Chapter 8

Technological Change

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INTRODUCTION

The effects of Medicare's prospective payment system (PPS) on the three critical aspects of health care previously discussed in this report—cost, quality, and access—depend to a large extent on its effects on the use of medical technologies and, more generally, on the process of technological change in medicine. The decision to develop or use one technology rather than another affects the availability of their benefits to patients and the level of health care costs to payers.

The process of technological change occurs in two stages (27). The first stage—research and development (R& D) —includes three phases:

- Basic *research* —original investigation whose objective is to gain knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications in mind **(368).**
- *Applied research* — investigation whose objective is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met **(368).**
- Development —systematic use of the knowledge or understanding gained from research in the design and development of prototypes and processes (315).

The second stage—the diffusion of a medical technology into the health care system—has two phases: the initial phase in which decisions are made to adopt (or reject) the technology, and a subsequent phase in which decisions are made to use the technology **(27).** Decisions regarding the *adoption* of a medical technology require that knowledge about the technology be communicated to physicians, hospital administrators, and purchasing departments. *Use* of the technology, once acquired, depends on such factors as medical indications, physician training, concerns about malpractice suits, the organization of medical care, and payment for medical services **(27).**

Technological change, in health care or in any other field, is influenced by a wide variety of economic, social, and organizational conditions. The individual effects of each are difficult to separate, and the effects of Medicare payment policies are similarly difficult to distinguish. The purpose of this chapter is to discuss strategies for evaluating the effects of Medicare's diagnosis-related group (DRG) based PPS on technological change in medicine,

[1]Medical technologies, as defined by OTA, are the drugs, devices, medical, and surgical procedures used in medical care, and the organizational and supportive systems in which such care is provided (304),

POTENTIAL IMPACTS OF PPS ON TECHNOLOGICAL CHANGE

Potential PPS Impacts on Six Emerging Technologies

As a prelude to the discussion of the way in which the development, adoption, and use of technologies can affect, and be affected by, Medicare's DRG-based PPS, this section describes six emerging technologies and the manner in which they interact with PPS:

- extracorporeal shock wave lithotripsy (ESWL),
- percutaneous transluminal coronary angioplasty (PTCA),
- implantable infusion pumps,
- intraocular lenses (IOLs),
- therapeutic drug monitoring, and
- thrombolytic therapy for acute myocardial infarction.

These technologies illustrate the variety of ways in which PPS must adapt to the introduction of new technologies and some of the dilemmas the system must face. They also illustrate the potential effect of DRG payment levels and classification methods on the adoption or abandonment of technologies.

Extracorporeal Shock Wave Lithotripsy

ESWL is a recently developed method of breaking up kidney stones through the use of shock **waves,** without a surgical incision (344). The lithotripter used in this procedure was developed by Dornier Systems of West Germany and is currently manufactured only by this company. Because of its extensive development abroad, this device arrived virtually full-fledged on the American market. It was approved by the Food and Drug Administration (FDA) in December 1984 (343), and Medicare coverage followed shortly thereafter (285). FDA approval of the Dornier lithotripter is only for upper urinary stones, although ESWL has the potential to be used for lower urinary stones and gallstones in the near future. These uses would greatly expand the market for the technology.

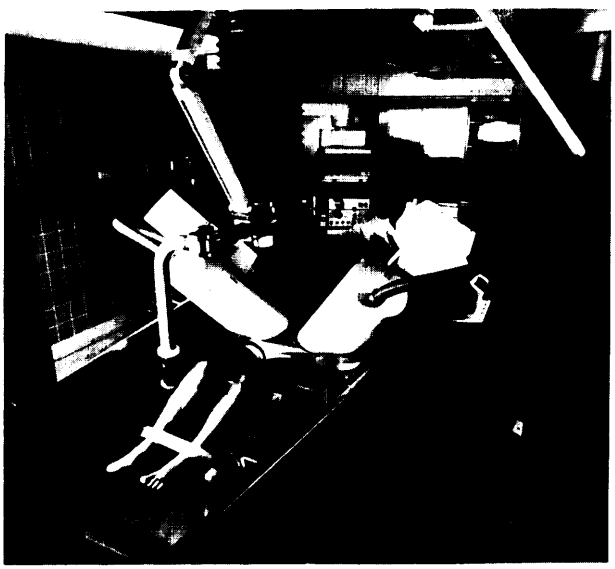

Photo credit Dornier Medical Systems, Inc , Marietta, GA

The extracorporeal shock wave lithotripter breaks up kidney stones through the use of shock waves, without a surgical incision. Dornier Systems of West Germany developed the device and is currently its only manufacturer,

Because of its noninvasive nature, the Dornier lithotripter is being considered by some hospitals for use on outpatients who can be available for pre- and post-procedure observation and testing. Even for inpatients, the hospitalization time for ESWL is less than that for alternative minor surgery procedures and about one-third that for major kidney stone surgery **(6).** The Dornier lithotripter is expensive to purchase, but if used to capacity (treating over 1,000 patients per year), it can lower overall hospital costs.

The dilemma that has surrounded ESWL and PPS concerns the manner in which the procedure should be coded into a DRG. Since ESWL is a new technology, there is no procedure code specifically intended for it in the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) (see box 8-A). During the brief investigational stage of the technology in the United States, the American Hospital Association (AHA) recommended that hospitals simply choose a code that was agreeable to any third-party payers covering the procedure **(65). Now,** for the purposes of Medicare reimbursement, hospitals must assign ESWL the same code as ultrasonic lithotripsy (59.95), the only procedure code available in the present ICD-9-CM coding system that represents stone disintegration. This code, when reported without a corresponding code for a surgical incision or other invasive procedure,[2] results in a patient's assignment to DRG #323 or #324, the medical DRGs for urinary stone treatment.

ESWL highlights the problems with using the ICD-9-CM coding system, designed for clinical and statistical purposes, as a basis for payment. It also illustrates the problem with basing the amount of the payment on a distinction between medical and surgical procedures. If ESWL were classified into a surgical rather than a medical DRG, payment for the procedure under PPS would approximately doubles If no other decision factors were involved, the low payment level

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'Normally, the code for ultrasonic lithotripsy is used in conjunction with a code for incision, indicatin$_g$a minor surgical ("percutaneous") procedure in which an ultrasonic lithotripter, a small endoscopic device, is used to fragment the stone before removal. Use of a code for incision as well as lithotripsy results in a higher paying surgical DRG assignment.

3$_A$third longer term alternative for ESWL under PPS is the creation of a new code and a new DRG for the procedure.

for ESWL might discourage some hospitals from adopting the technology or from using it for Medicare patients. (Of course, a low level of payment might prevent overpurchase of the lithotripters as well.)

However, the level of DRG payment is only one of several economic factors that will help determine whether the technology is adopted, whether Medicare patients have access to it, and whether outpatient ESWL becomes common. The contemplated incorporation of capital costs into DRG payments and of outpatient services into PPS will be of equal or greater importance, because the main financial impact of the lithotripter is the initial $2 million capital cost of its installation. And in the end, factors such as non-Medicare reimbursement for the procedure and the attractiveness of ESWL to patients may well overshadow all Medicare effects on the diffusion of this technology into the health care system.

Percutaneous Transluminal Coronary Angioplasty[4]

PTCA is a technique developed to mechanically open coronary blood vessels affected by arteriosclerosis, a disease commonly known as "hardening of the arteries. " It has excited interest because the only other widely available means of treating this kind of arterial obstruction, aside from medical treatment, has been coronary bypass surgery, an expensive procedure.

PTCA is suitable for only a small subset of patients with coronary artery disease. However, the treatment is successful in restoring blood flow in the arteries of over half the patients that receive it, and success rates rise considerably with appropriate patient selection and increasing experience of the person performing the procedure (124,163,200)-

The overwhelming advantage PTCA holds over bypass surgery is its substantially lower cost. A study of 11 institutions across the country found that the average charge for PTCA (and the associated hospital stay) was approximately one-half to one-third that for coronary bypass surgery (153). Another study at a single institution compared long-run charges of the two procedures (242). It found that even considering complications and the need for follow-up procedures (PTCA or surgical) in many of the PTCA patients, total expenditures for angioplasty were 15 percent lower after 1 year than total expenditures for bypass surgery.

Under current coding conventions, PTCA performed as the principal procedure on *a* patient places that patient in a high-paying surgical DRG, **#108.** Because this DRG also includes many more costly surgical procedures, it is likely to reward hospitals that perform PTCA. This apparently generous payment for PTCA has led both the Inspector General's Office and the Prospective Payment Assessment Commission (ProPAC) to recommend that the procedure be reclassified into a lower paying surgical DRG, #112 (238). In order for such a reclassification to take place, the computer program used by Medicare intermediaries to assign DRGs must be updated. In the interim, as the Health Care Financing Administration (HCFA) implementation the recommendation, fiscal intermediaries must be instructed to flag the ICD-9-CM code that includes the PTCA procedure; to check with the hospital to see if the procedure performed was actually PTCA; and to assign the lower paying DRG in the event that the procedure was PTCA (238).

Other economic factors besides the level of DRG payment affect incentives to perform PTCA. For instance, if PTCA is unsuccessful, bypass surgery may still be necessary. If the bypass surgery must be performed during the same hospital stay, the hospital will get paid only the DRG rate associated with the surgery. This incentive should generally work in a positive direction, since hospitals that have the highest success rates with PTCA have the greatest incentive to use the technology.

Implantable Infusion Pump[5]

The implantable infusion pump was developed to allow delivery of a drug at a constant flow rate

[4]This discussion is based on N. R. Powe, "Percutaneous Translum inal Coronary Angioplasty: Efficacy, Cost, and Effects of Pro spective Payment, " prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, July *1985.*

[5]This discussion is based on S. Yavner, D. Yavner, and S,N, Finklestein, "Medical Technology and DRGs: The Case of the 1mplantable Infusion Pump, " prepared for the Office of Technology Assessment, U, S. Congress, Washington, DC, December 1 Q84

Photo credit Infusaid Inc , Norwood, MA

The implantable infusion pump allows the constant delivery of a drug to a selected site in the body.

to a selected site in the body. Continuous fixed-rate drug delivery is medically desirable for treating a variety of clinical conditions, including diabetes and cancer. The implantable infusion pump permits stable circulating drug levels, and it allows high concentrations of a drug to be delivered directly to a specific site without harmful effects on other parts of the body. Furthermore, it has the potential to eliminate prolonged hospitalization and problems associated with external pumps and catheterization systems.

One manufacturer, Infusaid, currently has FDA approval for several implantable pump models to be used for infusion of heparin, morphine, and three anticancer drugs. Medicare approved coverage for the implantable pump in September 1984, but coverage is limited to use for cancer chemotherapy (331).

The full cost implications of the implantable pump are still unclear. At present, the pump appears to be cheaper per year than traditional chemotherapy, primarily because users have shorter hospital stays. However, the cost of the initial surgical implantation of the implantable pump is considerable. Thus, despite its potential quality advantages, the implantable pump appears to be more expensive than externally worn infusion pumps.

Since the implantable pump has a variety of current and potential applications, its use may place a patient in any of several DRGs. To further complicate DRG assignment, there is no single code that adequately represents the surgical implantation of the pump, its major cost. And if the primary procedure is coded as "infusion," the patient is placed into a medical DRG with a low payment rate, rather than a surgical DRG with a higher one. There is apparently a great deal of confusion among hospitals about what codes are appropriate at present. Given these ambiguities, PPS cost-minimizing incentives will probably act to inhibit rather than encourage widespread adoption of the implantable pump as standard therapy for its many potential uses.

Intraocular Lenses[6]

IOLs, lenses that are implanted directly in the eye to replace a natural lens, have become the preferred method of restoring sight to patients after cataract surgery. The alternatives, contact lenses or glasses, are considered less desirable for most patients because of inadequate vision correction or difficulty in handling and wearing contact lenses (10).

Although IOLs have been available since the 1970s, improvements in the lenses themselves and in the surgical procedure to implant them have only recently made them the treatment of choice for most cataract patients. The number of IOLs implanted per year nearly tripled between 1980 and 1983 (227), and more than 80 percent of patients now receive IOLs after cataract extraction (238).

IOLs are thus an example of a technology, recently established as a standard procedure, that is both cost-raising and quality-enhancing compared to the alternatives. The current reimbursement for DRG #39 (lens procedures) is based par-

[b]This discussion is based on M, E. Farber, "DRG Payment and Medical Technology: DRG 39, " prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, December 1985,

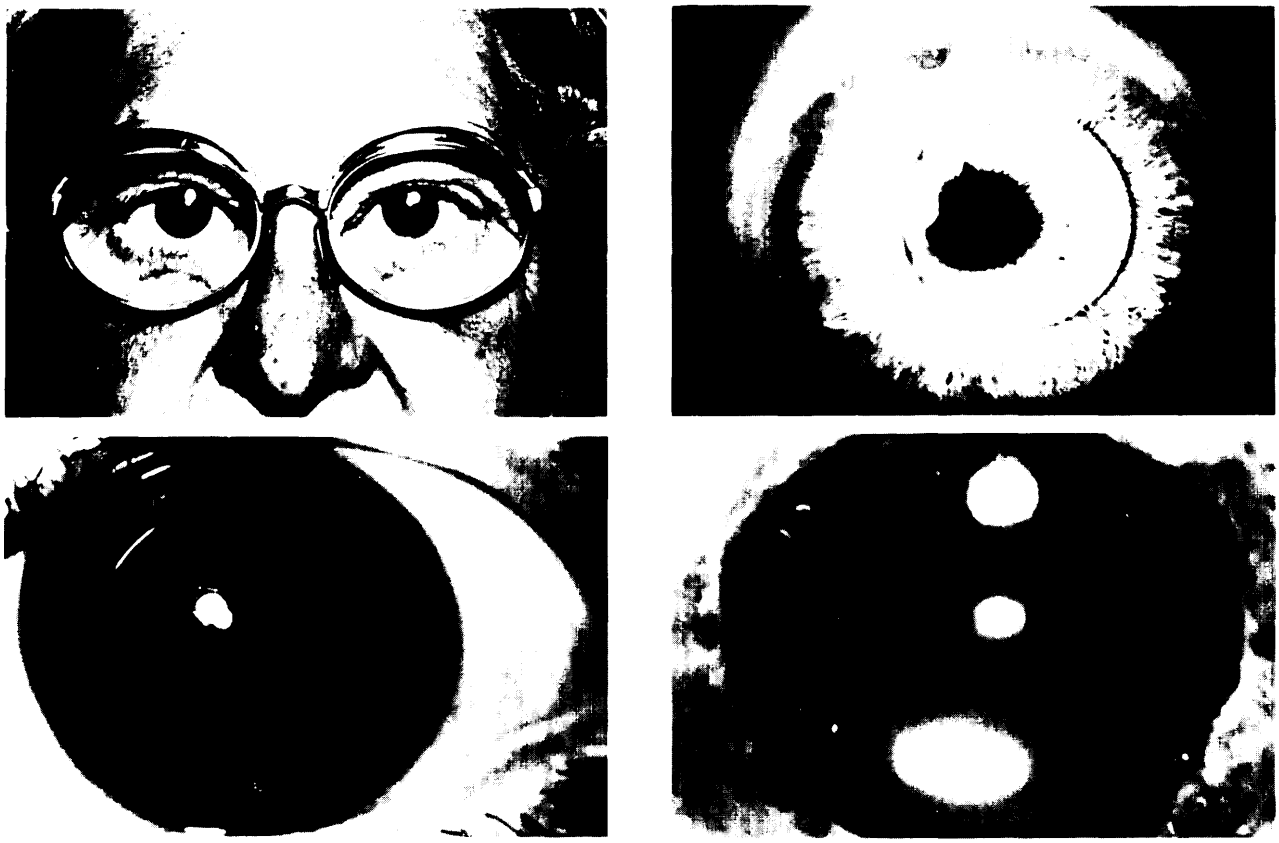

Photo credits American Academy of Ophthalmology

After cataract surgery, sight may be restored by the use of glasses, contact lenses, or intraocular lenses implanted in front of or behind the iris. Since the early 1980s, intraocular lenses have been the preferred method.

tially on the costs of normal cataract surgery at the time DRGs were created, before IOL implantation became standard procedure. Nonetheless, the benefits of IOLs were well established at the outset of PPS, and the new payment system is unlikely to hinder their diffusion or lead to their abandonment.

Changes in cataract surgery other than an increase in IOL use have also occurred. The most notable from the perspective of PPS are, first, that hospital average length of stay (ALOS) for cataract surgery patients has decreased by nearly one-third since 1981 (238); and second, that there has been a trend from inpatient to hospital outpatient and nonhospital sites as the setting in which cataract surgery is performed (10). Recalibration of DRG weights (see p. 121) will probably serve to account for both the inclusion of IOLs and the shorter ALOS of cataract surgery. However, PPS may well affect the setting in which surgery takes place.

The magnitude of the effect of Medicare policies on the trend away from inpatient cataract surgery depends on three factors: 1) the effect of PPS financial incentives on hospitals; **2)** the effect of Medicare outpatient reimbursement incentives on hospitals, physicians, and beneficiaries; and 3) the effectiveness of utilization and quality control peer review organizations (PROS) in monitoring hospital inpatient admissions for cataract surgery.

The effect of PPS financial incentives on hospitals is simple and depends only on whether the hospital's costs of treating a particular inpatient are higher or lower than the DRG payment.

The effect of outpatient reimbursement incentives is more complex. Hospitals that perform cat-

aract surgery on outpatients are reimbursed by Medicare for all reasonable costs of surgery (Public Law 96-499). Thus, whenever inpatient costs for cataract surgery exceed the DRG payment rate, hospitals have an incentive to provide the surgery in an outpatient setting. Physicians who accept assignment are reimbursed by Medicare for 100 percent of their reasonable charges for performing cataract surgery in hospital outpatient or freestanding ambulatory surgical settings, but only 80 percent of charges for cataract surgery performed in hospital inpatient or physician's office settings (47 FR 34082). Thus, many physicians also have an incentive to perform the procedure in outpatient settings (other than the office).

Many PROS are monitoring hospital admissions for cataract surgery. To the extent that it is effective, PRO monitoring may prevent admissions of low-risk cataract patients that would otherwise be DRG "winners" for the hospital.

The magnitude of the net effect of the three factors just discussed depends on how they ultimately balance out. The direction of that effect, however, will almost certainly be to continue the trend to outpatient cataract surgery.

Therapeutic Drug Monitoring

For certain medications, standard drug dosage regimens have different effects in different individuals, Some patients may respond well to the drug, while others receiving the same dosage have a subtherapeutic or a toxic response. One way to minimize such variability in patient response is to monitor the concentration of the drug in the patient's blood serum. This technique is known as therapeutic drug monitoring (TDM).

TDM has become accepted practice for a variety of drugs.[9] The assumption behind the technique is that there is a correlation between the concentration of the drug in the blood and its concentration in the tissue where the drug exerts its therapeutic effect. Combined with supporting clinical signs, too high a drug level in the blood indicates toxicity, while too low a level suggests a subtherapeutic response. The drugs particularly suited to TDM are drugs for which the toxic dose is quite close to the therapeutic dose, whose effect is difficult to detect, or for which there is some other strong reason for desiring rapid, detectable response to the drug **(390).**

The recent rapid growth in demand for TDM has been a result of both major advances in automated equipment and the growth of the clinical pharmacist profession, which has had a symbiotic relationship with TDM. The technology has aroused interest because of a number of anticipated positive effects on the cost and quality of medical care. These include reduced length of hospital stay; reduced drug-related toxic complications; prevention of hospitalization through outpatient monitoring; and improved outcome in cases where TDM enables the use of more aggressive antibiotic therapy.

PPS has the potential to significantly affect the use of TDM, particularly since the variety of drugs that can be monitored means that a number of DRGs are involved. Some of the effects may encourage use. Cost-containment incentives may encourage greater appropriateness of TDM testing, since such improvements could reduce laboratory costs associated with misleading or unneccesary testing. They could also reduce costs associated with toxicity or subtherapeutic responses due to dosage decisions based on improper samples. To the extent that the cost of improved testing is less than the savings it generates, PPS should encourage more of this kind of testing. It will also probably encourage the trend toward smaller, more efficient, less labor-intensive equipment.

Other effects of PPS may depress TDM use. For instance, the use of TDM does improve outcome in burn patients, but the improvement comes at a financial cost to the institution **(40).** PPS is unlikely to bring the use of TDM in such cases to a halt, but it may well lead to a decrease in the intensity of its use. It may also discourage the

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7A physician who accepts assignment for a Medicare claim agrees not to bill the beneficiary for any amount over and above the beneficiary's required coinsurance and deductible (where applicable) of the Medicare-determined reasonable charge for that service.

[8]This discussion is based on J.T. Barr, "The Interaction of Therapeutic Drug Monitoring and DRG Payment Levels, " prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, Nov. 16, 1984.

[9]The drugs for which TDM is being used include antiepileptics; cardiac active agents; antibiotics; antiasthmatics; antidepressants; neuroleptics; anticoagulants; immunosuppressants; and antineoplastics.

expansion of TDM methods to new drugs, where instituting drug monitoring is likely to increase overall costs, at least in the first stages of its diffusion.

Thrombolytic Therapy for Acute Myocardial Infarction[10]

An acute myocardial infarction, one form of heart attack, occurs when blood flow to the heart muscles is cut off, causing damage to the heart tissue. This condition occurs most often when a coronary artery is blocked by a thrombus, or blood clot. The development of thrombolytic agents to dissolve these clots has recently received much attention as a way of treating acute myocardial infarction before it has advanced far enough to cause permanent damage to the heart. Restoration of blood flow, of course, does not solve the underlying problem that caused the blockage in the first place. An acute myocardial infarction patient is a likely candidate for procedures such as coronary bypass surgery or PTCA.

Streptokinase, the first thrombolytic agent to be developed, received FDA approval in 1982 (365). Several clinical trials have demonstrated that streptokinase does indeed restore blood flow within a short time. However, it is less well established that restoration of blood flow (which may be temporary) actually decreases overall mortality in patients with myocardial infarction (165, 244), and so far, OHTA has recommended against Medicare coverage (365).

Streptokinase is not the only promising technology for acute myocardial infarction patients. Urokinase (a close relative), acylated streptokinase-plasmin, and prourokinase are all potentially useful thrombolytic agents **(172).** The alternative arousing the most interest at present, however, is genetically engineered tissue-type plasminogen activator, which acts more specifically on the clot than streptokinase. Early clinical trial results (372) suggest that it has great potential for use as an "easily administered, rapidly effective, and highly specific thrombolytic agent" (172).

There are two possible methods of administration for thrombolytic drugs: intracoronary, in which the drug is injected directly into the coronary artery; and intravenous, in which it is injected into a peripheral vein and carried in the bloodstream to the heart. Intracoronary administration has been shown to be more effective in clinical trials of streptokinase, but because it requires cardiac catheterization the drug cannot usually be administered immediately. Intravenous administration has great advantages in that it can be initiated immediately after the onset of acute myocardial infarction, in an ambulance or even at home, and it costs less because it requires fewer laboratory resources and less highly trained personnel. It can also be used in hospitals that do not have cardiac catheterization facilities. In fact, a primary reason for the excitement about tissue-type plasminogen activation is that because of its specificity for the clot, it is more effective than streptokinase when administered intravenously **(372).**

Intracoronary and intravenous methods of administration could result in the same DRG assignment, unless HCFA specifies otherwise when a decision to cover thrombolytic drugs is made in the future. Regardless of the method used, the administration of a thrombolytic drug can logically be coded under ICD-9-CM as 36,0, removal of coronary artery obstruction, and 99.29, injection of a therapeutic substance. The presence of code **36.0** as the principal procedure, in turn, places a patient in DRG #108, a highly weighted surgical DRG. If hospitals anticipate coding all uses of thrombolytic drugs into the same DRG, PPS incentives will favor both use of the lowest cost method of administration and the development of the least costly of the alternative drugs. At the same time, the generous payment that could result from use of thrombolytic therapy would encourage the adoption and use of the technology in general. (If the use of thrombolytic therapy did not "upcode" a patient into a higher paying DRG, PPS incentives to adopt it would depend on whether it lowers costs of treating patients.)

[10]This discussion is based on J.B. Perkins, "Streptokinase Treatment for Acute Myocardial Infarction and the DRG Payment System, " prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, Dec. 14, 1984,

General Impacts of PPS on Technological Change

PPS was never intended to affect uniformly the vast range of medical technologies. An expected outcome of per-case payment was to encourage the development and diffusion of cost-saving technologies and to discourage the use of cost-raising ones **(305).**

Payment effects on R&D are indirect and come about largely through changes in market signals to manufacturers of drugs and devices. To the extent that PPS affects the incentives for purchasers to adopt new technologies, it also affects the incentives of producers to develop them. This is particularly true in the later phases of R&D—applied research and development—when the medical potential of a new technology is becoming realized and its market potential is under investigation. PPS puts pressure on manufacturers to develop products that will be profitable to hospitals under the new set of constraints and opportunities.

Incentives to manufacturers affect not only the subject areas of research and the number of new products developed but also the form those developments take. A change in the number of new technologies produced does not necessarily mean an equal change in productivity. A decrease in the number of new technologies introduced on the market, for instance, could mean that manufacturers are directing their R&D resources toward a few potential "breakthrough" technologies rather than toward many minor modifications of existing ones. Similarly, an apparent increase in new technologies could mean more models of existing equipment rather than more significant innovations.

Hospitals face direct incentives under per-case payment to adopt and use lower cost technologies. All else equal, these incentives act to encourage the adoption and use of technologies in the hospital that:

- decrease per-case operating costs compared to alternative technologies;
- increase hospital admissions for simple procedures in profitable DRGs that otherwise might be done on an outpatient basis;
- are highly visible, attracting patient admissions and filling hospital beds.

All of these generalizations hold true for any particular technology only if the gains are not offset by other costs or by lower payment. If use of a new technology leads to classification of a case into a lower paying DRG, PPS may not encourage its diffusion even if it lowers operating costs.

The incentives regarding the use and adoption of new technology under PPS frequently conflict or produce unanticipated results because of other artifacts of PPS. The Dornier lithotripter, for instance, is very expensive, and its classification into a low-paying DRG may result in little or no profit per case. Yet PPS is unlikely to hinder its diffusion; the lithotripter is immensely attractive to patients, and the current passthrough for capital expenses under PPS means that the major cost of the lithotripter need not enter into per-case decisions. [11]

For experimental technologies, the ultimate effects of PPS on diffusion are particularly hard to determine because judgments about long-term costs and benefits must be made prospectively. For instance, hospitals are likely to be reluctant to adopt an expensive first-generation new technology if a cheaper second-generation model is expected. A technology that has long-run cost saving potential may be discouraged in the early stages of technological diffusion, when costs are higher and benefits less certain **(23);** costly but quality-enhancing technologies, which tend to be discouraged by PPS in any case, are particularly susceptible to such uncertainties.

Thrombolytic drugs and implantable infusion pumps are two examples of the way PPS may affect experimental technologies. The current coding convention for use of thrombolytic drugs might (once Medicare covered such drugs) result in the assignment of a patient receiving throm-

[11] At present (August 1985), capital costs (depreciation and interest) are reimbursed as incurred—a cost "passthrough"-in the same manner as before PPS. Congress has expressed an intention to include payment for capital by 1987 as part of the prospective payment rate and several alternatives have been proposed, but no specific method has yet been selected. The present cost-based method of capital payment is inefficient because hospitals have little incentive to consider the full costs of capital acquisitions (new plant, renovations, and equipment). Of particular concern is the incentive to adopt expensive capital equipment that reduces operating costs but raises total cost per case. Given no change in the current system, hospitals can be expected over time to become too capital-intensive (305).

bolytic therapy to a high-paying DRG, and consequently R&D on these drugs promises to be a highly lucrative investment under per-case payment. The implantable infusion pump, however, has uncertain cost advantages, particularly in its investigational phase. As long as physicians remain ambivalent about the benefits of the pump, PPS may have a depressing effect on its development and adoption, and even on the opportunities to demonstrate its benefits.

Non-PPS incentives compete with PPS incentives to further complicate the picture of PPS effects. Physician preference and belief in the benefits of IOLS, for instance, is strong enough that eyeglasses and contact lenses are unlikely to become the norm again after cataract surgery, despite their cost advantages. On the other hand, it is unclear whether the benefits of TDM to patients are great enough to result in its expansion to new drugs where it may initially increase hospital costs.

Impacts of PPS Structure on Technological Change: Updating, Recalibration, and Coding

The previous discussion illustrates the variety of ways PPS incentives can interact and the difficulty of generalizing about the net effects on any specific technology. It also draws attention to two very strong effects of the structure of PPS on technological change: 1) the impact of pricing changes that take place through updating and recalibration of the PPS base price and DRG weights; and 2) the effect of the coding system used to categorize patients (through the use of technologies) into DRGs.

Since the price paid for a DRG is the primary mechanism through which Medicare's PPS affects the adoption, abandonment, and site of use of technologies within that DRG, the methods of determining that price and of associating it with the use of a particular technology are of critical importance. The impact of the current mechanism for updating and recalibrating the DRG system and the effect of using the IDC-9-CM coding system to classify new drug- and device-embodied procedures are discussed below.

The legislation creating PPS allowed for two methods of changing DRG prices that consider technological change: updating and recalibration. *Updating* consists of an annual increase (or decrease) in all prices by an *update factor* that determines the overall generosity of the system. The update factor has two components. The first component reflects the amount of inflation in the hospital sector, The second component, known as the "discretionary adjustment factor, " accounts for cost increases (or decreases)[12] that are not necessarily captured by inflation measures, such as those due to changes in quality of care. This second component can also be used to account for the introduction of new cost-raising technologies in general, but because it raises the levels of payment for all DRGs simultaneously it cannot ensure that any particular new technology will be encouraged relative to its alternatives. The discretionary adjustment factor was originally set at 1 percent per year but was later limited by Congress to 0.25 percent for fiscal years 1985 and 1986. ProPAC has recommended to HCFA a 1-percent decrease, rather than an increase, for the discretionary component of the update factor for 1986, though the Commission did recommend an increase in the update factor overall (236).

The process of adjusting the prices of DRGs relative to each other, through changes in DRG weights, [13] is known as recalibration. This adjustment allows the price paid to a hospital for a DRG to stay approximately equal to the average costs of a patient within that DRG. Since the introduction of new technologies can change the costs of treating patients within a particular DRG, this adjustment ensures that those new costs will lead to a new price. The incentives to adopt new technologies, especially cost-raising ones, are strongly affected by the manner in which recalibration takes place.

Recalibration may take a number of forms. '4 Recalibration of all 468 DRGs can be done simultaneously in a statistical and reactive manner, through empirical reestimation of relative DRG

[12] In theory, th, discretionary adjustment factor, the inflation factor, and the entire update factor could all be negative rather than positive.

[13] The weight assigned a DRG represents its assumed resource 'se relative to other DRGs. The higher the weight, the larger the Medicare payment is.

[14] ProPAC's definition of "recalibration, " in contrast to that given here, includes only the simultaneous adjustment of all DRG weights. The adjustment of only certain DRG weights is called "reweighting" (237),

costs. It can be done as part of a central policy decision to change relative rates, where some DRG weights would be raised (or lowered) relative to the others to encourage (or discourage) use of particular technologies within those DRGs. It can also include mechanisms such as the creation of new DRGs as a way of paying a hospital only if it is using a particular technology **(307).**

The original PPS legislation required recalibration of DRG weights at least every 4 years (Public Law 98-21), and annual recalibration has been suggested by at least one observer **(287).** ProPAC is responsible for making recommendations to HCFA regarding updating and recalibration changes and has a charge to pay particular attention to new technologies when undertaking such matters. The ultimate authority for setting DRG prices, however, rests with the Secretary of the Department of Health and Human Services.

Coding issues are somewhat different from updating and recalibration issues because the PPS legislation did not establish any mechanism or specific authority for dealing with them. They were a largely unexpected complication of using the DRG classification system, and they can arbitrarily help or hinder the diffusion of a technology without regard to its actual benefits or detriments. Code assignment affects the incentives for adoption of a technology because the code assigned to a new procedure determines which DRG a patient is placed in when that procedure is used, and thus it determines the final payment level (see box 8-A).

Code assignment is a significant factor in four of the six technologies examined above: ESWL, PTCA, thrombolytic therapy, and the implantable infusion pump. In each of these four cases, a new technology is accompanied by a new procedure for which there is no directly applicable procedure code.

This situation presents two problems. First, until very recently, there has been no established mechanism for creating new codes except during the periodic updating of the coding system, once every 10 years **(50** FR 24374). Second, the use of ICD-9-CM as the basis for payment means that interim coding assignments for new technologies must consider not only which code describes the procedure the most closely for statistical purposes, but also which code leads to an appropriate reimbursement level. These two objectives may be inconsistent. In the past, most controversies regarding proper coding for procedures (or diagnoses) have been resolved by experts at AHA, with the support of other professional organizations and the National Center for Health Statistics (NCHS). This arrangement is now complicated by HCFA'S direct interest in how procedures are being coded for payment purposes, which may conflict with the interests of both AHA and NCHS.

PTCA provides an interesting example of how this dilemma is being resolved by HCFA. PTCA has been assigned the code that most closely describes it **(36.0, "Removal of Coronary Obstruction").** However, the DRG assignment based on this code leads to a payment for the procedure that ProPAC considers inappropriately high, and that Commission has recommended classification of the procedure into a lower paying DRG **(237).** HCFA agrees with this recommendation and intends to implement it in the upcoming revised GROUPER, the computerized DRG classification system **(50** FR **24370). Meanwhile,** however, it must instruct Medicare intermediaries to check with the hospital every time that code **36.0 appears to determine whether the code actually represents** a PTCA procedure or not. This method could be very cumbersome if many cases or many codes are involved.

ICD-9-CM coding is not the only coding system used in the United States. Physicians' reimbursement under Medicare Part B, for instance, uses a variant of the Current Procedure Terminology, 4th Edition (CPT-4), an annually updated system that codes procedures performed by physicians. CPT-4 is more detailed at coding procedures in most cases than ICD-9, making it possible to "map" one set of codes onto the other for data comparisons. In some cases, however, data from the two coding systems are incompatible.

Box 8-A —ICD-9-CM Codes and DRGs

The diagnosis-related groups used as the patient classification system in Medicare's PPS are based on a coding system known as the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). The ICD-9-CM has two parts. The first and largest part is a comprehensive list of diseases with corresponding codes. This is compatible with the World Health Organization's (WHO) list of disease codes, maintained for statistical purposes, and is updated along with the WHO list every 10 years. The second part of ICD-9-CM is a list of procedure codes. These are independent of the disease codes and are not directly based on an international system, although in the past, they have been revised concurrently with the disease codes. The National Center for Health Statistics (NCHS) is the official WHO coding liaison in the United States, but the development and maintenance of the American version of ICD has historically been a cooperative effort of representatives from a variety of Federal agencies and professional organizations (129).

Both the disease and procedure codes in ICD-9-CM are organized according to organ system (circulatory system, digestive system, etc.), with additional sections for subjects such as infectious diseases and accidental injury. Diseases are assigned three-digit codes, with fourth and occasionally fifth digits available to allow more specificity. Thus, for instance, hereditary anemia is code 282; sickle-cell anemia, one type of hereditary anemia, is code 282.6; and the particular form called sickle-cell / Hb-C disease is further specified as code 282.63. The procedure codes are organized in a fashion similar to the disease codes, except that maximum specificity is reached at four digits rather than five.

The process of DRG assignment depends on both the disease and procedure codes. The disease code for the principal diagnosis places the patient in a major diagnostic category and indicates which of several DRGs might be appropriate, The code for the principal procedure (or its absence) is used to determine whether the appropriate DRG is a medical or a surgical one. Surgical DRGs generally have higher reimbursement rates than medical ones. The final choice of DRG then depends on the specific procedure performed, the patient's age, and the presence or absence of coexisting diseases and complications.

The ICD-9-CM coding system, designed for clinical and statistical purposes, presents several problems when used as a basis for payment (129,152,273). First, if inaccurate or inadequate coding was frequent when the DRGs were designed, many hospital cases may have been inaccurately classified; consequently, the DRG weights may be inaccurate themselves. Second, some medical conditions can be described by more than one diagnostic code (152). While any of several diagnoses may be technically correct, their associated codes lead to different DRGs with different weights.

A third major concern regards the procedure codes. Procedures utilizing new technologies may not be appropriately described by any of the current codes, and confusion about which code to use can lead to wide variation in DRG assignment. The code that seems most applicable may lead to an apparently inappropriate DRG; conversely, a DRG with an apparently appropriate payment rate may be based on codes entirely unfitting to the new technology. Coding consultants at the American Hospital Association (AHA) and the Commission on Professional and Hospital Activities (CPHA) help to reduce confusion and promote coding uniformity, but through mid-1985, coding decisions for major problematic technologies have been made by an informal group of representatives from the Health Care Financing Administration (HCFA), NCHS, and several professional groups (notably AHA, CPHA, and the American Medical Records Association). A formal ongoing coding recommendations task force, jointly chaired by NCHS and HCFA, is currently being established (50 FR 24374).

APPROACHES TO EVALUATING THE IMPACTS OF PPS ON TECHNOLOGICAL CHANGE

Critical Evaluation Questions

There are two fundamental questions regarding PPS and technological change. First, how does PPS affect the kinds of technologies available to Medicare patients? And second, how does PPS affect the process of technological development and diffusion?

These can be restated as a number of more specific questions, such as the following:

- How does PPS affect the extent and direction of R&D that underlies technological change?
- How does PPS affect the development and diffusion of technologies that lower total Medicare costs? That lower health system costs?
- How does PPS affect the diffusion of cost-raising but quality-enhancing technologies?
- How does PPS affect the use of technologies that lower quality of health care relative to alternative technologies available?

None of these questions deals with the ultimate benefits and costs of any particular change due to PPS. That question must be addressed in the policy arena because its answer necessarily implies two judgments: one about the value of particular areas of R&D, and the other about the value of technological change in medicine as a whole. A decrease in the rate of technological change, for instance, could be harmful to the extent that it impedes attainable advances in the quality of medical care and the quality of life. It could be beneficial to the extent that it inhibits the adoption of inefficient technologies, or to the extent that it encourages a reallocation of resources to other areas of value. It is impossible to know what costs and benefits have been forgone in a technology that was never developed.

Impact Measures

There is no single measure, or group of measures, that can fully capture the complexity of technological change in medicine and the manner in which it is affected by PPS. The impact measures that do exist are on two levels: 1) aggregate data, in which a small amount of information is collected on a large number of technologies; and 2) focused studies, in which individual technologies or groups of technologies are examined for specific effects.

The aggregate measures available are limited to data on the earliest stages in the existence of emerging technologies. They cannot be used to measure the diffusion (either adoption or use) of technologies; at most, they can be examined as potential measures of the level of activity of R&D and of the changes in that activity. Industrial R&D, it is assumed, is likely to change in magnitude and direction as the market for new technologies shrinks and expands. Federally sponsored R&D is likely to be much less responsive to direct market effects because spending is directly tied to agency budgets.

These potential sources of aggregate measurement can be separated into two parts: the investment in R&D activity, and the *outcome* of that activity. Investment is measured in terms of the dollars spent, personnel time, or number of R&D projects. Outcome is measured by the number, type, and value of new products or procedures. For both investment and outcome measures, the areas of interest are changes in the overall level of activity and shifts in activity from one research area to another.

The available sources of data that provide aggregate measures of changes in R&D ,investment and new products are summarized in appendix F. Unfortunately, they are not very useful for evaluating PPS impacts. Information from R&D databases is unreliable for PPS evaluation purposes because it is not an accurate measure of investment in specific areas of medical R&D; even where these measures can trace changes in the magnitude of activity, they say nothing about changes in its direction. Data on new products, notably patent and FDA data, are also inadequate measures of new technologies. They tend to be incomparable, redundant, or incomplete; and they usually do not measure new techniques, smali but

important modifications, or new or unconventional ways of using old products. Furthermore, information from these sources is difficult to interpret because counts of new products say nothing about the quality or usefulness of the products, including whether the products are even being marketed or used. Finally, the medical products market shifts in response to numerous factors besides Medicare reimbursement, and attributing any changes in either the magnitude or direction of R&D activity to PPS with any level of statistical significance may be impossible.

Studies of specific technologies can take the form either of individual case studies or of studies of groups of technologies. Individual case studies frequently examine the entire history of development and diffusion of that technology and the influence of public policies on its history. Examples of such case studies are OTA's case studies of magnetic resonance imaging (279) and therapeutic apheresis (173). Group studies more frequently examine and compare the use and acceptance of those technologies in the medical environment, Examples are the studies of the impact of State ratesetting systems on the adoption of new technologies that were described in chapter 3 and studies such as those of Russell (253) and Cromwell, et al. (70), on the impact of cost-reimbursement insurance *coverage* on the diffusion of certain technologies.

As evidence of the impact of PPS on technological change, technology-specific studies have the advantage of enabling a detailed analysis of policy impacts. They can use statistical techniques to isolate and identify particular impact factors, and they allow an assessment of the actual clinical value of the technology to be considered in the evaluation of PPS effects. However, although studies like those cited above could be mounted to investigate the impact of PPS on technology development and diffusion, such studies inevitably depend on the technologies chosen. Conclusions based on these studies may present very biased views about the effects of the system because the most visible technologies, and thus those most likely to be analyzed, are the ones causing concern to producers and users. Focusing on these technologies can be important when making adjustments to improve the system, but it cannot allow a balanced evaluation. The difficulty of presenting an unbiased evaluation picture suggests the method of choosing the specific technologies for evaluation is critical.

The conclusions from these studies are also difficult to generalize because the studies tend to concentrate on expensive, capital- and device-embodied technologies rather than procedures, methods, or low-capital technologies (such as many drugs and biologics). One exception to the tendency to focus on device-embodied technologies is Sloane and colleagues' study of a number of surgical procedures (270). Their study found that "although common themes emerge, diffusion of each procedure has its own idiosyncratic features." This dilemma is precisely the one that will complicate studies of technology diffusion under PPS.

Organizational Arrangements for Evaluating PPS Impacts

The only governmental organization that currently has responsibility for evaluating the impact of PPS on technological change in any form is ProPAC (see ch. 10). One of the tasks that ProPAC performs is the examination of specific problematic DRGs, and in order to perform this task, the Commission conducts in-depth studies of individual technologies. The objective of these studies is to arrive at recommendations regarding DRG weights, or new DRGs, that would provide incentives for the appropriate level and use of the technologies while paying an appropriate price. One such study was mandated by the Deficit Reduction Act of 1984 (Public Law 98-369), which singled out pacemakers as needing particular attention under PPS (see ch. 10). Other studies have been encouraged by organizations such as the American Academy of Ophthalmology, which suggested that the Commission review the use of IOLS and the weight of the DRG that includes that procedure (238).[15]

[15] As of their first report to the Secretary of Health and Human Services cm Apr. 1, 1985, ProPAC had completed in-depth studies of three specific technologies: cardiac pacemakers, cataract extraction and IOL implantation, and PTCA. Other technologies that have undergone preliminary screening analyses are bone marrow transplantation: cochlear implants; ESWL; cyclosporine; magnetic resonance imaging; bilateral hip replacement; and treatments for alcohol dependence, cystic fibrosis, and dermatologic disorders (238).

Two characteristics of ProPAC's method for evaluating specific technologies are important. First, the focus of the technology studies is the impact of particular changes in technology use on DRG classifications and weights, not the impact of PPS on the technologies. Although these effects are interactive, they involve very different concerns. Second, the process used by ProPAC to select technologies for initial study is designed to be receptive to producers and users (Public Law 98-21). Technologies causing the most troublesome financial difficulties under PPS will undoubtedly surface by themselves given this outlet. This process is a much less efficient way of identifying those doing well under the system, however, since producers and users of technologies that are attractive under PPS have an incentive to keep their technologies out of the limelight,

Three organizations other than ProPAC have some responsibility for technology assessment and evaluation in the context of Medicare, but in no case does that responsibility include evaluating the impacts of PPS on technological change. The Office of Health Technology Assessment (OHTA) National Center for Health Services Research and Health Care Technology Assessment (NCHSR&HCTA) evaluates the safety and effectiveness of medical technologies that are being considered for coverage under Medicare and Medicaid. These activities have been recently expanded by Public Law 98-551 to allow examination of cost-effectiveness and medical appropriateness issues as well.

Public Law 98-551 authorized a National Advisory Council on Health Care Technology Assessment at NCHSR&HCTA to "assist the Director [of NCHSR&HCTA] in developing criteria and methods to be used by the Center in making health care technology coverage recommendations. " In the past, the selection of technologies for assessment by OHTA was based on requests for information from HCFA regarding coverage deliberations. The Advisory Council will supplement this selection mechanism, though the manner and extent to which it will select technologies for OHTA assessment is not yet clear.

Finally, Public Law 98-551 authorized a separate National Advisory Council on Health Care Technology Assessment at the Institute of Medicine to identify health care technology assessment needs in general and to develop criteria and methods for assessment. This council, not established or funded as of August 1985, is to include both Federal and private sector representatives. It has no direct charge to consider Medicare coverage or reimbursement impacts, though these could conceivably influence the criteria it develops.

CONCLUSIONS

Medicare's PPS may have strong effects on technological change in health care, but the ultimate impact of those effects on the overall benefits and costs of health care will be virtually impossible to analyze. The potential for measuring the impact of PPS on technological change in the aggregate is limited by lack of good operative measures; by poor integration of data; by the difficulty in attributing changes to the influences of PPS; and by the inability to know whether the net value of a change is beneficial, harmful, or neutral. Furthermore, while PPS does set up a framework of incentives for the adoption and use of technologies, these incentives may conflict with each other and with non-PPS incentives in such a way that each technology faces a unique set of impacts,

Although the ultimate impacts of PPS on technological change may never be known, evaluation on a less ambitious level might produce some useful information. Questions for evaluation divide themselves into two categories: 1) questions about the effects of PPS on the magnitude and direction of R&D; and 2) questions about the effects on specific kinds of technologies, such as those that provide an increase in the quality of health care but at some corresponding increase in cost. Consequently, there are two kinds of potential evaluation strategies.

First, current databases on R&D and new products (see app. F) might be enhanced and refined. Surveys such as the National Science Foundation's survey of industrial R&D, for example, might be enhanced to provide an indication of changes in the magnitude of R&D. Although changes in industrial R&D on medical products cannot be tied very well to PPS, they do indicate roughly how investment in new medical products is proceeding relative to other industries. Enhancing databases to the point where they are useful for PPS evaluation purposes, however, would be very costly and is probably impractical.

Second, analysis of the process of development and diffusion of specific technologies or groups of technologies under PPS could be useful. The strength of technology-specific studies is that they can assess the clinical value of a technology and use that assessment in an evaluation of the importance of PPS impacts.

Although databases containing information on new drugs and devices have little use as aggregate measures of technological change, they might be used as one screening mechanism for selecting individual technologies to study. Other possible identifiers of new technologies are changes in the annually updated CPT codes and surveys of experts in the health care field. A sample of new technologies chosen through one or more of these techniques might be tracked and their potential and real interactions with PPS analyzed. This kind of screening mechanism could allow a relatively unbiased set of technologies to be chosen for anal ysis.

A focused in-depth analysis of specific technologies based on such a screening mechanism could provide a measure of the impacts of PPS on a level that directly affects patients. In some cases, as with several of the technologies described in this chapter, features of the design of PPS that affect the development and diffusion of specific technologies can be identified. To some extent, the experiences of these technologies may be generalized to similar technologies and can serve as an early warning system for potential future effects. However, this method of monitoring is very sensitive to the technologies chosen for study. In particular, if the technologies chosen for analysis are those whose introduction is discouraged under PPS, the negative effects of PPS will be overemphasized.

Although there are several organizations with some responsibility for analyzing specific techncologies in the context of Medicare, none are directly responsible for evaluating the impact of the payment system on specific technologies or on R&D. Furthermore, in at least one case (ProPAC), those activities are part of the PPS structure whose impacts are to be evaluated. This situation does not necessarily preclude ProPAC or other involved organizations from assisting in the evaluation, but it does suggest that the evaluation of PPS impacts on technological change should be functionally separated from other responsibilities of such organizations.