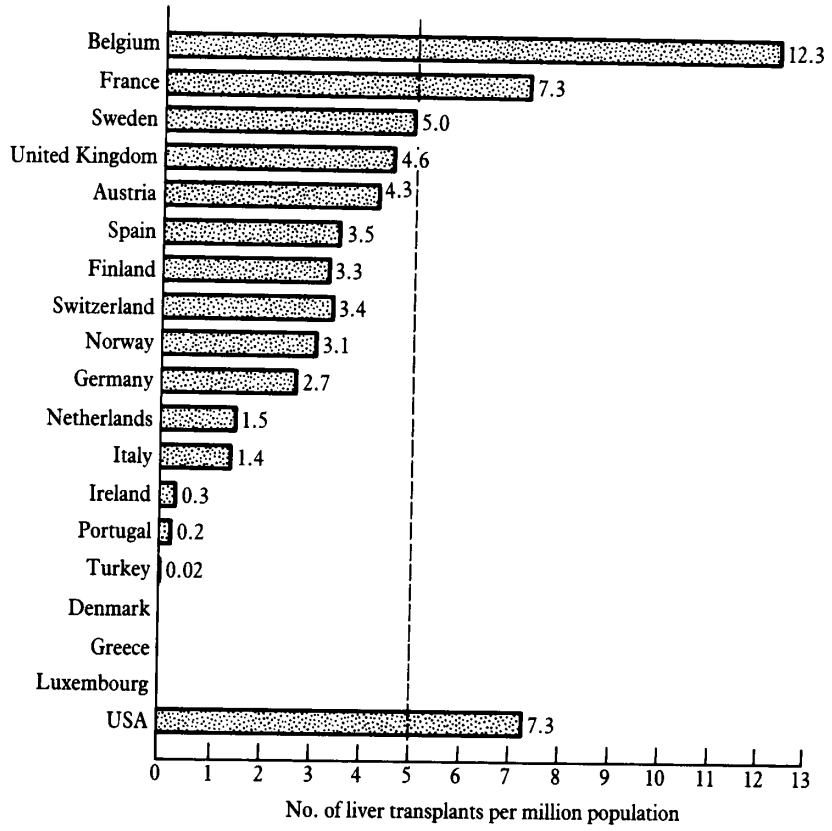
Figure 2
Heart transplantation rate in European countries in 1988 (ranking according to number of transplants per million population)



countries have been more influenced by the Catholic Church. As always, there are exceptions to the rule. While Belgium had until very recently very restrictive abortion laws this did not stop prenatal screening (nor, it seems, abortion of defective fetuses) from taking place.

The diffusion of heart and liver transplantation confirms a number of points already mentioned. The countries with a long-standing tradition of scientific interest in transplantation and immunology (France, UK and W.Germany) were pioneers. However, they are not necessarily the countries which have developed the largest clinical programmes. Belgium, for example, has overtaken both the UK and FRG. Figures 2 and 3 illustrate the position for heart and liver transplantation in 1988. Some of the southern European countries such as Spain, Portugal and Italy, have made very rapid progress although they were relatively late in starting these procedures. These same countries were also later in organising national or regional organ procurement arrangements.

Figure 3
Liver transplantation rate in European countries in 1988 (ranking according to number of transplants per million population)



Sources: US Department of Health 1990; European Liver Transplant Registry 1989.

A feature that is masked in these tables, however, is the number of centres undertaking transplantation, which is quite variable even among countries undertaking comparatively similar numbers of procedures. For example, in the UK, Belgium and Spain a single centre performs the majority of liver transplantations. This contrasts with France, where a large number of centres operate. The Scandinavian countries, the Netherlands and the UK have policies which have encouraged 'national referral centres' rather than the proliferation of centres.

Appropriateness in use

Given the uneven but fairly wide diffusion of most technologies in this study, are the right people receiving the technology to get the most benefit even within the limits of diffusion?

According to early estimates of need based on the number of open procedures, Europe is over-endowed with lithotripters. There are few data on which to draw, but what exists suggests that the clinical indications for stone treatment have been widened, so that asymptomatic stones are being treated as a preventive measure. The appropriateness of such treatment has not been established. Also it seems that some people who might be considered as good candidates for lithotripsy are receiving other treatments, especially PCN. In part this may depend on poor access to lithotripters. Geographical access is a factor, but more important probably is the willingness to refer. Some urologists who do not have lithotripters themselves may perform PCN rather than refer their patients to a lithotripsy centre. Overall then, despite a high level of provision there is the impression of a less than rational use of the technology – although èvaluation data are still lacking to define appropriateness more rigorously.

That geographical and informational access is an issue emerges strongly from the prenatal screening study. While all but two EC countries undertake amniocentesis this has not reached saturation level in most countries, and there is considerable within-country variation. Women living near capital cities (especially in France, Greece and Spain) and those with higher levels of general education appear from some surveys to have greater access to the test. Reports from the UK and Italy also indicate little correlation between a region's population and the number of cytogenetics laboratories. However, again it seems to be the attitude of referring doctors that is the most important factor, although that may be influenced by laboratory capacity, distance from centres, and so on.

The funding mechanisms of the countries might be thought to be a factor in the availability of the amniocentesis. However, despite disparate systems of funding all countries report uneven distribution of the test, and it may not necessarily be those at greatest risk who are obtaining amniocentesis.

MS-AFP screening is even more variable. Different countries have taken different positions. None has routine MS-AFP testing in all regions, although the UK is probably closest to it. The country distribution only partially correlates with incidence of neural tube defects.

Transplantation is the technology in this study where the clinical indications

have been examined most thoroughly. The indications are continuously expanding, however, and no country is yet at saturation point for kidney, heart or liver transplantation. Diffusion is limited not only by finance but primarily by the availability of organs for transplantation.

3 THE CHARACTERISTICS OF THE TECHNOLOGIES THEMSELVES

The technologies were included in this study because of rather different characteristics.

Prenatal screening

The tests are relatively cheap individually, though they cover a significant population. Little capital is required to start doing the tests and, apart from ultrasonography, there is little emphasis on equipment. Because of the ethical issues involved it was considered that consumers might have a greater influence here than with the other technologies.

Stone treatment, particularly lithotripsy

For lithotripsy a large, expensive item of equipment is involved, so it was expected that government regulations might play a significant part, as well as industry itself.

Organ procurement and transplantation, focusing especially on heart and liver transplantation

Because the resources required to set up a programme are significant it was again expected that governments and funding agencies would be influential. The procurement aspect also raises complex ethical issues.

By taking three rather different technologies we hoped to identify the commonalities and differences between them.

Some of the expected issues did turn out to have influenced diffusion. Small, cheap items did mean that there was freedom to innovate quickly without waiting for major funding. The initial diffusion of prenatal screening tests was then much more professionally determined than for the lithotripter, where national policy-makers become involved. It was often the availability of research funds or the ability to 'add on' an extra test which meant that prenatal screening tests were able to diffuse. However, sometimes governments provided the funding to get programmes going, for example, in Greece and Denmark. Liver and heart transplantations fall somewhere between the other technologies. They require considerable organisaton and funding and were such dramatic developments that governments became involved from early on. It was not the setting up of national advisory groups etc. by governments which made diffusion a fairly slow process, but the fact that only a small number of sites were capable of undertaking these procedures.

Thus, another characteristic emerges: whether the innovation requires a complex infrastructure or not and, if so, whether this infrastructure is needed generally or only at specialist centres. Lithotripsy could in theory be used in any urology department, so the infrastructure was already in place and fairly widespread. Transplantation required highly specialist skills, but many EC

countries already had a few centres and that level of expertise. Prenatal genetic screening did in the early days require the establishment of genetic centres. Initially, then, the spread was fairly slow but once that infrastructure was in place it was relatively easy to add in the new screening and diagnostic tests of MS-AFP and CVS.

The other key characteristic which emerged in the study had to do with perceived benefits, and the extent to which the technological imperative dominates: that is, 'if it can be done it should be done'. One might expect this imperative to be very strong with life-saving technologies. However, of the technologies in this study, transplantation falls most neatly into that category, yet its diffusion is not obviously much speedier. The constraint was at least partly about the risk-benefit ratio and about cost. Early on, heart and liver transplantation were not obviously 'life-saving' because the survival rates were poor. There were long periods of development for transplantation of all the organs in this study. The technological imperative only really begins to show with kidney transplantation, which is in a later stage of development. European countries seem to have decided that either transplantation or dialysis should be offered because they are life-saving, and that transplantation is preferred because it is more cost-effective, with a better quality of life for patients. There are, of course, still rationing issues and these have evolved over time.

The other two technologies are less clearly 'life-saving': prenatal diagnosis is about identifying handicapped fetuses and usually offering the option of abortion; lithotripsy was simply an alternative form of stone treatment. Both technologies did have imperatives of their own. In his overview, Kirchberger describes the use of economic or patient-benefit arguments which the innovators made to try to get lithotripters purchased. Compared to open operation there are obvious benefits, since the procedure is much less risky and the length of stay shorter. But as Kirchberger notes, many of the centres arguing for a lithotripter had already moved on from open operation to percutaneous treatment, which compares much more favourably with lithotripsy. The doctors arguing for lithotripsy may well have felt it was of benefit to patients compared to PCN but the arguments seem to have focused on the comparison with open surgery. Surprisingly too, governments seem to have accepted the arguments, and the debates were not about comparative cost-effectiveness, or there would have been more calls for clinical trials, but about how many lithotripters were needed, where they should go, and manufactured by whom.

The prenatal tests illustrate most clearly the concern about risks versus benefits. Although the need for diagnosis of defective fetuses comes out clearly in the reports as being an imperative, the difficulty arises with the concomitant risks – risks of miscarriage of normal fetuses with amniocentesis and CVS, risks of false negatives with MS-AFP, etc. Thus the risks of amniocentesis had to be reduced before it was accepted nationally in several countries, the risks of CVS compared to amniocentesis are being clarified, and the risks of false positives and false negatives of MS-AFP have to be weighed up, especially in places where there is a low incidence of neural tube defects. Only ultrasound appears as a risk-free technology and even with it,

Table 7
Characteristics of the three technologies as innovations

	Prenatal screening	Heart and liver transplantation	Lithotripsy
RELATIVE ADVANTAGE	Risks high in early days. Benefits: allows abortion of affected fetuses or preparation for handicapped child	Lifesaving but in early days survival poor	Alternative non-invasive treatment
COMPLEXITY	Quite complex to organise on national basis – involves different groups of doctors (GPs, obstetricians, geneticists)	Complex to organise as service – requires link to organ procurement agencies	Relatively straight-forward – remained in the domain of the urologists
COMPATIBILITY (with roles, beliefs, etc.)	Variable – very incompatible where abortion laws had not been liberalised	Compatible once brain-death issue resolved	Very good, did not pose major threats to beliefs
OBSERVABILITY	Not very visible	High media profile, therefore very 'observable'	Partial, publicly this depended on clinicians getting media attention for lithotripters. Within medical profession, high. Urologists travelled to see centres.
TRIALABILITY	Techniques could be tried out in particular centres	Yes, surgeons were able to experiment	Low. Had to purchase machine, could not try out on a small scale.

there have been some doubts about its long-term effects. Consequently, of these tests, ultrasound is the one which has diffused most completely through the EC health care systems.

These are some of the characteristics which emerge from the reports about the three technologies. There has been much work done elsewhere on the diffusion of innovations, and Rogers[2] has produced a summary of what he concludes are the key factors affecting diffusion: relative advantage (of the innovation over its comparators), complexity, compatibility, observability and trialability. It is interesting to analyse the three technologies according to these characteristics. As would be expected, since all of them have diffused to a considerable extent through EC countries, they all come out in a fairly positive light. Table 7 shows some of the contrasting features.

Relative advantage has been discussed. Complexity appears as an inhibiting feature for prenatal screening and transplantation because of the need to develop a service infrastructure. There were also difficulties in compatibility with belief systems in some countries for both these technologies. Observability is interesting and highlights the difficulty clinicians (or others) may have in countries where there is less opportunity to travel to international meetings or to the centres of innovation. Only for transplantation has media attention produced general awareness of the technology. Finally, trialability of two of the three technologies was high. It had to be for both prenatal screening and transplantation – in neither case was a fully developed technology available in the early days of diffusion.

4 THE COUNTRY CONTEXT

Critics of national health services might say that they lead to severe rationing, waiting lists, and a resistance to entrepreneurialism and change. Critics of pluralist fee-for-service systems might say they lead to the rapid and wasteful diffusion of totally unproven technologies. Variations on these types of health systems are the context in which the technologies in this study diffused, so how far are the critics' worst fears shown to be justified?

First, the health systems do not fall into quite such neat categories. Those with national health systems range from Scandinavian countries where there is much local democratic control, with local taxation a key source of funding but a great deal of adherence to national planning agreements, via the UK where in theory there is a monolithic health system but in fact quite significant local control and local variation, and Italy with a relatively new national service but with a large private sector caring for publicly funded patients, to Spain, Portugal and Greece attempting to pull together fragmented health care into a national system.

Equally those systems based on health insurance have great variability. West Germany is at one end of the spectrum, with its emphasis on independent medical practitioners outside hospitals and little national health care planning. France is somewhere in between, with insurance systems but much hospital care taking place in the public sector, and there is The Netherlands, with its national health insurance systems and considerable governmental control over the whole system.

Chapter 2 showed, however, that the diffusion of the three technologies does not fit a simple pattern. There is no direct correlation between the general type of health systems and the speed of diffusion. It seems that the incentives operating are more complex and it is in the detail of the systems' operations where these incentives can be seen to be influencing events. Some of the overall country characteristics which emerge as influencing diffusion may be as much to do with cultural characteristics and attitudes towards health care and to the medical profession as with features of the health system.

One influence which cannot be ignored is the country's wealth. As already demonstrated, there is a north–south divide in the uptake of new technologies, not merely reflecting the finance available in the health system, but also the availability of funds from industry, charities, etc.

A second characteristic concerns the different assumptions over the rationing of care, and the criteria which determine who should receive some medical technologies. For example, in the early days of a new technology when it is severely rationed in any country, it is common to include age limits in the eligibility criteria. In general these restrictions become less stringent as the technology diffuses. However, the UK stands out as a country which has operated such criteria more noticeably than others. The criteria have sometimes been quite explicit, sometimes more implicit in the way doctors have refused patients. A number of researchers have been interested in the way the UK has managed to ration the life-saving procedures of kidney dialysis and transplantations.[3,4]

There are also less tangible issues about the willingness of the health

system, and especially doctors, to conform to general policies and controls. All European countries are concerned about the rising costs of health care and are taking a variety of measures to contain costs, including controls over expensive medical technology. The impact of these regulations on the introduction of the three technologies is described below. However, a more general point emerges, which is that in some countries it seems to be more accepted that controls on medical technology are inevitable, even if not liked, and that evaluation of their benefits is an important prerequisite. The two countries which stand out most clearly in this regard are The Netherlands and Sweden. These are both countries where there is considerable state domination of services. For example, there is little private health care or private education. Both countries have gone further than others in establishing mechanisms for the assessment of new technologies. In addition there seems to be an agreement that decisions about widespread diffusion should await the results of trials. This rationality should not be overstated, since in both cases there are instances of events where the general conformity with policy was broken. Denmark also seems to fit with these countries in terms of research mindedness; it also seems to be possible there to question practices without this being seen as extremely threatening.

Aside from the intricacies of health system functioning there are other social and cultural characteristics which influenced the three technologies, and these concern attitudes towards life and death. The two major examples are (a) the debates about abortion and their effects on the diffusion of prenatal genetic screening, and (b) the debates about the criteria for death and its implications for the availability of organs for transplantation.

Amniocentesis was developing at a time when a number of countries were liberalising their abortion laws. Some people have suggested that these changes were a prerequisite for the acceptance of amniocentesis. Certainly, countries with restrictive laws against abortion in the main did not develop genetic screening services. However, it may have been that discussions about screening were also influential in changing the laws themselves. Cause and effect is not clear-cut.

It was mainly Catholic countries which were strongly opposed to abortion, and only recently have they changed their laws. Ireland still has not done so. However, in recent years differences amongst Catholic countries have emerged. Belgium is the most interesting, with a developed system of prenatal screening even though abortion was, until 1990, illegal.

Spain, Portugal and Italy fall somewhere between the extremes of Belgium and Ireland, with development of some services but with referrals highly dependent on the view of individual doctors about abortion of affected fetuses. For example, in Italy when abortion was first legalised 72 per cent of doctors were recorded as conscientious objectors to it.

Although abortion is the main issue, another cultural difference which emerges in prenatal screening, and in organ transplantation, is the involvement of society in debates about medical technology. For example, in some northern European countries newspaper and TV have been very active in promoting discussions about ethical issues around life and death. Others, such as Spain and Portugal, had severe restrictions on the press until recently,

reducing the role of the media in providing information about developments in medical technology and in reflecting and influencing societal opinion.

The media, particularly TV, have been heavily involved in the debates about brain death in at least two countries, the UK and Denmark. Only in 1990 did liver and heart transplantation begin in Denmark because the criteria for brain-stem death were not accepted and these transplantations require organs from heart-beating donors. Danes did, however, receive transplants in other countries. As expected, this led to some controversy outside Denmark since they were not contributing to the pool of donor organs but were receiving the benefits.

5 INFLUENCES ON THE DIFFUSION PROCESS

GOVERNMENT AND NATIONAL FUNDING AGENCIES

Governments would rather not have to make decisions about new medical technology. The impression in this study is that if the professionals could agree amongst themselves, governments did not want to be involved. This in part explains why diffusion may commence quite briskly, even with quite expensive technologies, and then suddenly governments or funding bodies such as Sickness Funds wake up to the implications and have to play a part. The other reason for the delay might be that governments do not have early warning systems about new technology – The Netherlands being an exception with its Steering Committee on Future Health Scenarios. Nevertheless ministries of health do contain informed people who know what technology is being developed, so the lack of early warning does not stand up as a good reason for the delay in response.

The underlying factors which persuade governments to become involved are: where there are identifiable costs, and governments are concerned that the innovation may diffuse rapidly and expensively; where major issues of life and death are involved (even this sometimes requires considerable media exposure before governments feel obliged to play a part); and where issues of equity emerge (e.g. geographical access is unbalanced, the private sector is already offering the service but it is not available in the public sector, etc.).

Once alerted, governments and funding bodies then take a number of steps. They will certainly take advice, and at present this seems to be mainly from the professionals concerned and their representatives. They may set up advisory groups or refer the issue for opinion to bodies established for that purpose, e.g. the Health Council in The Netherlands. Such advisory groups have been established for all three technologies in this study in one country or another. For liver and heart transplantation the majority of countries have had some sort of review. Governments may then try to ensure that evaluation takes place. This is quite variable from country to country and by technology, and is taken up in a separate section.

The question then is how do governments (or funding bodies) use the various regulatory instruments at their disposal to control or at least influence events? As reported in the earlier EC study on regulatory mechanisms[1], EC countries fall broadly into two categories: those which operate some form of global budgeting, often devolved to regional or lower levels, but with national or regional planning agreements; and those much closer to fee-for-service financing, where medical technology is usually controlled through central regulations requiring approval for purchase of major items of equipment, or sometimes for procedures, and through reimbursement regulations. The overall conclusion in the previous study was that if the general damping down of diffusion is the aim, the global budgeting approach is more successful. However, it is fairly indiscriminate, not necessarily sorting out technologies with good cost-effectiveness from poorer ones.

How then have these regulatory mechanisms been applied with the three technologies in this study, and how effective have they been?

Transplantation

Transplantation requires specialist skills and facilities. It does not, though, require major capital investment. The regulatory mechanisms to be used by governments and financing bodies over transplantation fall broadly into three groups:

National planning agreements
These are mainly in countries with global budgetary systems. In particular, Denmark and Sweden have planned their transplantation centres on a national basis. The UK is somewhat different. Although the initial transplantation centres received some earmarked funding, there are no controls, other than financial constraints, on the start-up of new centres.

Specific medical technology regulations
The Netherlands, France and Belgium all have specific regulations over medical technology. In The Netherlands this covers services as well as equipment, and transplantation has been well controlled. However, transplantation is outside the scope of the list in Belgium and France and there are no governmental controls. In France, however, France-Transplant approves centres for transplantation.

Transplantation laws
A number of later adopting countries (Spain, Portugal, Italy and Greece) have laws specifically relating to transplantation and these require centres to be approved before transplantation is allowed.

Finally, the FRG stands out as quite unusual in that there is no formal planning applied to transplant technology, although the National Dialysis Foundation (KfH), a private charitable organisation, influences diffusion through financing arrangements with the Sickness Funds.

While a variety of control mechanisms have been applied, only in a few countries is transplantation highly regulated. The one common issue is that regulations have ensured that most transplantation takes place in public hospitals rather than in the private sector.

Lithotripsy

Again, the types of regulatory approaches can be divided into a number of broad headings:

National systems with global budgets
In several of these countries (e.g. Denmark and Sweden) there were attempts at national planning of lithotripsy. In Denmark it was agreed to hold back diffusion until County Councils could obtain a nationally produced machine, but production was so long delayed that eventually the agreement was broken. In Sweden agreement lasted through a long phase of assessment of the first machine. However, even though it was then agreed the country needed only three machines, twice as many County Councils proceeded to purchase them.

In the UK, which falls into this category of system, there were no controls over lithotripsy other than financial constraints.

Regulated equipment lists
In these countries lithotripters did appear on the lists and so their diffusion could be controlled. How these controls were applied varied: in Belgium regulations were interpreted very generously; in France the regulations were used to control (indeed, virtually exclude) entry of foreign machines into the home market; in The Netherlands, where control might have been expected, there is none except it is agreed that budgets cannot be increased to cover costs of lithotripsy. This has led to relatively constrained diffusion, with groups of hospitals purchasing a single lithotripter.

No controls, or controls only in the public sector
In the FRG and in southern European countries there was little attempt to control the diffusion of lithotripters. In the FRG, individual states may have certificate-of-need legislation, but sickness funds may still pay even though equipment has not been agreed, so there is no control over diffusion. In Greece and Italy, there is control over purchase in the public sector through central financing. However, the private sector is unconstrained, even though it is often the public purse paying for treatments.

Overall there appears to be less successful control over the diffusion of lithotripsy than transplantation, despite the fact that it is a large item of equipment which falls unequivocally under various regulations. It may be that governments were easily persuaded of the benefits of lithotripsy. Other factors, though, include the lack of regulation over private sector purchase. Finally, as a relatively new technology it has been subject to the recent movement of some countries such as The Netherlands towards global budgetary controls and away from specific regulation of particular items.

Prenatal screening

The earliest test under this heading to be introduced was amniocentesis. In its early stages no governmental intervention was necessary: the test is small scale and not exorbitantly expensive, so it was possible to begin by using research monies. To establish a national genetic screening service required formal representations to government because at that time, about 1970, the necessary infrastructure of genetic centres was not available. In several countries (Sweden, FRG, Denmark and France) groups of doctors drew up blueprints of what was required and this is what broadly came about. Reid notes, however, that in many countries amniocentesis has never been given a formal stamp of approval, perhaps because of the often unspoken link with abortion, but has been left to develop without a strategy.

Thus government controls were less concerned with the early diffusion of the technology than with its general availability. A number of countries, notably, Greece and Portugal reported that resources had not increased to meet the rise in demand. Prenatal screening is rather different from the other technologies in the lack of use of regulations and planning mechanisms.

In conclusion, there are contrasts with government involvement in the regulation of these technologies, and their outcome. In the FRG there have been few if any central government controls, and diffusion has been relatively uncontrolled. In contrast, in the UK diffusion has been contained without a great deal of central government involvement, but through local budgetary constraints.

In countries where there have been specific medical technology regulations they have not been applied uniformly, either across those countries (France, Belgium, The Netherlands) or across the technologies. Denmark, and especially Sweden, stand out as the countries which have gone furthest in national planning for these expensive technologies, yet even there agreements have been breached.

PROFESSIONS

Policy makers and managers are well aware that it is the health professionals – usually doctors – in a particular field who develop or are the first to know about a new technology. It is these professional leaders who lobby them intensively for the resources or the permissions required to go ahead. It was therefore not surprising that the role of doctors in introducing technology into a country comes out strongly in this study. However, the approaches used by doctors for each technology and each country differed.

Lithotripsy

Key urologists began to visit Munich to see the lithotripter development as early as 1978/9. The first visitors brought the message back to their own country and began to lobby the relevant funding and decision-making bodies.

However, the next stage was not so straightforward. Only a few lithotripters would be needed in each country, and in any case Dornier had a limited production capacity. Only a few hospitals would therefore be likely to get the machine. In Denmark this resulted in agreement amongst key urologists that they would all wait until Denmark was able to produce its own machine. This seemed to be on the basis that if purchase were to go ahead immediately only one would get a machine, but if they waited several of them were likely to be satisfied. The agreement was weak, though, and in due course broke down.

In France the agreement was that since there was only likely to be one machine in the Assistance Publique hospitals of Paris, all ten urology departments should have access to it. Also, since its presence would put any one hospital at a considerable advantage, it was suggested that the site selected should be 'neutral', that is, not one of the urology departments. Further discussions showed this to be a rather impractical approach and in the end the Assistance Publique had to step in to decide on the location, which was in one of the hospitals but in a separate department from the urological service! Belgium followed a similar path, a military hospital being selected as the neutral environment. Again, this was highly unsatisfactory and discussions on purchase were delayed until eleven machines could be ordered in quick succession at the end of 1986.

This essential point about monopoly of use and the associated prestige was demonstrated in other countries too. A technology which is costly, limited by production or by legislative agreement is one which decision makers will undoubtedly need to take professional advice about. Equally, these characteristics make it unlikely that there will be consensus from the profession, especially about appropriate location.

Prenatal screening

Reid states in her review of prenatal screening procedures that the key people in their diffusion are members of the medical profession. Because the specialty of clinical genetics was not very advanced two decades ago they tended to be paediatricians or obstetricians. These individuals did not simply have to argue for a particular test but for the setting up of genetics services as a whole.

The early innovators often worked hard with the media and the public as well as with national policy makers. For example, the West German innovators worked to change the negative image of genetics following the Nazi era. They maintained a high press profile and encouraged meetings for lay audiences as well as scientific meetings. In Sweden, similarly, a small group of specialists in clinical genetics also put a great deal of work into 'selling' genetics.

Despite the professional enthusiasm in some countries, both for getting these services going and in ensuring that good assessments of safety and efficacy were undertaken, these same doctors could also be much more negative gatekeepers. Although in principle most people agree that first-trimester diagnosis of Down's syndrome would be preferable, when CVS was introduced neither its risks for the mother and for fetal loss compared to amniocentesis nor the risks of transabdominal versus transcervical CVS were known. An international meeting was held which agreed that CVS should not follow the pattern of unevaluated introduction which had been the case with amniocentesis, but that an attempt at central coordination should be made and that a a randomised clinical trial should be set up. Although the trial was set up and a number of northern European countries and Italy took part, some of the Italian centres dropped out of the trial and in general there was wavering commitment to the need for a trial. The German leaders argued that a trial was not needed because, as in the case of the lithotripter, CVS was self-evidently better.

The role the key figures play may depend on their personal interests. For example, the first centres taking up CVS obtained much 'kudos' but, of course, the next ones would not have the same status. In some places, then, leaders argued for and began attempting early amniocentesis instead of CVS. This competition for prestige is, of course, a great spur to scientific advancement, but it does not make for the most rational approach to the introduction of medical technology.

Another aspect to be considered is what happens when key figures are unenthusiastic about the technology. This seems to be what happened in France for CVS. The risks were thought to be high and, without a leader to

push forward the arguments, CVS has been left at a fairly low level.

These examples all illustrate doctors operating politically through whatever channels are available: press, scientific journals and meetings; national working parties and, as much as anything, informally behind the scenes. Their other role is, of course, with the individual patient. They may give information about particular tests or they may withhold it. Even if the patient is informed, doctors may be very influential in making or blocking access to services. There is strong evidence in the country reports (Italy, Spain and Portugal) that doctors are very influential in whether women get prenatal screening or not. In several countries, particularly Catholic ones, there are conscience clauses to permit doctors who do not wish to be associated with abortion to decline to do so.

Organ transplantation

Again, the coordinator, Bos, states that without exception the leading role in kidney transplantation was played by the medical profession. Only 10–15 years after the first transplant did governments and financing bodies become involved – mainly because kidney transplantation provided a better and more cost-effective solution than dialysis. In some cases governments, for example in Scandinavia, became involved in arrangements for organ procurement, but in others it was again doctors who promoted national networks for exchange of organs.

Similarly with heart and liver transplantation, decisions about where to start transplantation were taken by individual clinicians or transplant teams, often without any involvement of local health administrations or national bodies. Because of the publicity surrounding transplantation, many of the transplant surgeons became public figures. As governments became involved, which they did rather earlier than in the case of kidney transplants, many of these same clinicians served on national advisory bodies.

HEALTH PROVIDERS

Although professionals have been shown to have taken a leading role in the introduction and diffusion of technology, they may or may not have been supported by administrators/managers in the health settings where they operate.

For example, in countries where the private sector plays a large part in the provision of health care there is usually a strong incentive for them to take up a new technology. It is not simply a matter of prestige; a hospital may also stand to lose patients if it does not have the technologies which are available elsewhere. In several countries, too, while the public sector is subject to budgetary constraints or to regulatory controls, the private sector may be free from restrictions. For example, lithotripters in Greece and Italy are mainly in the private sector which is unconstrained in its purchase of equipment. Even if public sector patients have access to treatment it still leaves the government with difficult issues about distribution of the technology.

An interesting issue arose in Barcelona where there were adequate numbers of lithotripters in the private sector but because of the cost involved in paying for patients to be treated, the regional government decided to purchase additional lithotripters for public hospitals.

The hospital administration may not always operate in line with professional demand. In countries such as Sweden, Denmark, and in future the UK, where funds follow patients, it is in a hospital or local authority's interest to make sure that if a major investment is made adequate numbers of patients will follow. There is then an interest in some regional or national planning. The arguments for conforming to specialty planning on a wider basis will be balanced against the pressures from doctors and the prestige for the hospital of being associated with new developments.

As with national government involvement, hospitals and local responsible bodies are more likely to become involved when major investment decisions must be made. With procedures or smaller-scale technologies it may be easy for innovation to begin without any explicit agreement from managers.

CONSUMERS AND THE MEDIA

The main sources of information on new technologies for patients and the general public are their doctors or other health professionals, friends and relatives, consumer interest groups and the news media.

Of the three technologies in this study the one which has had the most media attention is transplantation, particularly of hearts. When Barnard undertook the first transplantation the news was relayed around the world. There is something special about the heart, with its association with emotions. Despite media interest, and perhaps because of these emotional associations, there was not a great demand from the public for diffusion of heart transplantation. It seems more that the public followed the stops and starts of transplantation as they had watched progress towards getting a person on the moon.

Kidney transplantation was rather different. In the UK, for example, where both haemodialysis and kidney transplantation are accepted technologies, but where the numbers of patients treated are low compared to other European countries, there have been TV programmes from time to time about the situation. General public concern over transplantation has been about selection criteria, for instance age discrimination, and waiting lists. However, these issues result more from organ shortage than from lack of diffusion of the procedures.

Media *influence* over transplantation has usually been mostly concerned with organ procurement. At different times and in different countries the influences have been diametrically opposed. For example, before the criterion of brain death was accepted, some of the media sensationalised stories about hearts being removed from donors declared dead too early. As a result the number of organs available for transplantation sharply declined. Brain death has been an issue in the UK and Denmark, and was only accepted in Denmark in 1990.

On the other hand, the media have also been instrumental in encouraging

donation of organs by spotlighting examples of those – children especially – waiting for organs.

The public has been involved in transplantation mostly through the media, except kidney transplantation, where associations of patients have been more active.

With stone treatment, public involvement has also been fairly low-key, and the media mostly portrayed lithotripsy as another technological miracle. Early on there were attempts by urologists to use patient power to lobby for machines. Urologists outside FRG said they were being pressured by patients for access to the treatment in Germany since it was not available in their own country. Waiting lists of patients were drawn up, for example, by the key urologist in Paris. However, as Kirchberger points out in his analysis, given that PCN was readily available as an alternative, it is not quite clear what these lists meant.

Prenatal screening differs from the others. There is a strong consumer movement associated with perinatal care and it might be expected that consumers would have more influence over diffusion. It is certainly true that the country reports describe more consumer involvement through interest groups, and more, recently, through individual patients requesting screening. Even so, the overwhelming impression is that the diffusion of amniocentesis, of MS-AFP screening and, more recently of CVS is determined by professionals rather than patients.

As with the other technologies the media played a part in informing the public about the availability of the tests. In Sweden and FRG professionals used the media quite explicitly to generate interest. In countries such as Spain and Portugal, which had repressive regimes in the early days of amniocentesis and MS-AFP screening, the restrictions on the press meant that the public were unlikely to have had much knowledge of what was possible. These countries are also the ones where the negative attitudes of many doctors to abortion meant that the public was not going to be enlightened by this source, either.

Patient–public involvement occurred most strongly in a few countries: Sweden, Denmark, UK, The Netherlands and FRG. The issues are rather different. In Sweden, the argument centred around the right to life for disabled people. This involved both the individuals themselves and parents, and although it was vehemently argued that defective fetuses should not necessarily be aborted this was not a uniform view across all groups. By contrast, in The Netherlands a group of handicapped people argued strongly for screening. In Germany, worries were based on the historic concerns about eugenics. In the FRG, feminist socialists have been most active in arguing against screening and the abortion of defective fetuses. The feminist group RotaZora planted a bomb which destroyed the genetic counselling centre at a medical school. In Denmark there was public debate around ultrasound and its safety.

Aside from organised groups there is some limited and anecdotal evidence that individual women's demands have affected diffusion. Several rapporteurs suggested that this was one reason why CVS was diffusing rapidly in their countries. In the UK, it was in trials of CVS versus amniocentesis that several

maternity interest/pressure groups became involved in helping to design trials and in providing information to women about taking part in the study. There have also been cases of patients sueing doctors because they asked for amniocentesis, were denied it and then delivered a handicapped baby.

While there is evidence that individuals and consumer groups have been active in prenatal screening, they still do not seem to have been strongly influential. This may be in part because of the conflicting views expressed by different groups. They are seldom as coherent a body as the medical profession. In some countries consumer groups have been unknown until recently, partly because of earlier press restrictions. It is also very clear that doctors are still acting as gatekeepers to these technologies, both at individual patient level and in their more general diffusion.

COMMERCIAL INTERESTS

Industry's role in the diffusion of technology is probably greater than might be suspected. For large machines such as the lithotripter, industrial interests are obvious, but even with prenatal screening a surprising amount of research funding came from commercial sources.

Taking the lithotripter first, there are two strands to the commercial interests. One concerns the interest of governments in protecting the home market for national firms, the other concerns the attempts made by industry to gain access to new markets by particular 'deals'.

Protecting national firms

Both France and Denmark in this study tried to gain time for machines to be developed in their own country. The French have a number of mechanisms available to achieve this policy: the Carte Sanitaire allows only certain numbers of items per head of population and can be used to delay diffusion; and the approvals required for the equipment itself, 'homologisation', mean that it is also possible for only certain types of machines to be approved. In Denmark these types of regulation did not exist, but the planning debates allowed a consensus to develop that machines would not be purchased until Danish machines were available.

Entering the market

It is unclear in the FRG how much of the early diffusion of ESWL was based on support for a German industry. It is known that the links between Dornier and the German Kidney Patients Association, which played a central part in the early diffusion, were extremely close. For a variety of reasons, then, the country where the lithotripter was developed remains today the one with the highest machine/population ratio.

To get a foothold in markets in particular countries the firm concerned often does 'deals' with groups of doctors or even planning authorities. In this study the most interesting example is the German firm Siemens' allowance of one year's free use of a machine by a group in Denmark, which broke the

consensus there about delaying purchase. Other arrangements about leasing, long-term loans, etc, also took place in other countries.

Prenatal screening was taken up earlier in countries where some financing from industry was available. The prenatal screening review cites three examples: the FRG where funds from a West German industry helped establish the clinical genetics programme; the UK where two firms contributed to funding the influential AFP collaborative study; and Italy where acquisition of equipment was achieved in part by charge-free loans from the manufacturing industry. More generally, research funding, sometimes from industry, was the base on which new tests could be 'piggy-backed'.

Although there is little specific evidence in the country reports it seems likely that support from the drug industry has helped take forward heart and liver transplantation programmes. There is strong mutual dependency: the industry needs transplant centres to test immunosuppressive drugs in a clinical setting, while the transplantation programmes cannot develop without these drugs.

Apart from direct finance, firms (particularly drug companies) sponsor international meetings at which ideas about new technologies are exchanged. Also, of course, industrial representatives visiting laboratories and service departments pass around the system a great deal of information about technological innovations.

EVALUATION: ITS ROLE IN THE DIFFUSION PROCESS

Some differences emerge across the three technologies and countries in the role of evaluation in the diffusion process.

For lithotripsy, it is clear that doctors were convinced both about clinical benefits and about cost-effectiveness very early on and went so far as to express the view that trials would be unethical. In several of the countries it was others, usually those responsible for investment decisions, who pressed for evaluation to be undertaken. Sweden, France, The Netherlands and UK are all known to have had considerable debates about evaluation of lithotripsy at the start of the diffusion process. In France and The Netherlands the first machines were funded on the understanding that evaluation would take place. In the event the French urologists did not provide data. In Sweden perhaps the most thorough evaluation took place through the insistence and provision of research funds by the Association of County Councils. The research included short-term treatment outcomes as well as longer-term stone recurrence rates and side effects in a comparative study against PCN, as well as a broader technology assessment. Results from these studies began to emerge in 1987 and were used for further planning decisions, although the recommendations were not fully adhered to subsequently.

In the UK the proposal from researchers to the Department of Health that there should be a randomised controlled trial (RCT) of lithotripsy against other forms of stone treatment was strongly resisted by urologists. In the end all that was acceptable was a descriptive comparative study. Even this brought out a number of questions about the cost-effectiveness of lithotripsy versus PCN for different patient groups. The results have been criticised because they do

not have the scientific rigour of an RCT! However, with gallstone lithotripsy there appears to be less conviction that the answers are clearcut and an RCT comparing lithotripsy with percutaneous treatments has been possible.

This differs considerably from evaluation discussions in prenatal screening. Although randomised controlled trials were not undertaken in the early stages of development of amniocentesis, the individuals responsible did carry out studies of risk of fetal loss. An RCT was subsequently done in Denmark. More recently there have been trials of amniocentesis versus chorionic villus sampling led by the professional groups and researchers involved in perinatal care and not by governments. Not all involved in CVS are convinced of the need for trials, however. The intention was to conduct trials using common protocols across a number of countries. This did not work out in practice, but the UK did go ahead with an RCT involving participants in Denmark, Italy and The Netherlands. Government and funding bodies have played a very minor role in evaluation. For MS-AFP screening large-scale collaborative studies in Sweden and the UK were undertaken to establish the risks and benefits of screening. These were funded from a variety of sources, both charitable and commercial.

In the studies mentioned, governments did of course pay a great deal of attention to the results. This was particularly so for MS-AFP screening, where a number of countries set up national working parties to advise on whether there should be a national screening programme.

Liver and heart transplantation lie somewhere intermediate between the two examples. The procedures were perceived as being expensive, and it was in the interests of the early innovators to collaborate with governments and funding bodies on evaluation. Individual clinician responses will clearly not be uniform, but there seems to have been reasonable agreement in the UK with the Department of Health about the need for a study of outcomes in terms of quality of life and of costs for heart transplantation. It is unclear how much influence the resultant study had. It gave a more positive view of the cost-effectiveness of heart transplantation than had perhaps been expected, and two centres were funded. Buxton argues[5] that policy followed behind local decisions rather than determining events. However, the evaluation probably influenced the spread and speed of introduction of heart transplantation.

Similarly, in The Netherlands the lead for evaluation came from the Sickness Fund and Health Councils. The Academic Hospital Groningen had already started a liver transplantation programme and the Academic Hospitals of Rotterdam and Leiden cooperatively had started heart transplantation. Thus the assessments were in effect imposed on them as a condition for funding these activities. The assessments were broad and the final reports in 1988 influenced the decisions of the Sickness Fund Council: to include heart transplantation in the set of insured care provisions but not to do so at that time for liver transplantation.

A number of other countries set up working groups to assess heart and liver transplantation but the only other countries to undertake anything approaching a full evaluation were Sweden and the USA. The US heart study, and particularly the US consensus conference on liver transplantation, were quite influential in discussions in various European countries.

Other literature,[6] including a study of randomised controlled trials by the US Office of Technology Assessment,[7] has shown remarkably little influence of trials on the initial diffusion of medical technology. In these studies RCTs, if established at all, took place rather late in the diffusion process. This is less the case with the technologies in this EC study, especially transplantation. For lithotripsy, trials were opposed by the doctors concerned on the basis of the self-evident improvement of care. Consequently there is less information than there should be about which treatments are appropriate for which groups of patients, especially when the long-term effects are considered. Governments, it appears, did not press heavily for evidence. For prenatal screening the lead has been taken by the professional groups and the results of clinical trials and cost-effectiveness studies do seem to have influenced the arguments and the practices, though not necessarily in a uniform way. For transplantation a number of governments/funding bodies have insisted on good studies as a basis for making funding decisions and doctors seem to have been willing to support the need for assessment. The effects of the results on policies and the diffusion pattern are less easy to determine, but certainly seem to have been influential in The Netherlands and Sweden.

The more southerly European countries have less of a tradition of evaluation research but have tended to draw on the results of studies from other countries. There is no information on how much trial evidence has been taken into account in decisions.

6 CONCLUSIONS

Three conclusions emerge quite clearly from this study: that the medical profession, as individuals and as a group, has been the dominant influence over the introduction and diffusion of these medical technologies; that the role of the consumer has been surprisingly weak considering that several of the technologies involved major ethical issues about life, death, and disability; and that in no country in this study was full central or governmental control over all the technologies attempted or achieved, though The Netherlands and Sweden stand out as having gone further in this respect than others. Even accepting that the diffusion of medical technology will never be an entirely rational process, there are several ways in which it could be improved.

Educating the medical profession

Given that doctors are the key actors in the process it is clear that little will change unless they accept the need for evaluation of new medical technologies to be built into undergraduate and postgraduate training. There is some evidence of a move to make medical education less fact-driven and to emphasise more 'learning how to learn'. The issue of scientific evaluation could be accommodated more easily under that scenario.

Even if better training were instituted immediately, such understanding would take time to become evident in the system. There is a need to develop the understanding of doctors in practice now. There is no easy route, but governments could work with the relevant professional bodies in each country to persuade them to take a lead. Because of the different health systems in EC countries and the way that doctors are financed, the precise mechanisms to be used to influence and educate doctors will have to be determined locally.

The major concern that doctors share when evaluation or technology assessment is discussed is that patients may be denied benefits during the evaluation period. Doctors need to be persuaded that it is worth some delay to ensure that health care resources are not wasted and that current and future patients receive appropriate treatment based on good evidence and not on unproven assumptions. But there is a challenge in this both to the governments concerned and the researchers undertaking evaluations. The evaluations need to be undertaken as speedily and conclusively as possible. Methodologies need to be improved so that early outcomes can lead to some early decisions as part of a gradual process.

Another concern is that innovation will be stifled and that scientific brilliance cannot be turned to national account. However, this is more of an issue about early support for the development of new ideas rather than an argument about good evaluation of emerging technologies.

Government's role

If doctors are to be helped to become more critical and to call for scientific evidence in the interests of their patients, governments and national financing

bodies will also have to show that they are serious about these issues. A strong sense came out of this study that governments would prefer not to have to intervene in medical issues but to leave it to the medical and related professions.

What seems to be necessary is for governments to be clearer about which technologies are emerging, which of them will require their attention, and which can be left to be 'managed' within the medical profession. The Netherlands have taken the lead with this approach with their Steering Committee on Future Health Scenarios.[8] The next step is to make sure that appropriate evaluations are undertaken. Often with the 'big ticket' technologies governments are in a position to insist that evaluations are done before initial introduction takes place. The regulation is wider, subsequent diffusion is more complex and, as described above, different countries have different policy levers they can use. Individual regulation of specific technologies has not been a very effective control mechanism, however, partly because it is subject to too many loopholes or abuses. More control seems to have been achieved where there is some commitment to regional planning. The acceptance of that approach at local levels may be strongly influenced by a realisation of the financial risks and penalties incurred by not adhering to the agreements.

As described in the earlier EC study,[1] budgetary constraints do work, but they can be a fairly heavy-handed control mechanism. It is no use keeping every innovation dampened down and not discriminating between those that have been proved effective and those that are unevaluated. Of course, there is no doubt that global budgets do make people think more carefully and a number of countries are moving in that direction; but better technology assessment information is essential for local decision makers if they are to assess trade-offs in the care they are providing within those local global budgets.

In The Netherlands and Sweden the introduction and use of medical technology appears to be somewhat more successfully controlled. The combination of three key factors makes this possible: acceptance of government's role in ensuring that technology assessments are undertaken; willingness of governments to use the policy levers which are available to them; and recognition by those at local levels of the need for controls and perhaps broad planning agreements.

Involving the consumer

The third issue is the role of the consumer. Some of the EC countries, especially those which have or have had tight controls over the press, have very little tradition of consumer involvement in health care. However, even in northern European countries, where consumerism is said to be strong, little evidence emerged of real influence over these medical technologies. In this study Denmark appeared to have gone furthest in exposing issues to public debate and public influence.

If it is believed that many medical technologies have such significant social and cost implications that the public does have a legitimate interest in their diffusion, how can its role be fostered?

The weakness of consumer groups in comparison to the power and greater organisation of the medical profession implies the need for some lead from governments if consumer groups are to be taken seriously. As in Denmark, there needs to be a positive move to open out issues to the public and to invite consumer groups into the medical and political settings where decisions are being made. An underlying requirement is that medical issues are explained in such a way that patients, consumer groups and the public can begin to understand what the issues and uncertainties are about. This is by no means impossible. Public consensus development conferences in Denmark, the UK and elsewhere have shown such explanation to be quite feasible. It does, however, require a willingness on the part of the medical profession to do so, and it is governments and other national policy bodies that will probably have to take the lead and set an example.

Overall then there is a clear if difficult agenda for action for policy makers and other leaders across Europe if technologies are to be introduced and used more appropriately in our health care systems. While the agenda is common, the approaches and solutions which are suitable for different EC countries will be quite varied. Nevertheless, there is a great deal to be learnt from each other as countries begin to move forward on these issues.

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Medical technology, defined broadly to include drugs, procedures and equipment used singly or in combination, has been of enormous benefit in improving the quality of health care. It has, however, raised many issues about how society can afford to pay for these often expensive developments and about associated ethical problems and social impact. This book, one of three dealing with different medical technologies, is about the effect of these issues on the rate of diffusion of these technologies in the countries of the European Community and Sweden, from the time of their introduction up to 1990. It is based on first-hand reports from informed observers of the health care scene in each country.

The three technologies are: prenatal screening for metabolic or anatomical disorders, especially Down's syndrome and neural tube defect; treatment of kidney stones by lithotripsy and/or endourological procedures; and kidney, heart and liver transplantation, with the attendant problems of organ donation and procurement. The influence of ideas of technology assessment, recently introduced in some countries, is critically examined at the end of each volume.

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