Minimally invasive surgery in Denmark: a case study contributing to the OECD KISA study

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Preface

The study is intended as a contribution to an OECD-initiated study entitled 'Exploring the role of Knowledge Intensive Service Activities (KISA) in innovation and economic growth'. More specifically, the study has been carried out in the context of the health care sector studies envisaged as part of KISA. The research theme 'Minimally invasive surgery in Denmark' has been approved by the KISA health care sector study coordinator Dr. N. Saranummi (Finland), and approval for participation has been provided by the Danish representatives at the OECD, Dr. M. Riis and Dr. S. Larsen.

The KISA set-up requires case studies to be based on a literature review and interviews. To this end a research proposal was written and submitted for funding. However, the study was deemed ineligible for funding by the Danish Government. As a compromise, the material presented here is exclusively based on a literature search. Notwithstanding this drawback I believe the study is still worthwhile, as a number of sources with outstanding quality were available for analysis. I hope the results of the study will serve the purpose of both the OECD KISA study and Denmark as a nation (and OECD member) by providing information on innovation, diffusion, and policymaking in this country, both at present and in the past, towards one of the most dynamic areas of technological change ever witnessed in health care.

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1 Background and introduction

Minimally invasive surgery (MIS) is a good example of a knowledge intensive health service. On the one hand there is considerable high-tech and IT knowledge embedded in the devices and procedures used in MIS, and on the other hand there is considerable training (skills) required to appropriately carry out most MIS procedures. In addition, the advent of MIS in the eighties has been judged by a number of analysts as a 'paradigm shift' in surgery, fostering innovation in other clinical areas and, more general, in the organisation of a variety of health care services as well. I believe that these developments can be well understood when using health technology assessment (HTA) as a theoretical framework. The paper therefore starts with a brief description of HTA, its background in technology assessment in general, and its present organisation in the country of study, Denmark. This section ends with a brief description of studies on the diffusion of health technology. Secondly, the methods of data collection, basically a literature search, are presented. Then the subject of minimally invasive surgery (MIS) is introduced in more detail, followed by a description of the development of the field and the communication channels that are used to transfer knowledge on this technology. Thirdly, the Danish health care system is described in as far as this is relevant for understanding the diffusion of MIS in this country. This is followed by a discussion of the role of the adopter (clinicians, hospitals) in the diffusion of MIS. A brief summary of diffusion studies of health technologies in Denmark precedes the presentation of three case-studies representing different types of technologies generally categorised under MIS: CT and MRI scanning, Extracorporeal Shock Wave Lithotripsy (ESWL) and laparoscopic cholecystectomy). Each of the case studies allows for conclusions to be drawn on issues associated with innovation, diffusion and economic growth relating to this new set of health technologies. The paper is finalised with a general discussion.

2 Technology Assessment, Health Technology Assessment and diffusion of health technology

Technology assessment (TA) was developed in the sixties. TA is seen as a comprehensive form of policy research that examines short- and long-term social

consequences of the application of technology. Thus, technology assessment is an analysis of primarily social rather than technical issues, and is particularly concerned with unintended, indirect or delayed social impacts. The goal of technology assessment is to provide policy makers with information on policy alternatives, such as the allocation of research and development funds, formulation of regulations, or development of legislation. As health technology became an important policy issue in the seventies, mainly due to concerns on its risks and benefits and rising costs of care, it was natural to attempt to apply the ideas on TA to it. Thus, health technology assessment (HTA) is primarily aimed at supporting decision makers in policy and practice on the application of health technology. HTA is an international, multidisciplinary activity, not only focusing on issues of safety and efficacy, but also on the 'value for money' of new health technology or new applications of existing technology. In addition, other aspects of health technologies may be evaluated, including ethical aspects, legal aspects, organisational- and educational aspects, and broader cultural and social aspects. Likewise, study of the diffusion or spread of health technologies in health care systems has been a long-standing tradition in health technology assessment, based on the recognition that it is not just the quality of evidence that determines the diffusion process. Examples of other factors that may have an impact on diffusion include patient demand and marketing efforts of industry (Banta and Luce, 1993). In international literature, the factors influencing diffusion are usually distinguished in four categories (Rogers, 1995). One category focuses on characteristics of the innovation or technology, e.g. its purchasing costs. Another category includes factors related to the adopter, in health care this usually refers to the specialist physician or hospital purchasing the technology. For example, the adopter may or may not be cosmopolitan in outlook, which co-determines his or her willingness to adopt an innovation. A third category relates to factors in the environment, e.g. the financing and organisation of the health care system, Finally, the way in which communication is organised around an innovation has been shown to be relevant for the overall process of diffusion. Examples include the role of international conferences and the activities of opinion leaders. In general, diffusion of health technology is complex and not well understood, and many authors have advocated for more research in this field (Banta and Luce, 1993, Rogers 1995). The factors distinguished by Rogers (1995) will be elaborated upon in the case of MIS in Denmark.

Developments in the recent past with regard to the diffusion of MIS in Denmark have taken place in an environment that is increasingly oriented towards evaluation. In late 1993 the Nordic Cochrane Centre was established in Copenhagen, which has partly focused its activities on evidence-based surgery (Wille-Joergensen and Goetzsche, 2004). The Danish Institute for Health Technology Assessment was established in 1997. Its key function is to implement the National Strategy for HTA issued by the National Board of Health in 1996, which was updated in 2001. The Institute merged with the Centre for Hospital Evaluation in 2001 and now hosts, among other programmes, the national clinical guideline programme (see http://www.cemtv.dk) and a programme evaluating the quality of a number of surgical procedures, e.g. hysterectomy. In addition, three regional HTA centers were established in 1999, covering the eastern, western, and southern part of the country, respectively.

3 Methods

The material presented here is based on a literature search in the major clinical databases, Medline and Embase, covering the period between 1988, when the first laparoscopic minimally invasive procedure, laparoscopic cholecystectomy, started to diffuse, to 2004. Information on the search strategy is available at the author on request. A number of sources with outstanding quality were available for analysis, of which three deserve to be mentioned in particular: 1) a study carried out in 1993 documenting the diffusion of minimally invasive surgery (MIS) in Denmark (Schou 1993), 2) a PhD on health technology assessment and diffusion of health technology, largely focusing on MIS in Denmark, published in 1999 (P.B. Poulsen) and two special issues devoted to MIS in the principal Danish medical journal Ugeskrift for Laeger in 2004. Additional data were collected from the National Board of Health, and from the publication list of the Danish Centre for Evaluation and Health Technology Assessment (CEMTV). Finally, websites of hospitals and medical societies were checked for relevant information.

4 The technology: minimally invasive surgery

An elaborate description of minimally invasive surgery was produced by Banta (1993). He writes that, in the past, surgery was exclusively done by large open

incisions, which gave good visualization of a potential problem and also sufficient room to remove a problem such as a tumour, to tie blood vessels, and so forth. However, already before the advent of minimally invasive techniques, surgery gradually changed. People did and do not like to have large surgical scars on their bodies. In addition, open surgery can be associated with serious short- and long-term complications. New instruments made it possible to do surgery through smaller incisions. Surgeons became more skilful. Therefore, surgical incisions became smaller and surgical techniques changed. Examples of such less invasive surgery include lumpectomy instead of mastectomy in treatment of breast cancer and rectum-saving operations in colon cancer surgery. The pace of change, however, dramatically increased due to the advent of minimally invasive surgery (MIS) in the mid-eighties (Banta 1993). As a consequence, MIS is a field that has gained a great deal of attention. In general, MIS is a rapidly growing area of medical treatment that causes substantially reduced trauma to the person undergoing it. In part, it is made up of changing techniques, but it also depends in most cases on new and advanced technologies, especially vascular catheters, medical imaging devices, and endoscopes. Nowadays, nearly every organ system in the body can be approached by these technologies. Furthermore, gradually a number of tools have been incorporated into endoscopes. Miniature forceps, scissors and tools for tying ligatures were first, and they are still being improved. Within the last 30 years, other advanced tools, including lasers, heater probes, electrocoagulation devices, and cryotherapy devices, have also been incorporated into these scopes. Catheterization, based on developments in cardiac catheterization, has been a diagnostic tool for more than 50 years. More recently, it became the basis for innovative treatment procedures. New imaging techniques are also important in MIS. Imaging techniques have two purposes which interact with each other. One purpose is to identify and characterize a lesion requiring treatment. The other purpose of imaging is to assure that the treatment modality is in the correct location and to monitor the treatment. Imaging makes other contributions to MIS as well. For example, in CT scanning, radiologists have recognized that biopsies could be guided by such imaging. Later, CT scanning and ultrasound were used to guide therapeutic procedures, such as draining abscesses in the abdomen. Drugs can also be installed in certain parts of the body by guided needle. The newer endoscopes are in themselves imaging devices. Perhaps the most important fact about endoscopes is that their images can be projected onto colour monitors, resulting in a

situation where high quality images can be seen in the operating room, and can be observed by participants simultaneously (Banta 1993).

Many MIS procedures are carried out as either day surgery or requiring relatively short hospital stays. MIS has and is expected to continue to reduce the need for hospital beds and is changing patterns of specialization and practice. This trend has been reinforced due to the fact that conventional procedures also tend to improve, allowing reduced lengths of hospital stay. An example is the development of mini-laparotomy for cholecystectomy, which will be discussed later in more detail. This has resulted in a situation where an increasing number of the planned operations to be replaced by minimally invasive procedures are carried out as a day-case, resulting in reduced differences in length of stay of conventional versus MIS procedures (Hirsch and Hailey 1995).

Because MIS has fundamentally changed surgery, its development has been characterized as a 'seminal shift in philosophy', a 'revolution' (Wickham 1993, Himal 2002), and a 'paradigm shift' (Mack 2001). For patients, it holds the promise of improved outcomes manifested as improved survival, fewer complications, and more rapid recovery resulting in quicker return to functional health and productive life (Mack 2001). For the health care sector, MIS holds the promise of increased cost-effectiveness of care. As a consequence, there may be benefits as well for society as a whole. However, evaluation is relatively scarce in this field, so more evidence is needed to substantiate these claims in most cases.

5 Communication channels & establishment of the field

In the late eighties it was felt that an attempt should be made to bring together diverse strands of interests into one recognizable society. The key groups seemed to be surgeons interested in MIS, interventional radiologists, and the instrument manufacturers. A number of interested parties inaugurated the first meeting of a new society in London in 1989, where the group, in order to accommodate radiologists, agreed to the term 'minimally invasive therapy' instead of choosing 'minimally invasive surgery' (Wickham 1993). One year later a new journal was established, entitled 'Minimally Invasive Therapy and Allied Technologies'. In 2000, the Society

was formally changed to 'Society for Medical Innovation and Technology' (SMIT), acknowledging the fact that an increasing range of technological innovations plays a role in the development of MIS (SMIT 2004). In the past decade, a myriad of more specialised societies have emerged in this field as well, both national and international in scope. An example of the latter is the International Society for Minimally Invasive Cardiac Surgery (ISMICS). The ISMICS was formed in Paris in 1997, following a World Congress of Minimally Invasive Cardiac Surgery. A journal was established in 1998, entitled 'The Heart Surgery Forum'. Technological development in this field is extremely rapid, reducing the invasiveness of e.g. coronary artery bypass surgery by allowing operating on a beating heart, eliminating the need for a heart-lung machine (Mack 2001). More recently, the use of robotic surgery systems has started to diffuse widely as it has the potential to further increase the sophistication of minimally invasive procedures in cardiology (Anderson 2004). Another clinical field where rapid technological change can be witnessed is oncology. In these fields, the newly established societies have in common that they provide an effective forum for discussion of technological developments. Virtually all societies organize annual meetings, either nationally or alternating between Europe and the USA. Concurrently, in a number of countries regional centers for minimally invasive surgery have been established that provide opportunities for training and research in a variety of specialties. As a Danish example, Aarhus Hospital (Skejby) hosted the fifth Scandinavian Masterclass in Laparoscopic Urology, in September 2004. From these activities it can be inferred that those who have an interest in MIS have adequate platforms for being informed on the state of the art in highly specialized fields and, increasingly, to receive appropriate training, which is critical in obtaining good clinical results.

6 The environment: financing and organisation of the Danish health care system

The Danish health care system has been characterised as a public and decentralised system, distinguishing between a national level (central government), regional level (counties), and local level (municipalities) (Christiansen 2002). The present organisation dates back to the early seventies. The legal regulation of the Danish health care system is performed though the Danish Parliament. At the central government level, the role of the Ministry of the Interior and Health is largely

administrative. It is responsible for health policy, including e.g. the planning and coordination of services and the development of guidelines and legislation on the provision of services (WHO 2002). The Ministry of Finance plays a key role in setting the overall economic framework for the health care sector. The National Board of Health is responsible for the technical aspects of health care, such as supervising health care personnel and institutions and advising different ministries, counties and municipalities on health issues. The National Board of Health is particularly influential with regard to postgraduate training (WHO 2002), which is important in the case of MIS. The responsibility of financing and running hospitals lies with 14 counties and one hospital authority in the metropolitan area of Copenhagen (the Copenhagen Hospital Cooperation). The private hospital sector is very small. General practitioners are private entrepreneurs but work under contract for the counties (Christiansen 2002). The 275 municipalities take care of the elderly through home help and nursing homes, and are responsible for school dental care, home nursing and a number of preventive services such as those provided by health visitors (Christiansen, 2002).

In 1999, total expenditure on health care in Denmark accounted for 8.4% of GDP (6.9% public expenditure and 1.5% private expenditure) and US$ 2275 per capita (in current prices PPP). About 82.7% of these expenditures were financed by taxes, the rest is paid for through user co-payments (16.2%), predominantly with regard to pharmaceuticals, medical aids, dental care, eye care and physiotherapy, and voluntary supplementary health insurance (1.4%) (WHO 2002). About 80% of public expenditures are financed through the taxation system at the regional and local level but there are no earmarked health taxes. In addition, the state allocates block grants (subsidies) to the counties and municipalities with the aim of both equalizing the budget revenues irrespective of the local income level and of equalizing expenditure in relation to need (Christiansen 2002). Access to GPs and hospital care is free at the point of use for all Danish residents.

The size of the total county and municipal budgets is normally decided after negotiations between the Ministry of Finance and representatives from the counties and municipalities who usually set a ceiling to the total tax revenue or the total budget (the so-called ‘budget cooperation’) (Christiansen 2002). In recent years, besides

limiting overall health care expenditures, the central government has increasingly tended to use these negotiations as a means of influencing the direction of the health care system. It does this by highlighting priority areas such as cardiac surgery, e.g. by means of setting targets for the number of CABG's to be performed (see also the next section). Another clinical area that has been emphasised in recent years is cancer treatment. In addition, extra financial support has been given to reduce waiting times in specific service areas, e.g. elective surgery, combined with waiting time guarantees (Christiansen 2002, WHO 2002). The county councils limit expenditures in hospitals in their jurisdiction by prospective global budgets which are set in negotiation with hospital administrators and based on past performance and modified at the margin to account for new activities, changes in tasks and areas of specific needs as described above (WHO 2002). General practitioners are paid by a combination of capitation fees and fee-for-service. Other health care employers outside the hospitals are self-employed as well, but payment for their services follows a contract between their respective unions and the Association of County Councils (Christiansen, 2002).

There is no national plan or national planning agency, instead the counties and municipalities are required to develop a plan every four years for the coordination of all their preventive and curative health care activity, which needs to be submitted for comments to the National Board of Health, serving as a link between the county councils and the Ministry of Health (WHO 2002). However, as an exception to this rule, there has been a tradition on regulation of transplantation programmes, e.g. renal transplantation and haemodialysis facilities (Andreasen 1988) and liver tranplantation (Hansen and Kirkegaard 2004). In addition, the National Board of Health has issued general guidance on the introduction and evaluation of new health technology, aimed at the hospital level (National Board of Health 1999). In some cases, the attempts of the National Board of Health to centralize low-volume and high-skill treatment to selected hospitals has led to competition between hospitals and between county councils. Another reason why attempts to plan and centralise purchase of expensive technology have often failed is because hospitals received private donations for the purpose of purchasing a specific technology (see case study on ESWL). However, some counties have in the past cooperated in a share system on expensive technology (Schou 1993). The past decade has witnessed a general trend in the Danish hospital

system to centralize treatments (e.g. from local to regional hospitals within one county) and close down a number of small hospitals.

A number of developments seem to slowly erode the position of the counties in the health care system, including the introduction of the opportunity for patients to choose treatment in hospitals outside their county of residence (1993), which was followed by the introduction of DRG rates for the associated procedures, replacing a system of flat rate (per diem) payments (2000). Although it has been predicted that the reforms would lead to a rise in the overall costs of the health care system by attempts to attract patients (from other counties) by offering high-technology treatment (Schou 1993), the overall effect seems as yet to have been limited (WHO 2002, Vrangbaek and Bech, 2004).

In principle, the decentralised aspects of financing and organisation of the Danish health care system may impede the diffusion of minimally invasive therapy in Denmark, as MIS may increase costs of health care services at the municipality level due to the more rapid discharge of patients and increased need of community care services, while potential cost-savings may be realised at the county level. Of course, these cost savings can only be realised after a considerable capital outlay for the initial investment, which often is a problem. Furthermore, it is likely that the tendency of counties to be close to fully self-supporting in terms of the supply of health care services and the absence of an authoritative central planning agency, have contributed to widespread conventional surgical practice variation with sometimes poor quality results as demonstrated by the surgery project of the Danish Centre for Evaluation and Technology Assessment (CE MTV 2004).

7 Characteristics of the adopter

As a general characteristic, Danish clinicians do not introduce new health technology on face-value or simply because a technology is new. Because Denmark is a relatively small country it is impossible to organise randomised controlled trials for all new technological developments on a regional or national basis, so in many cases results from abroad are awaited before adoption decisions are made. As a consequence, adoption of new technology usually follows patterns of adoption and use elsewhere,

but (usually) later in time (Schou 1993, Kristiansen et al., 2002). In case of MIS, Rosenberg (2004) (a surgeon), lists a number of reasons for this phenomenon. Apart from the role of evidence and the tendency to wait until safety issues have been resolved (e.g. the probability of metastasis-inducing spread of cancer cells when performing laparoscopic hemicolectomy in case of colon cancer), he indicates that patient demand for laparoscopic surgery plays a limited role in Denmark e.g. in comparison with the US. This implies that the pressure for change from patients and patient organisations is usually low. Furthermore, he notes that physicians work in a budget-constrained health care (hospital) system, which is impeding adoption of MIS. Although, according to this author, the latter problem by en large has been solved by recent capital injections, more persistent problems relate to education and training.
In a contribution to a global analysis of technological change in management of acute myocardial infarction, Kristiansen et al. carried out a case study in Denmark (Kristiansen et al 2002). It was noted that adoption of coronary artery bypass grafting (CABG) and percutaneous transluminal coronary angioplasty (PTCA) occurred relatively rapid, but that actual use lagged behind most other countries. The former was attributed to innovative physicians who learn about new technological possibilities for their patients and persuade the hospital managements and boards to adopt them. In addition, both cardiologists and heart surgeons were described to actively persuade politicians to increase funding to increase treatment capacity, but with limited success until a number of consecutive, National Board of Health coordinated Heart Plans were launched.

8 Diffusion studies focusing on MIS in Denmark

Relatively few studies on the diffusion of health technology have been carried out. In the eighties and early nineties, Danish researchers contributed to a number of studies that were organised in the European Union, most of which were focusing on highly expensive technologies that were subject to regulation in most participating member states (e.g. Kamper-Joergensen et al. 1988, Stocking 1988, Stocking 1991). These studies were rather descriptive in nature. A study on the diffusion of minimally invasive surgery in five European countries was published in 1993, including Denmark (Banta 1993, Banta and Vondeling 1993, Schou 1993). This study is of particular interest as well as it included both medium- and big-ticket technologies in

different stages of their life cycle. At the time, the most important conclusion of the Danish sub-study was that, although there were marked differences between the ten cases studied in each country, the overall diffusion of MIS was still relatively limited in Denmark compared to the other nations included in the study (Schou 1993). A subsequent study, limited to laparoscopic procedures, by en large confirmed this picture (except for laparoscopic cholecystectomy) (Poulsen et al. 1998, Poulsen et al. 2001). Since then, no comprehensive studies on the diffusion of MIS have been published. More recently, however, articles on the state-of-the-art of MIS in the Danish Journal for Physicians (e.g. Rosenberg 2004) indicate that its adoption and use has become more of an ongoing development. Just as in other countries, MIS seems to have arrived at a stage in Denmark where it is considered here to stay.

9 Three case-studies

For the purpose of the KISA Health study, a few case studies on the diffusion of MIS have been selected, all illustrating particular points of interest. The cases are: CT- and MRI Scanning, Extracorporeal Shock Wave Lithotripsy (ESWL) and laparoscopic cholecystectomy.

CT- and MRI scanning

CT and MRI scanning have been ranked at the top of a list of 30 technologies that were judged by general internists in the US on their relative importance in contributing to health care improvements for their patients in the past 30 years. CT and MRI scanning received a top-rating mainly through the capacity of these devices to reduce uncertainty in diagnosing illness (Fuchs and Sox, 2001). Although the early diffusion of CT and MRI scanners in Denmark is undocumented, in 1988 P. B. Andreasen reported that by 1985 23 scanners were in operation in this country, of which 16 were whole-body scanners and 7 head-scanners only (P.B. Andreasen 1988). The author noted that the distribution of scanners across the country was very uneven, as in some counties whole-body scanners had been installed at the level of district hospitals, whereas e.g. Herlev Hospital, a university hospital with an affiliated oncology centre, did not possess whole-body CT scanning facilities. The author blamed the uneven distribution of the technology to the absence of established

guidelines on the purchase of CT scanners at the national government level, leaving the investment decisions to the discretion of the individual counties. At the time, the first MRI scanner had been installed in Hvidovre (University) Hospital, mainly for research purposes. In the period between 1985 and 1999, diffusion of CT and MRI scanners continued at a modest pace, resulting in a combined total of 81 CT- and MRI scanners combined by the end of 1999 (Karstoft 2004). By that time, a national advisory committee on diagnosis and treatment of cancer recognised the partly unrealised potential of scanning in this clinical specialty, and recommended the total number of scanners to be increased to 134. The Committee published their recommendations on behalf of the National Board of Health. By the end of 2000, the organisation of county councils announced that the recommendations would be realised by the end of 2002. Data from July 2003 show that 73 CT scanners (1 more than expected) and 53 MRI scanners (7 more than expected) were in use in public sector hospitals. In addition, there were 2 CT scanners and 4 MRI scanners in use in the private sector. So in about 3.5 years time the combined number of scanners had increased from 81 to 130. These absolute figures can be standardised as 10 CT scanners per million and about 14 MRI scanners per million population, respectively. This remarkable change has been attributed to an earmarked investment grant of 400 million DKK (about 54.8 million euro) in cancer care in 2000 by the central government. Political motivation for these expenses was fuelled by a general notion that cancer care in Denmark could not live up to care provided in neighbouring countries and that Denmark was lagging behind other countries in uptake of scanning devices (Lindequist et al., 2001). Similar concerns had been voiced earlier on a more general level (in 1988) by Andreasen, related to budget cuts for the hospital sector as part of a cost containment strategy that had its origins in an economic crisis that hit Denmark in the eighties (Andreasen 1988). Karstoft (2004) notes that the increase in the number of scanners has primarily been located in the six cancer centers. But other specialties too have voiced a need to increasingly use these devices, implying a pressure for continued diffusion of scanners in the near future. In summary, the case demonstrates a long history of limited investments in imaging devices in the Danish health care system, counterbalanced by a single capital injection in the year 2000 that has resulted in a marked increase of the diffusion of scanners in more recent years. The case also shows the relatively minor importance of the private sector in imaging technology diffusion. This implies that public hospitals will hardly face any

competition from the private sector in case of slowly adopting particular types of costly new health technologies.

Extracorporeal Shock Wave Lithotripsy

For a number of reasons, the case of Extracorporeal Shock Wave Lithotripsy (ESWL) in treatment of kidney stones is an interesting example in the context of the KISA health studies. Firstly, the idea of using shock waves to fragment stones inside the body, and thus cure patients without even having to touch them, was revolutionary. Secondly, the Danish government initiated its own R&D programme for ESWL, and the organisation of multi-county collaboration in employing a mobile machine was also a novelty. The description originates largely from Schou (1993). She writes that ESWL was used for the first time in Denmark in 1987, and that the procedure became routine in 1989-1990. In 1993 it was estimated that more than 50% of kidney stone patients were treated by this method. Nowadays, virtually all kidney stones are treated with ESWL. In a recent article, Walter (2004) states that the standard open technique, percutaneous nephrotomy (PCN), which was performed several times a week before the advent of ESWL, has become a rare procedure.

In case of ESWL, originally developed in Germany in 1980 by a firm called Dornier, the Danish government attempted to delay its diffusion as early as 1981 in order to favour a Danish second generation machine. The official motives to embark on this activity included the high capital costs of the Dornier machine (18 million DKK), and the conviction that it would be possible to construct a smaller, more practical and cheaper alternative (Holm 1988). To start with, a laboratory model was constructed, which was completed in late 1984, later than originally planned due to financial problems. In 1985 a company was established (NITECH), uniting the original contributors to the project (the Copenhagen County Hospital in Herlev, The State Academic Hospital (Rigshospitalet), the Danish Institute of Biomedical Engineering, and the Technical University of Denmark) with private investors. NITECH and the National Agency of Technology between them funded the project through 'The Industrial Research and Development Fund' (Holm 1988). Again, the project was delayed, and became a source of controversy (Schou 1993). The media played an important part in the process, on the one hand informing patients about the attractive

non-invasive treatment, and on the other hand promoting the forthcoming Danish project. But as a consequence of he delay of the project other machines were purchased in the meantime. So in spite of attempts of central planning, the first ESWL machine was installed by Siemens in 1987 at Bispebjerg Hospital in Copenhagen (free of charge for one year). In 1988 a Pizolit machine was installed in Aalborg (in the north of Jutland), donated by a private foundation. In 1990 a Siemens machine was installed in Aarhus (central Jutland) and a mobile Pizolit (Wolf) was purchased to serve four counties in southern Jutland and the island of Funen. Finally, in 1991, the Danish NITECH was introduced for testing in the two major Copenhagen hospitals that had contributed to its development. Thus, by 1991 a total of five ESWL machines were in use in Denmark (Schou 1993). At that time, however, the market was virtually saturated.

As indicated above, four counties had decided to share a mobile machine. The arrangement was considered fairly satisfactory by most of the hospital departments involved. Each department disposed of the machine for 9 days at a time. The advantages of the arrangement included: avoiding the necessity of choosing where to place a stationary machine; avoiding reimbursement between the counties for this treatment; more physicians and departments could gain experience with treatment; and patients were treated locally. Among other factors, disadvantages of the arrangement included: it took longer time to gain experience with the techniques compared with a situation with exclusive disposal of a machine; and the number of patients to be treated by each physician was relatively low, which may have affected treatment outcome (Schou 1993).

Laparoscopic cholecystectomy

Schou (1993) was the first to describe the initial diffusion of laparoscopic cholecystectomy in Denmark in detail. The procedure was first used early 1991 at Hilleroed Hospital north of Copenhagen. Soon Aarhus University Hospital and the Copenhagen Community Hospital in Hvidovre followed. At the time, according to Schou, most surgeons considered the procedure to be nothing but a smart idea. Less than a year later, the acceptance of the technology had spread very fast and most surgeons had become interested in using the procedure. The reasons why this interest

could not immediately be converted to investments in the technology were predominantly related to budget restrictions. In a very short time, however, funds were made available, increasing demand from the manufacturers to the extent that by mid-1992 most hospitals, regional as well as local, were put on a waiting list to obtain the equipment. The explanation Schou provides for the remarkable decision by the counties to make investment funds available is that they were easily convinced that the procedure would result in cost-savings in the health sector by reducing the length of hospital stay compared with the conventional procedure. In addition, the claimed reduction in productivity costs achieved by more rapid convalescence and earlier return to work allegedly played a role in the counties' decision making. In Denmark, cholecystectomy was a procedure that was traditionally performed in all types of hospitals, both regional and local, and this may also have had an important impact on the interest of the surgeons in the local hospitals, eager not to lose yet another function to the regional hospitals. Media attention and patient demand played a role as well, so all ingredients were present for a rapid uncontrolled diffusion of the procedure. This process was documented and explained in detail by Poulsen et al (1997) in a study on the diffusion of laparoscopic cholecystectomy and four other laparoscopic procedures. The study showed that between January 1991 and August 1995, every surgical department in Denmark performing cholecystectomy had adopted the laparoscopic procedure, with half of the hospitals adopting within 14 months after its introduction in the health care system. In addition to the factors identified by Schou (1993), Poulsen (1997) found that opinion leaders and the associated communication channels, e.g. conferences and related activities, had been very stimulating for the diffusion of this procedure.

The introduction and rapid diffusion of laparoscopic cholecystectomy had taken place without proper evaluation, as the advantages of the laparoscopic procedure, based on case-series, soon seemed convincing to the extent that it was regarded as unethical to organise randomised comparative studies. The process had largely been driven by gastroenterologists, at the expense of general surgeons who, in a reaction to losing patients and in the absence of evidence from randomised controlled trials, adjusted the open surgical procedure to a mini-open laparotomy (characterised by a scar of only a few centimeters). In addition, the post-operation discharge procedure was reviewed, with more intensive follow up explicitly aimed at early discharge (accelerated patient

management). As a consequence, the hospitalisation period after the open procedure was reduced from 7 to 10 days to only a few days (Rosenberg 2004), reducing the alleged differences between both procedures. Rosenberg (2004) interpreted this course of events as a situation where the advent of new technology (MIS) had resulted in innovation of both the original procedure and the daily routine after the operation (until discharge).

In 1997, an assessment of laparoscopic versus open cholecystectomy was published in a joint publication by the Danish Centre for Evaluation and Health Technology Assessment and the Danish Institute for Public Health (Joergensen 1999). The report resulted in a lot of discussion, and subsequently the subject of diagnosis and treatment of gall bladder disease was included in the national clinical guideline programme. A guideline on the issue was published in 2002 (SFR 2002), concluding that laparoscopic cholecystectomy should be treatment of first choice for gall bladder stones, but also concluding that, in skilled hands, the 'mini-open' procedure can be regarded as a treatment option on an equal footing with the laparoscopic procedure. In clinical practice, however, the laparoscopic procedure is the preferred procedure (Kristiansen 2004). Increasingly, case series are reported on patients where laparoscopic cholecystectomy has been carried out on an ambulatory basis, with associated cost savings compared with day-case procedures (Rosen et al., 2001).

10 Discussion and conclusions

We have seen that minimally invasive surgery comprises a set of highly innovative health technologies that have wide ranging consequences for health care systems. It has taken some time, but in 2004 it was concluded that MIS has come to the stage where it can be regarded as an ongoing development in Denmark (Rosenberg 2004). The case of CT-and MRI scanning provides a good example of relatively slow diffusion of a non-invasive, high-cost technology that is regarded of tremendous clinical importance. In an environment characterised by budget restraints, barriers to more widespread diffusion of these diagnostic devices were only overcome after implementation of a national policy plan, in this case the National Cancer Plan. The case of ESWL demonstrates the impact of revolutionary thinking in 'no-touch' treatment of patients, with initial diffusion in Denmark restrained due to a policy that

can be labelled as a case of 'technology-nationalism'. Such a policy can only be successful if the domestic product can be introduced shortly after the original product has become available and the product should of course have some competitive advantages as well (e.g. in terms of price, performance, servicing, training, etc.). The case of laparoscopic cholecystecomy is exceptional in the sense that it demonstrates how fast the diffusion of a new medium-ticket technology can occur (without proper evaluation!) in a situation where all relevant stakeholders agree on the benefits of the new technology. Furthermore, as laparoscopic cholecystectomy gave rise to the development of 'mini-open' cholecystecomy and an accelerated discharge procedure, the case demonstrates how the advent of new technology stimulates innovation in existing procedures (Hirsch and Hailey 1995, Rosenberg 2004).

The decentralised organisation of the Danish health care system seems to have a variety of consequences. On the one hand decentralisation allows counties to be sensitive towards local priorities (Christiansen 2002), but on the other hand the absence of central government legislation on planning of hospital facilities results in a rather uneven geographical diffusion of new health technologies (e.g. Andreasen 1988, Schou 1993). Interestingly, in case of MIS a number of authors, mostly surgeons, have advocated centralisation or at least regionalisation of most procedures, recognising the close relationship between patient load, training level, and treatment outcomes (e.g. Kehlet et al 2004, Wara and Rosenberg 2004). This echoes recommendations of the National Board of Health which, with some exceptions, have not been followed up by the counties (Kehlet et al. 2004). This situation may change as a number of wide ranging reforms are pending after the Danish health sector has been subject to a critical analysis carried out by a Government Advisory Committee on the Health Care Sector. In the second of its two reports, published in 2002 and 2003, respectively, the Committee recommended, among other measures, to reduce the number of counties and to increase the powers of the National Board of Health to ensure a professionally relevant development of the health care sector (Bech, Pedersen and Christiansen 2004). This implies a move away from decentralisation and offers the opportunity for improved hospitals facilities planning. Implementation of these reforms, conditional on Parliamentary agreement, is due in 2007. A smaller number of counties, most likely 8 'health regions', may each have a relatively increased investment budget for new health technology compared to the current 14

counties, so these reforms may foster innovation the Danish health care system in general, whereas in the past structural innovation has much relied on the development of national policy frameworks oriented toward individual clinical specialties, e.g. the National Cancer Plan, the National Heart Disease Plan and the National Diabetes Plan.

In conclusion, MIS represents a coherent set of technological innovations which slowly but certainly are having an impact on the Danish health care system, with spin-offs on the innovative capacity within a number of clinical specialties involved. MIS is definitely to stay in Danish health care, and it can be expected that, gradually, its benefits will be harvested to an increasing extent, benefiting from an environment that is increasingly oriented towards health technology assessment and evidence-based medicine and where pending structural reforms in the health care system are likely to improve the climate towards innovation and improved planning of health services.

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