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Introduction and Summary

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INTRODUCTION

Nuclear magnetic resonance (NMR) imaging[1] is an exciting new diagnostic imaging modality that has captured the interest of the medical profession for a number of reasons. First, it employs radiowaves and magnetic fields rather than ionizing radiation, thus eliminating the risk of X-irradiation that is associated with use of devices such as X-ray computed tomography (CT) scanners. Second, in addition to providing excellent distinction between adjacent structures (spatial resolution), the technique uses differences in the density and the molecular environment of different substances to provide excellent tissue contrast without the need for injection of potentially toxic contrast agents. Third, because bone does not interfere with NMR signals (the absence of signal artifact from bone), physicians can visualize areas such as the posterior fossa, brain stem, and spinal cord with NMR that previously were not well seen with other noninvasive imaging techniques. Finally, and potentially of greatest importance, because NMR imagers are sensitive to fundamental physical and chemical characteristics of cells, the technique offers the possibility of detecting diseases at earlier stages than is currently possible and of permitting accurate diagnoses to be made noninvasively.

Along with these attractive attributes, however, NMR has its disadvantages. At present, NMR imagers are expensive, and installation of them is costly and logistically difficult. Furthermore, until (and possibly after) more experience with the modality is obtained, NMR imaging may require more physician time in performance of patient examinations than is the case with X-ray CT or other imaging techniques. Moreover, despite the rapid improvement in the quality of NMR images that has occurred over the past several years and the increasingly large number of clinical situations in which NMR imaging might prove to be of value, the exact role of NMR imaging in clinical medicine, particularly its efficacy compared to other imaging modalities, has yet to be defined.

Despite these concerns, NMR imagers are diffusing very rapidly. In January 1983, 14 units were in place in the United States outside manufacturers' facilities. By October 1983, 34 units had been installed in the United States, and by August 1984, at least 145 units were installed worldwide, of which 93 were in the United States.

Given the rapid rate of change in both the clinical and scientific status of NMR imaging, as well as in the number of units being installed worldwide, it *is* impossible to publish *a review* that accurately describes the "current status" of NMR imaging in almost any dimension. Such a review quickly becomes outdated as the field continues to evolve. This case study was written, therefore, with the following limited goals in mind:

- To provide a vehicle for gaining insight into the impact that Federal policies have had on the development of NMR imaging as a modality, on the industry that manufactures the imagers, on the hospitals and medical centers that might consider acquiring NMR imagers, and on a public interested not only in the timely introduction of valuable innovations, but also in protection from unsafe devices and rapid increases in health care costs. By identifying and analyzing a number of policy issues, the case study is intended to help the Federal Government and other interested parties assess the process through which new devices are made available.
- To make available a large amount of technical, clinical, industrial, and policy information under a single cover, and in the process to provide a "snapshot" view of the status of NMR imaging in several dimensions.[2]

[1] The term "NMR imaging," used in this case study, is increasingly being replaced by the term "magnetic resonance imaging."

[2] The material was first compiled in fall 1983. App. C and policies of the Food and Drug Administration and third-part, payers were updated in August 1984.

SUMMARY

The body of the case study is organized into nine chapters. Each of the chapters is briefly summarized below.

NMR—Historical and Technical Background

The existence of the NMR phenomenon was first demonstrated in 1946 by two American scientists, Felix Bloch and Edward Purcell, who jointly received the Nobel Prize for Physics in 1952 for their discovery. The first NMR image (of two tubes of water) was published by Paul Lauterbur of the State University of New York (SUNY) at Stony Brook in 1973, the same year X-ray CT scanning was introduced into the United States. Remarkable progress in the quality and capabilities of NMR imaging has been made in the years since Lauterbur imaged his two tubes of water, with no plateau in the rate of improvement in sight.

The nucleus of the hydrogen atom (proton)[3] has been most successfully exploited to produce high-quality NMR images because of its desirable magnetic properties and the high concentration with which it is present in the body. NMR images are fundamentally different from X-ray CT images. The latter rely on partial absorption and partial transmission of X-rays (linear attenuation) to produce images that reflect differences in the electron density and specific gravity of adjacent tissues. Proton NMR images are formed without the use of ionizing radiation and reflect the proton density of the tissues being imaged, as well as the velocity with which fluid is flowing through the structures being imaged and the rate at which tissue hydrogen atoms return to their equilibrium states after being excited by radiofrequency energy (proton relaxation time). The excitement about and investment in NMR have arisen from the belief that enormous clinical benefits might derive from the ability to obtain information about both the tissues of the body and certain kinds of chemical activity.

[3]Since the hydrogen atom has one unpaired proton, the terms hydrogen atom and proton are used interchangeably.

Clinical Applications of NMR

Concerns regarding the safety of NMR imaging have focused on magnetic fields and radiofrequency energy. To date, since adequate precautions have been taken, no significant biological risks associated with use of NMR have been identified. Other potential sources of concern relate to damage that could be caused by the possibility that metallic objects in the vicinity of NMR magnets could become projectiles, or that the strong magnetic fields used in NMR imaging could damage computer tape or other objects in the surrounding environment.

The National Radiological Protection Board in the United Kingdom is maintaining a record of patients and volunteers who have undergone NMR imaging studies in order to evaluate problems that arise in the future in individuals undergoing NMR scanning. The American College of Radiology is attempting to collect similar information in the United States. It would seem advisable to establish uniform guidelines for worldwide collection of this type of data, at least for the near future. Issues of who should be responsible for collecting and maintaining such data, and at whose expense, as well as issues pertaining to patient confidentiality, remain and need to be resolved.

The clinical application of NMR imaging in which the most experience has been gained and which so far has proven most efficacious is imaging of the brain and central nervous system. Results of studies of NMR imaging of the heart and pelvis are also particularly promising.

The scope of the role of NMR imaging in medicine is yet to be determined. Although there is some plausibility to the hundreds of applications that have been cited for NMR imaging, the majority of such applications must, for now, be considered potential rather than demonstrated.

Although future NMR production models are likely to simplify image acquisition for physicians, and although the time required to produce high-quality NMR images will likely decrease, it should not be assumed that images of the same quality

as those being published by research institutions will necessarily be produced immediately in hospitals that are not able to spend equivalent time and effort on their production.

In the early stages of evaluation of NMR imaging, many, if not most, of the patients that have been studied have appropriately been patients with known pathologies. It is not necessarily the case that NMR will be shown to have the same sensitivity and specificity when used to image patients with unknown pathology. Given the rapid improvements taking place in NMR imaging, however, current assessments may underestimate the ultimate sensitivity and specificity of NMR imaging in many applications.

It is likely that algorithms with pulse sequences (patterns of radiofrequency energy used to excite protons) specific to different pathologies will be built into NMR software in the future. While this means that NMR images of individual types of pathology are likely to become even better than they are today, it also means that if patients with unknown types of pathology are referred for a "screening" NMR scan, multiple scans, using multiple pulse sequences, may have to be performed in order to exclude with a reasonable degree of certainty the existence of an abnormality. Such use of multiple pulse sequences may increase the time and expense required to perform NMR studies.

To the extent that use of multiple pulse sequences does increase patient examination times, a tension may develop between the economic pressure to maintain reasonable patient flow and the clinical requirement that pathologic abnormalities be excluded with a high degree of certainty. To the extent that the latter predominates, the number of patients seen may decrease, producing a rise in average cost per NMR study, To the extent that the former predominates, the sensitivity and specificity of NMR may decrease.

Because the risks of NMR imaging appear to be low, NMR scans maybe performed on patients repeatedly over time to monitor therapeutic progress or the natural history of disease. Such usage could result in increased demands being placed on NMR machines and in increased health care costs .

Within certain numerical ranges, relaxation times may provide sufficient pathologic specificity to be clinically useful. Because of overlap between the relaxation values of normal and abnormal tissues, however, relaxation times alone are unlikely to permit reliable pathologic diagnoses, despite the theoretical attractiveness of using such measurements. The possibility exists that nontoxic contrast agents can be devised that will enhance the pathologic specificity associated with relaxation time values. Considerable research remains to be done in the exploration of what physical, chemical, and biological factors give rise to and influence NMR relaxation times. Only through answers to these questions will it be possible to exploit relaxation times' full medical and scientific potential.

NMR is also used to perform in vivo phosphorus NMR spectroscopy, in which the "chemical shift" phenomenon is used to provide an indication of the relative concentrations in which compounds such as phosphocreatine, adenosine triphosphate, and inorganic phosphate are present in intact human tissues or organs. Much additional research is required before an assessment can be made of the extent to which in vivo NMR spectroscopy can be used to provide diagnostically useful information regarding the metabolic and functional status of normal and abnormal tissues.

It should also be recognized that the technology required for in vivo human NMR spectroscopy is considerably more sophisticated than that required to perform proton NMR imaging. Thus, most of the NMR imagers that are generally being installed in hospitals today cannot currently be used to perform NMR spectroscopy. Hospitals desirous of performing spectroscopy and imaging may need either to obtain more than one NMR machine or to tolerate potentially costly amounts of time while field strengths are changed and the NMR machine is not operational. For the present, in vivo NMR spectroscopy should be considered an exciting and promising area of research that is of questionable feasibility for most hospitals.

The NMR Imaging Device Industry

The NMR imaging device industry, as it now exists, is both dynamic and intensely competitive.

Since 1976, at least *23* companies worldwide have decided to enter the NMR imaging marketplace. Eight firms have reached an advanced stage of development, whereas at least three others are engaged in intermediate-level activities. The industry has a multinational character, with firms based in the United States, Japan, West Germany, Great Britain, France, Israel, and The Netherlands. All but three of the firms have multiple product lines. The industry appears concentrated among four firms, which accounted for 79 percent of the 145 known worldwide placements existing in August 1984.

At present, small firms can enter the market, but entry depends on several key factors, including their ability to attract capital and scientific or technical talent for research and development (R&D), to develop strong university or medical center ties for collaborative research, and to market products once they have been developed. The pathways to market entry are varied, but involve essentially four different routes: government-supported R&D, university-based R&D, acquired technology, and internally based R&D. Initial capitalization for market entry is estimated to be between $4 million and $15 million. University or medical center research ties are considered essential in the industry, and every firm that has attained either intermediate or advanced stage R&D has a close collaborative relationship with one or more universities or major medical centers.

The existence of at least *19* NMR imaging device manufacturers suggests that patents have not created a significant barrier to the entry of competitors into the marketplace. Whether patentable discoveries will emerge, prohibitively expensive cross-licensing agreements will be devised, or pending lawsuits will be settled in such a way as to change this situation is difficult to predict. It is also difficult to assess how beneficial the protection afforded by patents has been to the commercial development of NMR imaging in this country. It is possible, if not likely, that many manufacturers have opted to retain discoveries as "trade-secrets, " rather than to reveal confidential information in patent applications.

There is considerable diversity in the product lines and operations of firms in the NMR imaging industry. Sixty-three percent of the companies manufacture non-health-care related products either directly or through a parent firm. Since the 1970s, the NMR imaging device industry has witnessed a large number of acquisitions, mergers, and trade agreements. At least three mergers in the industry have involved vertical integration either to acquire magnet manufacturing capabilities or to expand sales or distributorship networks to specific geographic areas. Vertical integration is expected to increase in the industry over the next 2 to 5 years.

Most firms in the industry believe that non-price factors will prove more important than product price in determining future NMR sales and market share. Product differentiation is expected to figure prominently in the non-price competition strategies of NMR imaging device firms. Manufacturers believe that the most important factors are likely to be image quality, product features or capabilities, product reliability, and product service. Various manufacturers are placing different emphasis on these factors as part of their marketing strategies. Buyers' perceptions of a corporation's chances for long-term survival will probably also be important.

It is expected that NMR imaging sales will become an important source of company revenues for many manufacturers over the next few years. Firms are expected to maintain heavy investment in R&D activities even after receiving Food and Drug Administration (FDA) premarket approval and introducing commercial NMR imaging prototypes. NMR sales could increase from $100 million per year in 1983 to $2.5 billion per year in 1988, amounting to an annual rate of growth in sales of 90 percent. The percentage of diagnostic imaging industry sales attributable to sales of NMR imaging systems could increase from 2.5 percent in 1983 to 30 percent by 1988.

Hospital Costs and Strategies

One of the major concerns that has emerged regarding NMR imaging relates to the impact this new technology will have on health care costs. These concerns derive in part from the high anticipated costs associated with the purchase and installation of an NMR imaging system and from uncertainties regarding the extent to which NMR imagers will be used in conjunction with other diagnostic modalities.

Capital and operating expenses for NMR imaging are primarily determined by the type of magnet (resistive, permanent, or superconducting) used to produce the static magnetic field. Purchase prices range from approximately $800,000 for a resistive system to $1.5 million for a permanent magnet system or a 0.5 tesla superconducting system and to over $2 million for a 1.5 tesla superconducting system. Installation costs range from $25,000 to $75,000 for a permanent magnet system to up to $1 million for a 1.5 tesla superconducting system. Estimates of the average cost of an imaging study, exclusive of professional fees, are difficult to make at this time, but range from as low as $180 for a resistive system to as high as $700 for a superconductive system. These estimates are quite sensitive to a number of key assumptions, such as the time needed to process patients.

The likely effect of NMR imaging on health care costs will depend on how it is employed by physicians in actual practice situations. Several factors need to be considered in this regard. First is the extent to which NMR imaging is performed instead of other diagnostic modalities in the management of specific patient complaints or disease entities. Second is the extent to which NMR is used in situations in which no diagnostic modality is currently used. Such situations are likely to include the use of sequential NMR scanning to monitor the natural history of diseases and the progress of chemo- and other therapies. Finally, much will depend on such factors as how much surgery is avoided, whether hospital lengths of stay are shortened, and whether diagnostic workups that were performed in the hospital are shifted to the outpatient setting.

Most of the early NMR units acquired by hospitals have been installed in university teaching hospitals. This situation is not surprising, given the interest such hospitals have in performing research and being at the "cutting edge" of medical developments, and given the research needs of manufacturers in order to obtain FDA premarket approval. In addition, university hospitals have been able to use their special strengths to obtain NMR imaging systems at decreased or nominal cost. Price and operating costs of experimental systems have frequently been further subsidized by research grants from manufacturers and have often been shared between hospitals and universities. These observations suggest that many of the university hospitals that have obtained NMR imaging systems to date may have done so in part because they did not have to be so concerned with acquisition costs and early operating costs as other hospitals have to be.

In *1983* the Veterans Administration (VA) decided to initiate a staged program of acquisition of NMR devices with a single NMR demonstration and evaluation project. The decision to acquire an NMR device for the VA system derived from an interest in "helping the VA march into the future" (171). No estimates of the impact of NMR on the cost of patient care were made. The decision to restrict the initial purchase to a single unit emanated from a concern about the rapid rate at which NMR technology was changing and the resultant desire to avoid installing a large number of systems that might soon become obsolete. NMR manufacturers have suggested, however, that due to the ability to upgrade their systems, early obsolescence may be less of a problem with NMR imagers than it was with X-ray CT.

Investor-owned hospitals have also followed a cautious approach to acquisition of NMR imaging equipment. The Hospital Corp. of America and Humana, for example, have each decided to acquire a small number of systems in the near future in order to conduct in-house evaluations of the cost, utility, and ideal configuration of NMR imaging systems in the community hospital setting. Others, such as American Medical International, National Medical Enterprises, and Lifemark, have postponed acquisition of NMR equipment until additional information regarding the cost, utility, and reimbursement rates for NMR imaging is available. Finally, investor-owned companies that operate hospital chains plan to use their ability to buy in volume to obtain special price consideration from manufacturers.

History of Funding for NMR Research

In the United States, both the National Institutes of Health (NIH) and the National Science

Foundation have provided considerable support to basic NMR research over the past decade. NIH is currently funding approximately $2 million in research in at least 10 different institutions relating to NMR imaging or in vivo spectroscopy. Announcement of awards from the Diagnostic Imaging Research Branch of the National Cancer Institute to assess the comparative efficacy of NMR imaging and other diagnostic modalities were made in mid-1984.

At least three different noncommercial entities provided support for NMR research in England and Scotland over the past decade. These include the Wolfson Foundation, and two government entities, the Medical Research Council and the Department of Health and Social Security in England.

Certain contrasts between the history of the development of NMR imaging in the United States and Great Britain can be identified. Unlike the situation in the United States, in Britain the government undertook a concerted effort to develop technology that might be of use specifically in hospitals. This effort was focused through a program funded by the Department of Health and Social Security which lent considerable financial support to the development of NMR imaging techniques. It is interesting to note, however, that once it became apparent that the development of NMR imaging systems was not only commercially viable, but also potentially extremely profitable, U.S. manufacturers rapidly and intensively began investing in NMR imager development programs.

In Britain there also seem to have been several interdisciplinary groups that collaborated on the development of NMR imaging techniques. In the United States, in contrast, most of the early work on NMR imaging was done by Lauterbur and Damadian with apparently little, if any, interaction between the two, despite the fact that both were at campuses of the State University of New York. There also seem to have been fewer centers in the United States in which scientists with varied backgrounds collaborated on the type of interdisciplinary research that resulted in the advances in NMR imaging that took place in Britain.

FDA Regulation

FDA authority over NMR imaging devices derives from two Federal acts: the Radiation Control for Health and Safety Act (RCHSA) of 1968 and the Food, Drug, and Cosmetic Act (FDCA), as amended in 1976. FDA has not established radiation emission performance standards for NMR devices under its RCHSA authority, and it is not likely that the RCHSA will have a significant impact on the development of NMR imaging as a medical diagnostic modality. The FDCA, in contrast, has had and continues to have a significant impact on the development of NMR imaging devices.

The 1976 Medical Device Amendments require that all medical devices be classified into one of three regulatory categories based on the extent of control necessary to provide reasonable assurance of safety and effectiveness. NMR imaging devices are the first imaging devices to be classified into Class III for which premarket approval (PMA) has been required. The premarket approval applications (PMAAs) submitted by three companies were deemed “approvable” by the FDA Radiologic Devices Advisory Panel in July 1983, and were granted formal premarket approval by FDA in spring 1984.

Some general insights into the PMA process can be gained from examining how NMR has fared in its interactions with it to date. It should be realized, however, that the experiences that an extremely promising, high R&D-cost device such as NMR has had with the FDA may not be representative of those that other devices may have in the future.

In the case of NMR, it appears that the FDA PMA process is primarily playing a quality-assurance role—a role that Congress intended it to play. PMA does not appear to have constrained NMR technological development. However, in its attempt to assist manufacturers and institutional review boards to define when experimental use of NMR does not pose a significant risk, FDA may have influenced the technological development of NMR devices.

FDA clearly has not constrained the number of NMR imagers that could be installed on an experimental basis in the United States. Of the approximately 34 NMR systems installed in the United States by October *1983, 15* were by a single manufacturer. It appears, therefore, that the FDA PMA process will not act as a major constraint on the rate at which NMR devices are adopted and used throughout the United States. This situation may, in large part, be a result of the long gestation period required for development of a production model of a high R&D-cost device, such as an NMR imager.

If PMA is not granted to other manufacturers in a timely fashion, however, manufacturers may begin to suffer from delays in receiving revenues to cover their development costs. Because the Health Care Financing Administration (HCFA) requires FDA approval of a device before it approves coverage for it, undue delay in PMA could injure manufacturers because of the constraining influence that the absence of Medicare reimbursement would have on hospital acquisition decisions.

Two final impacts of the FDA PMA process should be identified. First, in their quest for PMA, manufacturers have subsidized a considerable amount of research in order to establish the safety and effectiveness of NMR imaging devices. How much of this research would have been subsidized or performed by manufacturers in the absence of the PMA process is impossible to estimate. Finally, it appears that the PMA process may prove capable of conferring a competitive advantage upon those manufacturers who are first to receive PMA, particularly if third-party payers decide to approve coverage only for those manufacturers' devices that have received PMA. How much of a financial benefit, in both the short run and the long run, accrues to those "early bird" manufacturers who obtain PMA while others still await it may help determine not only the future of the NMR manufacturing industry, but also the speed with which manufacturers pursue development of other new technologies in the future.

Third-Party Payment Policies

In determining coverage policy for new medical technologies, third-party payers look first to FDA for some indication of a device's status. Third-party payers generally will not reimburse for clinical services performed with "investigational" devices. HCFA will provide coverage under the Medicare program only for those devices, services, or procedures that are determined to be both "reasonable and necessary. " HCFA generally does not approve coverage of a new device unless FDA has already found it to be "safe and effective. " FDA determination of safety and effectiveness, however, does not ensure that the device will satisfy HCFA's criteria of reasonableness and necessity.

Other third-party payers, such as State Medicaid programs, Blue Cross and Blue Shield plans, and private insurance companies consider similar factors in making coverage decisions, but vary in their general procedures, methods of assessment, and decision criteria.

HCFA conducts the most in-depth assessment of a new technology, with the aid of the Public Health Service's Office of Health Technology Assessment (OHTA).[4] In performing a technology assessment, OHTA gathers and analyzes relevant data on clinical safety and efficacy from various public and private sources. The assessment process often takes between *8* and 18 months to perform.

The national Blue Cross and Blue Shield Association also conducts technology assessments at the request of member plans. Association staff review available literature and elicit expert opinion from medical specialty societies in determining the safety and effectiveness of a new device. Staff assessments of new technologies frequently result in Uniform Medical Policy statements, which are intended only to guide coverage policy decisions of member plans. Each plan, however, may make its own independent coverage decision.

Commercial insurance companies follow a less formal procedure in conducting technology assessments. The Health Insurance Association of America (HIAA), a private organization serving the commercial insurance industry, furnishes information on new technologies to its members. At the request of a member company, HIAA will solicit an expert opinion regarding a new device

[4]This executive office differs from the Health Program in the Congressional Office of Technology Assessment.

from the Council on Medical Specialty Societies. The information will be synthesized and forwarded to member companies, who independently interpret it and make coverage policy decisions.

The major third-party payers also differ in the criteria they employ in setting payment levels for covered services. Important factors in these decisions include where the technology will be used (e.g., hospital, physician's office), in what circumstances it will be used (e.g., certain clinical situations or diseases), and by whom it will be used (e.g., physicians with general versus specialty training). Payment levels are generally based on criteria of "prevailing, customary, and reasonable" charges, allowing for differences in geographic area, past experience of individual practitioners, and prevailing market prices or fees.

Third-party payers are evaluating their coverage of NMR imaging. Some third-party payers have already begun to pay for NMR scans. Technology assessments of NMR imaging are now being performed by OHTA (for the Medicare program) and by the Blue Cross and Blue Shield Association.

State Certificate-of= Need Programs

Although State certificate-of-need (CON) programs were never specifically intended to constrain the diffusion of medical technology, they constitute one of the major policy mechanisms available to health planners for control over technology adoption. CON review of "need" may be based on numerous factors, including clinical use of technology, institutional characteristics, economic and financial effects, and population-based considerations. In the past, CON programs have employed at least four different policy orientations or strategies regarding technology introduction and distribution: pro forma denial, formalized strategy of delay, predetermined limits on diffusion, and uncontested approval.

The CON experience with X-ray CT scanners points out two problems that could arise in the future with NMR imaging: the fragility of shared-service arrangements among hospitals and the creation of incentives that encourage "anticipatory acquisition" of new technology. The latter situation can produce a "franchising" effect whereby hospitals that adopt technology early—often while the technology is still considered "investigational''—become well-positioned to keep the technology once its status changes and diffusion accelerates. Those hospitals that wait to submit CON applications risk being "disenfranchised" from obtaining the technology.

Various State and local planning agencies report increasing CON activity related to NMR imaging. As of September 12, 1983, at least 33 CON applications for NMR had been reviewed nationwide. Of these, 19 had received approval: 16 by State Health Planning and Development Agencies and 3 by local Health Systems Agencies. Twenty-five health planning agencies across the Nation also reported that they either had NMR-specific review criteria in force or were planning to develop them in the near future. Pending or recently enacted State legislation or regulations related to NMR were reported in at least six States.

Several distinct CON strategies regarding NMR appear to have emerged among the States. For example, New York, Illinois, Ohio, New Jersey, and Kentucky have each adopted predetermined limits on NMR imager diffusion. The Southeast Kansas Health Systems Agency has invoked a moratorium on NMR until community hospital planning has been completed. The District of Columbia CON program also has statutory power to employ a formalized strategy of delay. Nebraska, by contrast, is encouraging group applications involving shared-service arrangements among hospitals. Utah and California, through recent amendments to their respective State CON laws, appear to be following a strategy of uncontested approval for NMR imagers. No CON program, on the other hand, has adopted a policy of pro forma denial. It is anticipated that CON agencies will witness a rapid increase in the number of NMR applications filed by hospitals once HCFA policies regarding NMR are finalized.

Regulatory Overview

Since FDA has granted premarket approval to the first NMR imaging manufacturers, third-party payers have a position of major influence over the rate at which NMR imagers are acquired by hospitals. This influence will derive from their decisions regarding: 1) whether to cover use of

NMR imaging at all; 2) whether to cover NMR devices only of those manufacturers that have received premarket approval or those of any manufacturer; 3) which types of NMR scans to cover (e.g., head studies only or head and body studies); 4) the monetary level at which use of NMR will be reimbursed; and 5) the level at which professional fees for NMR imaging are set. If initial coverage of NMR is limited to a small number of clinical circumstances or reimbursement rates do not reflect the increased professional time that will initially be required for NMR scanning, hospitals may be restrained in the speed with which they acquire NMR devices.

The introduction of prospective payment based on diagnosis related groups (DRGs) under Medicare is also expected to affect the rate of diffusion of NMR devices into hospital settings. Hospitals now have to weigh financial considerations against patient care benefits more carefully when deciding whether to acquire an NMR imager and in deciding how an acquired NMR scanner is to be used. For some hospitals, such as municipal facilities serving large Medicare and Medicaid populations, the DRG payment system may exacerbate an already financially distressed situation and further impede those institutions' efforts regarding capital formation. The net effect may be to weaken the hospitals that serve as primary sources of care for disadvantaged populations. The ultimate impact of the prospective payment system on acquisition of NMR scanners is likely to depend on future HCFA decisions regarding recalibration of DRG payment rates to take account of introduction of new technology over time and regarding inclusion of capital expenditures in the DRG rate,

The final major regulatory influence on the rate at which new technology, such as NMR imagers, diffuses throughout the medical system is State certificate-of-need (CON) policies. There is already evidence that CON agencies are delaying the acquisition of NMR devices by some hospitals. Whether State agencies are adequately informed to be able to make appropriate decisions regarding whether and when NMR scanners should be introduced into hospitals is questionable.

A number of problems with CON policies that have appeared over the past decade in the experience with X-ray CT are likely to affect the course of NMR as well. Evidence for "franchising" and "anticipatory acquisition" of NMR is already available and will need to be addressed by CON programs. In addition, there is evidence of considerable interest on the part of private radiology groups, as well as hospitals, in establishing outpatient diagnostic centers which will include, but not be limited to, NMR devices. In most States, such ambulatory placements do not require CON approval. If State agencies are interested in controlling the introduction of new technologies, such as NMR, they will have to address themselves to this limitation in their purview. Alternatively, CON agencies could leave control over the "introduction" of technology to the FDA and third-party payers and concentrate on playing a complimentary role by assuring equitable distribution of new technologies within their jurisdictions.

In addition to these influences on the rate at which new technologies such as NMR imagers diffuse, two final policy issues should be addressed. First, there appears to be a large amount of duplicated effort on the part of FDA, third-party payers, CON agencies, and hospitals with regard to the assessment of new technology. Although it is unclear whether it would be beneficial to increase the coordination among these separate technology assessment efforts, the issue should be addressed. If HCFA is to continue relying on the Public Health Service's OHTA as an impartial source of advice, attention should be given to whether the resources available to OHTA are adequate.

Finally, as more technologies become available, it becomes increasingly important that the comparative efficacy of each be adequately evaluated and defined. How such comparative efficacy data will be acquired and who will fund the studies necessary to generate them are increasingly important issues that the Federal Government and others need to address if appropriate reimbursement policy decisions are to be made. In the case of a rapidly evolving technology, such as NMR imaging, the question of when to perform such comparative assessments also needs to be addressed. This "moving target" issue has hampered comparative efficacy assessments in the past.