Chapter 1

Summary and Policy Implications

Chapter 1

Summary and Policy Implications

INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) is revolutionizing the treatment of kidney stones. This technology, which disintegrates stones in the kidney and other upper urinary areas through the use of shock waves, does not require an incision and is immensely attractive to patients who suffer from such stones. Although great uncertainty still remains as to the long-term effects of ESWL treatment, at present it appears to be both effective and highly desirable for many of these patients. Many hospitals and physicians are eager to provide this treatment, and third-party payers of health care are eager to reimburse for it. Yet the arrival of ESWL on the American market has presented a challenge to U.S. health policies and the health care system.

The Federal Government actively influences the development of ESWL technology and its diffusion into the health care system in many ways. Trade policies and monetary policies affect the availability of the Dornier lithotripter, and other ESWL devices manufactured outside the United States, to U.S. hospitals. Science, patent, tax, and other domestic policies affect the willingness and ability of U.S. companies to develop competitive devices. Federal health policies, the focus of this study, govern to a greater or lesser extent the marketing, purchase, payment, and planning for medical technologies, These health policies include the requirements of the Food and Drug Administration (FDA), which affect the manufacture and marketing of ESWL devices. Other Federal health policies relate to the payment and planning for medical services, which affect the acquisition and distribution of the devices.

The lithotripsy device is large and very expensive, It is most comparable in price to major diagnostic imaging equipment. A complete lithotripsy facility, with adjunct cystoscopy rooms, recovery room, and anesthesia capabilities, is comparable to a surgical suite. And a single ESWL unit can serve a large population, analogous to the specialized services of a heart surgery center or a burn unit.

Despite the fact that it is not a "typical" medical technology, ESWL deserves close attention for two reasons. First, it has illustrated a number of ambiguities and problems in the Medicare payment system, and many of the dilemmas it has posed—and still poses—to Medicare also face other third-party payers. These dilemmas may well occur a second time if the technology is successfully extended to treatment of gallstones. Lessons from Medicare's experience with ESWL may also benefit a variety of other medical technologies that, like ESWL, are not easily categorized for the purposes of Medicare payment.

Second, and more importantly, ESWL has great cost-saving potential that may never be realized under current health payment and planning policies. If ESWL is provided in regional centers that are used to capacity, it will cost less per patient to the centers and perhaps to payers than most alternatives. But because ESWL, if available at only a small number of centers, is potentially very profitable to those centers, many hospitals, physician groups, and other organizations wish to be among those who own a lithotripter. ESWL is a very attractive technology to patients, and hospitals and physicians expect to benefit from providing it. Conversely, hospitals without an ESWL unit, and physicians without access to one, expect to lose patients. These circumstances create strong incentives to install and use an ESWL unit, even if competition from nearby ESWL centers means the unit itself will generate little, if any, revenue greater than cost.

This case study analyzes the effects of Federal health policies on ESWL and its integration into the American health care system. As background for this analysis, the study first describes the incidence of urinary stones and the need for stone treatment (ch. 2) and presents a brief overview

[1]The diffusion of a health care technology refers to the extent and manner of its adoption and use by health care providers and patients.

of the literature on the safety and efficacy of alternative treatments for urinary stones (ch. 3). Chapter 4 reviews the evidence on the safety and efficacy of ESWL itself and discusses the effects of the requirements of FDA on its development. Chapters 5 and 6 describe the costs and economics of providing ESWL and the payment policies of the Federal Government, particularly Medicare, that affect the adoption and use of this technology. Finally, chapter 7 examines the effects of health planning policies on ESWL and discusses its future direction and use.

The remainder of this chapter summarizes each of these topics and their implications for Federal policies.

SUMMARY

Urinary Stones

Urinary stones, or calculi, are a familiar phenomenon with known characteristics but with often puzzling origins. Stones of the urinary bladder are common in less developed countries, while stones in the kidney and upper ureter predominate in developed nations, Differences in diet and fluid intake may be partially responsible for this phenomenon. Predisposing factors for developing urinary stones include a past history of stone formation, certain hereditary conditions, and disabilities due to spinal cord injuries (which reduce the body's control over the urinary system). Males and persons of Caucasian ancestry seem to develop stones more readily than others in the population, though this result may obtain partially from sampling error and the fact that men seem to form stones at an earlier age than women.

Although the exact factors that cause the body to alter its metabolic environment are unknown in many cases, several metabolic conditions are correlated with stones. Persons with calcium-containing stones, the most common type, usually have abnormally high concentrations of calcium or uric acid in the urine. Persistent urinary tract infections and the presence of certain conditions and diseases, such as renal tubular acidosis, are also consistent predictors of stones. Medical treatment of metabolic disorders can often reduce the incidence of stone recurrence, and advances in such treatments may affect the number of patients with stones requiring more aggressive treatment.

Urinary stones are quite common. Data on stone incidence in the United States indicate that approximately 3 out of every 2,000 persons annually require hospitalization for urinary stones (196). The rate for men is higher than average, about 2 hospitalizations per year for every 1,000 men in the population; approximately 10 percent of men will form urinary stones at some time in their lives (83). Incidence of stones varies considerably by region, with persons living in the Southeastern United States more likely and those in the West less likely to form stones. There is strong evidence that stone incidence in the United States has increased over time, but whether this trend will continue is still a matter of debate (14).

Estimates of the exact incidence of upper urinary stones in the United States are fundamental to analyses of the impact of stone treatment technologies. Most estimates are from hospital discharge data; these probably underestimate the total number of symptomatic stones, but they may be a reasonable estimate of the number of stones requiring aggressive treatment. The extent of the market for each treatment alternative depends on the extent to which stones that could be treated less aggressively are considered eligible for that treatment. It also depends on the extent to which the alternative is applicable to stones other than upper urinary stones, particularly stones in the lower urinary tract and the gall bladder.

Alternative Treatments for Urinary Stones

ESWL aside, physicians' options for treating and preventing urinary stones have greatly expanded in recent years. Patients with very small stones, which may pass out of the body without assistance, are commonly treated with pain medi-

cation and high fluid intake. Prevention of stones can also be accomplished in many instances with careful diet and a small but growing number of drugs that can help reduce stone recurrence. The willingness of a patient to comply with a long-term strict dietary regimen, however, may be a limiting factor in prevention.

Surgical procedures have been standard treatment for problematic urinary stones for some time. Although traditional open kidney surgery is usually successful, it is associated with a significant risk of complications, and successive surgeries can eventually damage or destroy a kidney. Due to the great expansion in alternative techniques, open surgery is now on the decline, though it will continue to be the treatment of choice in a small proportion of cases not suited to other approaches.

Transurethra1[2] manipulation of stones can often be used to extract lower urinary stones without an incision, as instruments are passed up the urethra to the bladder and lower ureter. Simple catheterization (insertion of a tube up into the urinary tract) may also induce a stone to pass. Transurethral manipulation, and particularly catheterization, is frequently used in conjunction with ESWL.

Percutaneous procedures, which require only a small incision and an established passageway to the stone through the intervening flank tissue, are a recent addition to the urologists' armamentarium. They carry about a 4-percent risk of significant complications (166). Their benefits over traditional open surgery include reduced hospitalization and convalescence and, in most cases, less expense. Percutaneous fragmentation and extraction of stones is sometimes performed either before or after ESWL for very large renal stones. Its use, either alone or in combination with ESWL, has increased dramatically in recent years and is still expanding rapidly.

A variety of tools are available to fragment and/or extract stones in either transurethral or percutaneous procedures. Mechanical crushers have been used but are rare; special forceps and baskets to extract stones are much more common. Dissolution of stones through prolonged direct application of drugs has also been used but is not widely accepted. Combination therapy of dissolution treatment and ESWL has been tried (149).

Two methods of fragmenting and removing stones with power tools are electrohydraulic and ultrasonic lithotripsy. Both tools are incorporated into probes that are inserted to the point of the stone. Electrohydraulic lithotripsy, which relies on shock waves produced by a spark to fragment stones, has been most successful in transurethral removal of bladder stones (108). Ultrasonic lithotripsy, in which the fragmenting energy is produced by an ultrasound device, has been more commonly used in percutaneous treatment of renal stones. Other power lithotripters, utilizing laser energy or microexplosion techniques, are currently under investigation but are not approved for marketing in the United States.

ESWL: Efficacy, Safety, and Regulation by the Food and Drug Administration

ESWL is a very new technology with characteristics unlike any other treatment for stones. Approved by FDA only since December 1984, for treatment of upper urinary stones, the Dornier lithotripter uses shock waves produced outside of the body to fragment stones without an incision. Stones are pinpointed during the procedure by an X-ray system that is part of the device. Only one manufacturer, Dornier Medical Systems of West Germany, presently has FDA approval to market the device, but several other companies around the world are developing their own models.

Despite concern in animal trials about damage to lung and other tissue, experience with ESWL thus far demonstrates a very low rate of complications with the procedure.[3] The most common

[2]This study includes as transurethral procedures those procedures that are transureteral as well, i.e., require that instruments be passed through the urethra and bladder and up into the ureter.

[3]Two patients have died under circumstances associated with ESWL. One patient died of a heart attack during the procedure during clinical trials of an early ESWL device model in West Germany. However, the cause of the heart attack was determined not to be related to the application of shock waves. The second patient, a U.S. patient about to undergo ESWL, died of anesthesia complications in 1985 (203).

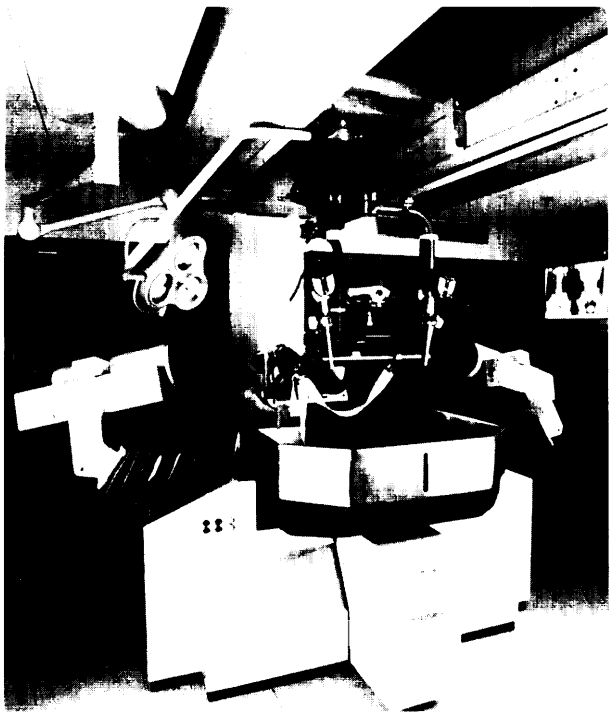

Photo credit: Dornier Medical Systems, Inc., Marietta, *GA*

As of April 1986, Dornier Systems of West Germany was the only manufacturer of ESWL equipment with approval to market the technology.

side effects of ESWL are pain and bloody urine; the former is treated with medication in about two-thirds of patients in the United States undergoing ESWL, and the latter usually resolves without treatment. Radiation from ESWL is higher than that from X-rays associated with standard open surgery but lower than that from percutaneous procedures.

Since the Dornier lithotripter was a new device, substantially different from any technology marketed before 1976 (when the Medical Device Amendments were enacted), the lithotripter had to obtain FDA approval before it could be marketed in the United States. While awaiting approval, the device underwent clinical trials at 6 U.S. hospitals to support data from over 2 years of clinical trials in West Germany. Approval was granted in December 1984, 10 months after the first ESWL device was installed in the United States.

ESWL has already emerged as the preferred treatment among many urologists for most upper urinary stones. It is estimated to be effective, alone or in combination with other therapies, in treating up to 95 percent of the patients for whom it is used, and the majority of patients treated with ESWL show no signs of stones 3 months later. As many as one-quarter of ESWL patients may require repeat or adjunct procedures; these patients often have stones that are large, located in the ureter, or accompanied by a urinary tract infection. Over 50,000 people worldwide had been treated with ESWL as of October 1985 (81), and the number has increased substantially since.

ESWL technology has continued to advance at a rapid pace. At least three American manufacturers are developing their own ESWL devices, although as of December 1985 only one had received permission from FDA to begin clinical trials. At least one French device is also in clinical trials in France. It is unlikely that any devices competing with the Dornier lithotripter will be available on the U.S. market before the end of 1986. Dornier itself is developing an ESWL device that will fragment gallstones; the device has begun clinical trials in West Germany.

The impact of Federal premarket approval policies may be felt by manufacturers developing ESWL devices to compete with the Dornier device. Some of the alternative devices being developed are significantly different from the Dornier device in the source of the shock wave, the path through which it travels, and the imaging system. Although manufacturers would probably undertake substantial clinical testing of new ESWL devices in any case, for marketing purposes, FDA requirements for testing and data collection will probably encourage more rigorous and extensive testing than would otherwise have been done. These requirements will help ensure the safety of new ESWL devices, but an unintended effect of premarket approval policies maybe to retard the speed with which competitors can get their devices to market to compete with the Dornier device.

The Costs and Economics of ESWL

An important characteristic of ESWL is that it is very costly to purchase but can save overall medical expenditures if used efficiently. In 1985, the cost of purchasing and installing a Dornier

lithotripter was approximately $2 million, depending on the exchange rate and on extent of renovation and building needed for the facility. Manufacturers of alternative extracorporeal lithotripters under development report anticipated purchase prices of $400,000 to $850,000 for their devices; how these devices will compare in quality to the Dornier device is still unknown. The costs of operating a lithotripter will probably vary less among upcoming and established models. The most likely source of future variations in operating cost would be the development of a longer lasting and less expensive power source for the shock wave. Because of the high fixed costs of performing ESWL, per-patient costs decline dramatically as the number of patients treated increases.

The high fixed costs of ESWL, combined with its use for a single, definable population (those with urinary stones), make this technology one that may be most appropriately and efficiently provided in a few regional centers. Observers have predicted a "need" for ESWL of as few as 17 units (155) and as many as 175 units (11), depending on how many urinary stone patients are assumed eligible for the treatment and how many patients per year each unit treats. Dornier had already installed 50 ESWL units by the end of 1985 (125), equal to the median estimate of units "needed" as calculated by the Blue Cross and Blue Shield Association (14), The attraction of this technology to patients, and thus to providers, has generated concern that hospitals and other purchasers may overpurchase ESWL units, leading to higher costs to payers and to the ESWL centers themselves.

The cost to physicians of performing ESWL is difficult to define, because of the problem in valuing time and experience. [4] Physician charges for ESWL, approximately $1,800 to $2,000 for single treatments, have been based on their charges for open surgery. However, ESWL will probably be less expensive for physicians to perform than open surgery or percutaneous lithotripsy in the long run, because it appears to require less physician time. If payments to physicians for ESWL are equivalent to those for invasive procedures, physicians are likely to have strong financial incentives to gain access to, and perform, ESWL. These incentives are strengthened by the attractiveness of ESWL to patients, who may seek out physicians performing the procedure.

An attractive feature of ESWL is the potential for minimizing or eliminating hospitalization. ESWL is being performed on ambulatory patients at some centers where patients have adequate medical and social support, such as easy and rapid access to urgent care services for pain medication. Another important consideration for patients is the short recuperation time from ESWL. Most patients can return to normal activity in less than a week of the procedure, minimizing work time lost. Alternative surgical technologies for removing stones can involve back-to-work delays as short as 1 week (for percutaneous lithotripsy) and as long as 6 weeks (for open surgery) (129,170).

Comparing total institutional and professional costs of alternative treatments for upper urinary stones is difficult because no studies of the range of alternatives available have been performed on randomly chosen or well-matched patients. Independent studies of total historic charges in two hospitals, however, combine to suggest that ESWL is usually less expensive than alternatives when performed alone. Reported charges indicate that one-stage percutaneous procedures may sometimes be less expensive than ESWL, but since neither institution performed both procedures, this conclusion is a tenuous one. Total charges for stone removal and associated hospital services in these studies were higher for open surgery than for either ESWL or most percutaneous methods.

ESWL and Federal Payment Policies

Federal payment policy exerts its *greatest influence* through the Medicare program, both because of Medicare's actual payment methods and levels and because it is often a model for State and private payment for health care services. Medicare has covered ESWL provided in hospitals since March 15, 1985.

[4] "The distinction between costs and charges is often unclear in the medical literature. "Costs," as used here, refers to resource costs of the provider of services. These are inputs such as physician time, labor and administration costs, construction and depreciation, and the costs of medical devices and drugs, "charges," on the other hand, are essentially "list prices" assigned by the provider (53). Because a provider may charge more than its costs for one service to make up for losses in another service, charges are not necessarily directly related to costs.

Medicare payment for the operating costs incurred by hospitals for inpatients is made under the Prospective Payment System (PPS), which pays a set rate for each of 469 diagnosis-related groups (DRGs). Because ESWL is unlike any current invasive procedure, its use as the sole procedure places a patient in one of two DRGs that include most medical treatment for upper urinary stones. These DRGs pay considerably less than do the DRGs for surgical treatment for urinary stones, and thus the payment a hospital receives for providing ESWL is considerably less than the payment it would receive for providing surgery. Payment for these medical DRGs is likely to cover actual operating costs for a patient only if that patient has a short hospital stay and if the hospital is very efficient, treating a large number of ESWL patients.

Capital costs are not incorporated into PPS, but are paid by Medicare according to its share of those costs. At present the capital costs of purchasing an ESWL device are quite large, and if capital costs become reimbursed as some percentage increase in current DRG payments (as has been proposed), the DRG payment might not cover ESWL costs even for hospitals providing ESWL efficiently. The extent to which this payment system would discourage purchase of ESWL devices depends on the mechanisms used by hospitals to evaluate capital investments and the development of less expensive ESWL devices.

Medicare will pay for ESWL provided to hospital outpatients but not for the facility costs of ESWL provided in other ambulatory centers. Experience with ESWL provided to ambulatory patients is small but growing. If ambulatory ESWL becomes widely accepted, there are likely to be incentives for hospitals to encourage physicians to treat patients as hospital outpatients, since payment for these services is currently based on the costs of providing the services rather than on a DRG rate. Coverage of ESWL provided in ambulatory surgical centers (ASCs) requires a separate decision by the Health Care Financing Administration (HCFA) to include ESWL on the list of procedures payable by Medicare in this setting. Even if ESWL were covered in ASCs, however, these facilities would have little financial incentive to perform ESWL on Medicare patients at current Medicare payment rates for procedures in this setting; the highest ASC payment rate for a single procedure is $336.

The issues ESWL raises regarding Medicare physician payment are somewhat different from those regarding hospital and ASC payment. Medicare pays physicians the “approved charge” for covered services, an amount calculated from the actual and historical charges for each service. Because ESWL is a new technology, there is no charge history for it. Some urologists have argued that performing ESWL should be reimbursed at the same rate as performing surgery for upper urinary stones. Medicare carriers in the first States with ESWL have generally chosen to reimburse at a level slightly below this rate; HCFA is suggesting that a reasonable rate for the procedure may be quite a bit lower than charges for surgery. A problem with the current Medicare payment method is that, although the costs of performing a new procedure often decline over time, charges tend to remain at initial high levels or rise. Alternative payment methods currently under discussion, such as fee schedules, payment for packages of services, and cavitation payment, might provide a context for more systematic reevaluation of payment rates. Alternatives in which physician payment rates are unchanged by the treatment chosen, such as cavitation payment, might also promote the least costly of the range of appropriate treatments for any given patient.

Federal payment policies can have a substantial effect on ESWL. Although Medicare patients are a minority of those persons who have stones, these patients may be more likely than younger or more able-bodied persons to be recommended for ESWL treatment because Medicare patients are at a higher risk of complications from surgery. Medicare policies, through the level of payment for ESWL treatment, can have a significant impact on patient access; high payment levels might encourage hospitals to provide the technology, while low levels might discourage purchase of ESWL units and the provision of ESWL services to Medicare patients. However, high hospital payment levels could also encourage the overpurchase of ESWL units, driving the costs of treating each patient upward because the purchase cost of each unit would be distributed across only a few pa-

tients. Furthermore, under Medicare's current physician payment method, initial payments to physicians that are comparable to rates for surgery may encourage provision of ESWL to Medicare patients, but such payments have tended to remain high even after costs declined and a technology was widely provided. A payment method that incorporated subsequent review or occasional renegotiation of prices, such as through contracting with individual ESWL centers for the care of Medicare patients, would be more successful at reducing payments as costs declined.

The Veterans Administration, the Department of Defense, and the Indian Health Service (IHS) are also significant Federal purchasers of health care. The Veterans Administration is installing one donated Dornier lithotripter and plans to purchase two or three more in the near future, to be situated at centers serving a high number of spinal cord injury patients *(102).* The Department of Defense operates military hospitals through its Armed Services branches. It has not yet purchased a lithotripter. IHS similarly operates a number of hospitals for its own client population. Its hospitals, however, are primarily small rural ones; none now owns a lithotripter and none is likely to acquire one in the near future. In some areas, IHS also contracts for certain services that are available in community hospitals but not in IHS hospitals. Where urgent stone treatment is such a service, an IHS beneficiary might have access to ESWL if the contracting community hospital provides this service.

The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), operated by the Department of Defense, provides health insurance for dependents of active members of the Armed Services, for retirees, and for the dependents of retirees. Although CHAMPUS provides strong incentives for its beneficiaries to receive care at military hospitals, beneficiaries may in some cases also be reimbursed for care in the community. CHAMPUS pays for physician services on the basis of "reasonable" charges and is currently paying the charges submitted by physicians for ESWL until it has a sufficient experience with these charges to do otherwise (69).

Effects of Federal Policies on Planning for ESWL

The Federal Government affects health care planning both indirectly, through payment policies, and directly, through planning regulation and funding. It regulates the acquisition of major medical equipment in two ways: through the section *1122* provision of the Social Security Act (Public Law 92-603) and through the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). Section 1122 permits the Department of Health and Human Services to enter into voluntary agreements with States. These agreements allow Medicare and Medicaid to withhold certain capital-related payments for patient care in which major medical equipment was used if the acquisition of that equipment was not approved by a State planning agency. If a State certificate-of-need (CON) law is in effect, section 1122 is largely redundant. However, unless capital costs are incorporated into PPS by October *1986,* or Congress passes some alternative legislation, section *1122* review will become mandatory in every State, providing Medicare with potential grounds for denying capital payments for ESWL in some cases.

The Health Planning Act required States to pass regulatory planning laws in order to receive certain Federal health-related funds. These State CON laws were to require all hospitals and other specified institutions wishing to add facilities or acquire major equipment to receive prior approval from a State planning agency. Some States regulate the acquisition of certain medical equipment by physicians' offices as well. In recent years Federal enthusiasm for the State CON programs has waned, and the penalizing provisions of the Health Planning Act have not been enforced.[5] As of December 1985, eight States had no CON program at all.

CON laws in the past have not been found to be particularly successful at restricting acquisition of expensive equipment. They are unlikely to be sucessful overall in preventing overpurchase of ESWL, but in a few cases the State planning proc-

[5]On Feb. **4, 1986,** the House of Representatives passed a bill (HR 3010) reauthorizing financing for health planning but terminating such funding after the current fiscal year, which expires Sept. **30, IQ86.**

ess seems to be facilitating some innovative arrangements to share the technology. The local planning and purchasing arrangements for ESWL are enormously varied. In some areas, such as Ohio, the existence of CON laws seems to encourage hospitals and physicians to share the purchase and provision of a single ESWL unit (113). In other areas, such as southwestern Pennsylvania, health planning agencies have been unsuccessful at encouraging sharing (36). Instead, agencies are rationing permission to acquire ESWL by approving only one or two applications in order to discourage overpurchase, awarding lucrative near-monopoly rights to those centers. Still other areas, such as Chicago, are apparently unable to limit the number of ESWL units even in this way.

Planning for ESWL and anticipating its future are complicated by the existence of a market that is changing on five fronts:

1. advances in preventive technologies for urinary stones,
2. improvements in invasive treatments,
3. emergence of devices competitive with the Dornier lithotripter,
4. greater experience in using ESWL, and
5. modifications in the Dornier lithotripter itself.

Of these, improvements in invasive treatments and increased experience in the use of the Dornier lithotripter will have the most immediate effects. Competitive devices and extended applications of the Dornier lithotripter may exert some effect on the market in a year or two. Preventive technologies could have major effects, but their impact is neither certain nor imminent.

CONCLUSIONS

The available evidence to date suggests that, relative to alternative invasive technologies, ESWL for upper urinary stones is equal or better on safety and efficacy grounds, when performed by an experienced physician in a hospital setting. The rapid expansion of the technology into ambulatory settings offers opportunities to provide ESWL at lower cost than at present. However, safe ambulatory ESWL requires the availability of transportation to appropriate emergency care after the patient leaves the ESWL center, as well as appropriately coordinated followup care by the patient's own urologist. Ambulatory treatment will not be appropriate for many patients who lack access to these services, and its quality compared to the quality of ESWL in inpatient settings has not yet been thoroughly evaluated.

Considerable research remains to be done regarding the appropriate use of ESWL instead of, or in conjunction with, endoscopic procedures for upper urinary stones. Percutaneous lithotripsy has evolved very rapidly, side by side with ESWL, and is being performed in some centers with results comparable to those obtained with ESWL, at comparable cost. As ESWL is applied to lower urinary stones, the appropriate use of ESWL vs. transurethral procedures will also become an area requiring clinical scrutiny. In any case, evidence suggests that open surgery is no longer the most appropriate treatment for most urinary stone patients.

Substantial uncertainty regarding the long-term use of ESWL remains. ESWL as currently performed includes significant ionizing radiation; the development of high-resolution ultrasound imaging equipment may reduce this potential long-term danger. More difficult to assess are the implications of any renal damage that might develop in the long run for patients who undergo repeated ESWL for stones, or a single procedure with a high number of shock waves. No evidence regarding this potential danger exists.

The United States may house enough Dornier lithotripters to serve the domestic population by the time other manufacturers can bring their devices to market; indeed, by some calculations, the necessary number has already been reached. More devices will improve patient access, but they will also raise both the costs to hospitals (and other

centers) of treating each patient and, under current payment arrangements, most likely the expenditures of payers. Conversely, localization of ESWL to a few regional centers may lower per-patient cost but implies more difficult access to those patients living at great distance from these centers. As with any expensive and sophisticated technology, this problem will be especially acute for rural inhabitants, such as many American Indians, since small rural hospitals (including IHS hospitals) will not be able to afford or justify acquiring ESWL capabilities,

Hospital managers and physician groups may urge the purchase of ESWL units despite the problems that may be encountered with oversupply of the service, particularly if the payment rates of Medicare and other payers are generous, On the one hand, if a facility acquires an ESWL unit in an area that produces a sufficient stone population to support the unit, that facility will reap both prestige and profits. Furthermore, by not acquiring the device, a facility may lose a significant proportion of its patients to other facilities in the area that do provide ESWL. Hospitals may wish to acquire ESWL because they compete for patients directly, and because they compete for physicians as a way of drawing the patients referred by those physicians. These considerations are strong incentives to purchase the machine, despite the fact that if many facilities in one area provide ESWL, they will all have small caseloads and consequently high costs and low profits or losses, Furthermore, these incentives operate to some extent even if payment rates are low, exacerbating the low or absent actual financial gains. In theory, either payment or planning policies could prevent overpurchase of ESWL and assure a distribution of units consistent with population size and stone incidence. In practice, neither will probably fully achieve these goals.

Finally, the combination of payment and planning effects may have a significant effect on the urology specialty. In any community in which not all urologists have access to, or are trained to use, ESWL, the urologist to which a patient is referred may have a strong influence on the treatment received, Urology may develop a "subspecialty" of those physicians who can perform ESWL and have access to ESWL units. Such a development could have positive implications for the quality of care afforded those patients receiving ESWL, since their ESWL physicians would be highly experienced. However, it might result in great variations in treatment for the same indications, if urologists who do not have access to ESWL units are reluctant to refer their patients to urologists who do. The incentives would be for urologists without access to ESWL to underprescribe this treatment for their patients, perhaps by routinely performing surgery on younger patients with first stones. Conversely, urologists with access to ESWL would have an incentive to overuse it, perhaps by recommending the procedure when medical treatment might be sufficient.

Universal access of urologists to ESWL is no panacea, however. In areas where a large number of urologists have access to an ESWL center, patients have the greatest potential access to ESWL through their urologists but could receive lower quality treatment if each urologist does ESWL only a few times a year and is consequently less proficient at the procedure.

ESWL exemplifies the service specialization and regionalization of tertiary care, as "stone treatment centers" specializing in urinary stone care proliferate. The lessons learned from current payment and planning experiences may well be applicable again as ESWL technology is turned toward treatment of gallstones, involving an entirely new set of physicians and other providers and requiring new payment levels and a new assessment of the appropriate role for ESWL, The fact that ESWL for gallstones is likely to require a dedicated device, at least in the short term, suggests that its diffusion may parallel that of ESWL for urinary stones.