

# Health Care Technology in France

by *Caroline Weill*

4

## OVERVIEW OF FRANCE

**F**rance is an industrialized country with a large agricultural sector. Its population in 1991 totaled 57 million. According to the Constitution of 1958, France is organized as a parliamentary democratic republic. Separation of legislative and executive powers, multiplicity of political parties, and respect for the Constitution and the Human Rights Declaration are the guaranties of democracy.

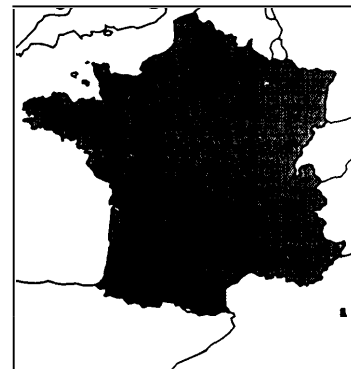
The French Constitution refers to health as a fundamental right. According to this document, France guarantees to everyone, "especially to the child, the mother and the aging worker," health protection.

### Government and Political Structure

The main French powers are the *President de la Re'publique*, the Parliament, the government (*Conseil des Ministres*), and the Prime Minister. The President, who serves as the head of the French state, represents the French nation. He is also the chief of foreign policy and the commander in chief of the French army. The President is elected through universal franchise (all citizens vote) for seven years and can be reelected.

The French Parliament is divided into two chambers: the *Se'nat* and the *Assemblée Nationale*. Senators are elected by elected members of local assemblies for nine years. Members of the *Assemblée Nationale*, called *deputes*, are elected through universal franchise for five years.

The *Conseil des Ministres* executes the laws passed by the Parliament. The Prime Minister is the leader of the government; he is nominated by the President. The government is responsible to the Parliament for its policy and programs.



Metropolitan France is divided geographically into 95 *departments* (departments) including four overseas departments. Under the authority of prefects, the departments administer the local services of most of the ministries. The departments are grouped in 22 *regions*, whose prefectural authorities are responsible for implementing the government's regional economic development policy. A total of 37,000 local administrative units (*communes*) have wide powers for managing major public services, including health services.

The 1982 and 1983 Decentralization Acts were intended to confer greater decisionmaking powers on the lower echelons of local government; general policymaking was to remain the responsibility of the central government. These acts distinguish between two types of authorities in each administrative unit: the appointed representatives of the central government and the elected representatives of the local communities. The former are the *prefets* (prefects), of whom one grade has responsibility for the departmental level and another for the regional level.

The elected representatives of the local communities (*communes*) are headed by the president of the assembly, an elected local representative. The elected councils are the *Conseils Municipaux* for the towns, the *Conseils Generaux* for the departments (i.e., several towns), and the *Conseils Regionaux* for the regions (grouping several departments).

The Decentralization Acts transferred to local elected authorities various functions formerly performed by the central government. Each community is fully responsible for its functions, for which it raises taxes, and each acts freely without control from other communities. Generally, the localities are responsible for public services; the *departements* are in charge of social aid, health, and welfare; and the *regions* carry out economic responsibilities, including planning.

Departmental councils are in charge of maternal and child health, immunization activities, and medical assistance for the uninsured. These councils can issue regulations for the services and residential establishments they supervise. Communal

health services, under the authority of each town's mayor, comprise the Communal Hygiene Service and community health centers and dispensaries that carry out primary local health care activities and preventive work.

The central government, through its regional directorates and coordinated by the regional prefects, establishes and implements rules for public hygiene. The central government is also directly in charge of policies concerning mental illness, drug addiction, and alcoholism. It establishes regulations for social welfare and health insurance, controls the finances and activities of public hospitals, and is in charge of health planning.

### Population Characteristics and Health Status

In 1991, 27 percent of the French population was under 20 years of age and 14 percent was over 65 years. The crude birth rate—which has been decreasing over the past 20 years—was 13.3 per 1,000 inhabitants in 1991 (31).

Since 1980, life expectancy at birth has continued to improve, reaching 77 years in 1991 (for females, 81.1 years, for males, 73 years). Infant mortality decreased from 10.1 deaths per 1,000 births in 1980 to 7.3 per 1,000 in 1991. The death rate (standardized) for the entire population fell to 9.2 per 100,000 in 1991, compared with 10.0 in 1985 and 10.6 in 1970.

Five major categories of causes of death account for more than 80 percent of all deaths in France: diseases of the circulatory system (37 percent), cancer (24 percent), injuries and poisoning (9 percent), diseases of the digestive system (6 percent) and respiratory diseases (6.5 percent) (31). In France, mortality differentials among males indifferent social strata exceed the differentials between men and women (31). The categories of people most likely to die prematurely are (in decreasing order): manual workers, skilled workers, service personnel, and unskilled workers. The same general relationship is apparent in mortality differentials among females but is less marked. Mortality and morbidity also differ

among geographical regions; rates are generally higher in the northern and eastern regions of France.

The incidence of infectious diseases (e.g. tetanus, diphtheria, poliomyelitis, and tuberculosis) is very low. AIDS, on the other hand, has become a very serious problem in France, which has the third-highest incidence and the highest prevalence in Europe. There were 3584 new cases in 1991 (0.32 per 100,000), and a total of 18,508 cases registered. Disabilities among the elderly are becoming more and more serious problems, given the increase in the number of people who are more than 80 years old.

Certain behavioral factors cause health problems (31). Smoking rates, for instance, increased for some time but have now stabilized. A 1991 law strongly limited propaganda and advertising for tobacco and has prohibited smoking in public areas. Fat consumption has increased, but alcohol consumption (still very high in France) has decreased from 16.2 liters per person in 1983 to 12 liters in 1990. Alcohol-related mortality rates are significant: the estimated number of deaths due to cirrhosis and alcoholic psychoses was 14,000 in 1992 and another 14,000 deaths are attributed to cancers of the respiratory and digestive systems. Alcohol-related accidents are estimated at roughly 21 per 100,000 people, more than twice the rate in the United Kingdom.

## THE FRENCH HEALTH CARE SYSTEM

The health care system in France combines freedom of medical practice with nationwide social security. Every employed person or student, individuals on welfare or retired, and both French citizens and foreign residents benefit from the system, in which participation is compulsory. Health care is provided by a range of institutions, both public and private, and patients have free access to any physician. Patients' expenses are paid directly either to the hospital or to the practitioner by the social security insurance system, or they are paid by the patient and then refunded.

Universal availability of health care is guaranteed largely by the national health insurance sys-

tem. In addition, the Social Aid Scheme provides benefits for individuals not enjoying full social security coverage (i.e., people who have been unemployed more than one year and who cannot benefit from a parent's coverage). This corresponded to 390,000 persons in 1986, and 550,000 persons (1 percent of the total population) in 1992.

That said, the funding of health-related expenses is a chronic social policy problem in France. The principle of providing a high standard of care for the entire population, set against a background of rising costs and, more recently, decreasing income (due to increasing unemployment), is causing a financial gap that the government is struggling to close. Health-related expenditures rose from 6.1 percent of Gross Domestic Product (GDP) in 1970 to 8.9 percent in 1991. More than 75 percent of health expenses are covered by public-sector mechanisms; the remainder is covered by private individuals or complementary private insurance schemes.

## General Administration

In the field of health care and welfare, treatment continues to be a central government responsibility. Accommodating the elderly and the handicapped is now the responsibility of the departments (4). Public and private treatment facilities are opened, expanded, or merged on the basis of a planning tool known as the "health map" (*carte sanitaire*), drawn up by the Ministry of Health in accordance with a 1970 law (modified in 1991). For the major disciplines of medicine, surgery, and gynecology and obstetrics, this map is based on a list of health care facilities by region and, within the regions, by "health sector." Using requirements expressed in terms of bed-to-population or equipment-to-population ratios, the map quantifies the needed numbers of beds and of equipment considered costly (or "heavy") relative to calculated theoretical levels.

The 1991 revision of the law transferred to the regional representatives of the central government the main responsibility for the health care facility planning process. (This planning process and the definition of "needs" are discussed in more detail

below.) The process does not concern private office-based practice; physicians may establish practices wherever they choose.

In each department, public hospitals and private facilities operating within the public sector are administered by the Departmental Directorate for Health and Welfare (*Direction Departementale des Affaires Sanitaires et Sociales*) under the authority of the prefect. The elected president of each departmental council supervises the day-to-day administration of the Departmental Directorate for Health and Welfare. At the next level, the prefect for the region supervises the Regional Directorate of Health and Welfare, which has responsibility for (among other things) regional health and welfare planning, inspection and management audits of facilities, and regional investment policy.

### ***The Hospital System***

The hospital system is composed of public hospitals as well as commercial and nonprofit private hospitals. The public and nonprofit private institutions participate in the Public Hospital Service and operate for the general welfare of the population. Through this service, all patients are accepted into public hospitals at all times (27). Public hospital management is undertaken by both elected local authorities and the Ministry of Health. Public hospitals are run by a board of directors chaired by the mayor; members include representatives of local communities, Sickness Fund, and medical and nonmedical staff.

The Ministry of Health is responsible for the administrative and budgetary supervision of all hospitals. The Ministry's departmental representative must concur with every decision of the board of every public hospital. This is, understandably, a source of constant tension between local and national views. Public hospitals are generally hospital centers comprising treatment units (e.g., medical, surgical, obstetric), "medium-stay" centers for patients needing convalescent care, curative care units (e.g., spas, addiction centers), centers for rehabilitation or treatment of

mental illness, and long-term medical centers for elderly people who can no longer live independently.

Public hospitals are legally classified in terms of the size of the populations they serve and the types of services they provide. The main categories are general hospital centers, specialized hospital centers, regional (teaching) hospital centers, specialized psychiatric hospital centers, cancer treatment centers, medium-stay centers (for convalescence therapy and rehabilitation), long-stay centers, and local hospitals, where local private physicians have access to beds for their own patients or may treat them there. Regional hospital centers (27 percent of all public hospital beds) provide regional coverage and undergraduate teaching and bring together a large proportion of specialist care and medical services.

Public hospitals are funded by a lump sum grant from the central government determined in agreement with the Social Security bodies under the supervision of the state (see the section on Coverage of Health Expenses). But the Social Security entities and not the state provide most of the financing for hospitals by covering the costs of their insured. In addition, a hospital may, for its investments, receive grants from the state or from a local community, and it may takeout financial and bank loans.

Private hospitals play a major role in the health care system and account for one-third of all hospital care in France. Some are commercial, others nonprofit. Private hospitals are particularly important in certain fields, such as obstetrics and digestive surgery. Physicians in such settings usually work as private practitioners and are paid by patients on a fee-for-service basis. Like public facilities, private hospitals are controlled by the health map.

Since 1980, the number of hospital beds and stays has decreased, and the rate of admissions has slowed. Present policies favor development of the long-stay and medium-stay sectors and a reduction in the short-stay sector. The total number of

beds is still considered too high (247,813 in 1991, two-thirds of which were in the public sector).

Physicians practicing in public hospitals are paid a salary, but to a certain extent they can carry on part-time private practices outside a hospital.

### ***Other Medical Services***

Most doctors practicing in communities provide their services on a private basis, as do dentists, ophthalmologists, pharmacists, and allied health professionals (e.g., nurses, physiotherapists, pediatricians, hearing-aid specialists). Some, however, are employed by the health insurance system, friendly societies, or official authorities—for instance, health centers whose main function is to provide health care for people on low incomes. A large network of public and non-profit private establishments operate facilities offering specific services, such as special services for mothers and children.

### ***Health Care Professionals***

Between 1981 and 1992, the number of physicians in France increased dramatically, from 108,000 to 155,896 (259 per 100,000 population) with a disproportionate increase in the number of specialists. In 1992, specialists accounted for 49 percent of all physicians, compared with 39 percent in 1981. Physicians in private practice represent 80 percent of the total. Since 1985, to limit the number of physicians, the number of students admitted to medical schools has regularly decreased (going from 8,500 in 1970 to 3,500 in 1993). Nevertheless, the total number of practicing physicians in France will increase until the year 2010.

Restrictions on medical practice are not straightforward under the French system. Even if some of the rising costs of health care may be related to an excess of medical activity, some young physicians now experience difficulties in seeing enough patients to make a living. In 1991 a report of INS ERM (*Institut National de la Sante' de la Recherche Me'dicale*, the French equivalent of the U.S. National Institutes of Health) to the Minister of Health suggested that some medical practitioners might receive complementary training to be-

come epidemiologists, lawyers, economists, statisticians, or prevention officers in a renovated prevention system. This idea has not, however, been put into action on a large scale.

The number of nurses also increased, from 246,000 to 294,000 between 1979 and 1986, with a trend toward private-sector employment. A high turnover rate in nursing stems from increasing dissatisfaction with jobs, position, status, and income (especially in the public sector).

Health care personnel are unevenly distributed geographically, with a disproportionate representation of medical and allied professions in private practice in the south of France and the Paris region. Regional differences are greater in the most specialized professions.

### **Payment for Health Care**

Health costs totaled more than 573.4 billion francs in 1991, representing an average of 10,000 francs (\$US1,800) per capita and 8.9 percent of the Gross National Product (GNP). France leads the European Economic Community in its health expenses, which have risen 7 percent annually in recent years (see table 1- 1). Nearly 97 percent of this total is spent on medical goods and services; 3 percent is spent on preventive medicine (e.g., industrial medicine, school health services, mother-and-child protection).

Hospital care and treatment account for almost half of the total expenditure, office practitioners for 30 percent, and medical supplies (e.g., drugs, spectacles, orthopedic appliances) for 20 percent. Finally, costs are concentrated on a relatively small number of people: 10 percent of all patients account for 75 percent of total expenditures.

### ***The Social Security System***

Most of France's health care expenditures are paid for through a system of compulsory health insurance within the nation's general social security scheme. Health insurance is funded by contributions of both employers and employees. The system is directly managed (under State supervision) by employers and trade union representatives.

Contributions are calculated as a percentage of employees' salaries and cover the health care expenses of any member of that individual's family. In July 1992 the percentages paid by the employer and the employee were 12.8 percent and 6.8 percent, respectively, of the employee's salary. Typically the Parliament has not been involved in payments for health care. Nevertheless, in 1990a small percentage (3 percent) of the employee's contribution (the *contribution sociale ge'ne'ralis&e*, or CSG) was added to the salary-based contribution. The CSG, being a tax voted by the Parliament, gives the Parliament the right to discuss health and social security issues.

Since 1988 the National Sickness Fund (*Caisse Nationale d'Assurance Maladie des Travailleurs Salarie's*, CNAMTS), has covered 73.4 percent of all insured persons' health expenses. In the event of hospitalization, whether public or private, the fund reimburses the hospital directly on behalf of the insured.

When consulting a doctor, however, each patient must generally pay the fees and then obtain reimbursement from the National Sickness Fund. The patient himself is responsible for about 25 percent of the total and is reimbursed for the rest according to a tariff fixed by agreement between the CNAMTS and the doctors' professional associations. The cost of prescription drugs also is reimbursed to the patient.

An increasing number of physicians (18 percent in 1985, 28 percent in 1990) have been allowed by the agreement to charge more than the tariff (*de'passement*), and a few (3 percent) with high qualifications have chosen to practice outside the agreement. The latter can charge what they want, and the reimbursement is close to nothing: however, the patient may receive a partial refund from private insurance. Confronted with a notable increase in the number of physicians choosing to overcharge, the government decided in March 1990 to "freeze" the number of physicians able to do so. After negotiation, this decision was accepted by the physicians' representatives.

The costs for which the insured remains personally liable (i.e., the *ticket mode'ateur*) can be covered by a private insurance scheme or by a

nonprofit organization directly managed by its members who traditionally play an important role in this regard. These organizations are usually structured to cover individuals in certain jobs or professions.

The Social Aid Scheme is organized by local authorities to meet the needs of people of inadequate means. It can either act in lieu of Social Security or complement the latter's benefits. The role of Social Aid is now greatly reduced.

### **Price Setting**

Prices for ambulatory care are determined by a governmental decree after negotiations between the National Sickness Fund and the national trade union of physicians. Price setting is based on a list of medical procedures. The private practitioner must give the patient a file to be sent to the National Sickness Fund in order to claim reimbursement. To protect medical confidentiality, medical procedures are not registered individually but expressed through "key letters" (C for a consultation, Z for radiology, B for biology, K for surgery, etc.) combined with a coefficient; the key letter corresponds to a certain price, and the coefficient is a multiplier. The key letter is unrelated to any diagnosis. Unfortunately, one consequence of this system is that it is difficult to ascertain what medical practices are actually performed on a routine basis; they can be classified only in aggregate (e.g., several procedures have the same "290" code).

More than 4,000 procedures are classified under 50 key letters. The list is not frequently or regularly modified, so the valuation of the procedures is approximate and usually does not represent real costs. New technologies are classified through "assimilation" to older, comparable procedures; which may lead to some highly profitable technologies and other highly under-reimbursed ones. Updating this list appears to be quite difficult because of the multiple and contradictory goals involved (e.g., health benefits, cost containment, support of the medical industry). The seeming impossibility of updating the list has been one of the most evident limits of French health policy since the beginning of the 1980s.

Private physicians' activities and prescriptions account for 50 percent of total health care expenditures. The annual growth rate of private office practice in France was 8.5 percent in 1989 and 7.2 percent in 1990, in contrast with 6.8 percent from 1980 to 1988. Because physicians are paid on a fee-for-service basis and prices are set by a legal tariff, it is clear that physicians must increase their activity in order to increase their personal income; moreover, overall activity increases as a result of an increase in the number of physicians. A law passed in January 1993 was aimed at allowing a negotiated limitation of this increase. This law defined the principle of an annual financial goal for the profession as a whole (*enveloppe*)-which, according to the law, is to be based on "national medical references" of practice, taking in to account several factors (e.g., general population characteristics, the state of medical technology, the knowledge base in epidemiology, and the state of medical supplies). The law stresses the responsibility of the National Sickness Fund for the control of rising health costs.

The annual agreement signed at the end of 1993 between the National Sickness Fund and the private office practitioners' trade unions included several important clauses, including the use of treatment protocols, based on fully assessed scientific literature as rules of practice for private office practitioners. During the summer of 1993, the medical board of the National Sickness Fund devised such rules for 80 well-documented conditions. These drafts were reviewed by experts nominated by the physicians' unions, and by the Agency for the Development of Medical Evaluation (ANDEM). These protocols will be used to evaluate statistically the activity of practitioners. Practitioners who treat more than 20 percent of their patients not in accordance with the protocols risk financial penalties.

To implement these rules, physicians will have to report (anonymously) details of their activities. A new database will be created in two steps: first, prescriptions will be registered openly; later, the database will include diagnosis-related prescriptions in private office practice. A medical record (*carnet de liaison*) will be established for each pa-

tient by general practitioners. This file will become the center of a medical information network, and all patients will carry a summary of their medical records that they will have to show every time they see a doctor in order to be reimbursed. (Every physician attending a patient as well as the medical board of the National Sickness Fund will be allowed to review the patient's medical record.) At first, only patients over 70 will be involved in this reform.

Until 1985, hospitals were reimbursed by the National Sickness Fund on a fee-for-service basis. For each day spent by a patient in a hospital bed, the hospital received an amount that was to cover the average cost for a given medical specialty. As a result, the hospital's income was automatically adjusted for expenses. This method had dangerous inflationary consequences. Since 1984, a new payment system has been established by the government (initially for the public sector only) based on an annual global grant for each hospital defined by the Ministry of Health and allocated to each public hospital every year for the following year.

The basis for each hospital's budget has been, for year 1 (i.e., 1985), the level of its income for year 0; thus, at the start, the most efficient hospitals were penalized. Every year the budget of a given hospital may increase after a negotiation between the hospital, local Social Security representatives, and state representatives. The budget reflects the hospital's activity at the end of the fiscal year plus an amount of money determined through the application of a "national rate of acceptable increase in expenses" established by the government after overall prices and wages in the industry are reviewed.

Each hospital's annual budget is then submitted by the director in accordance with government rules and either approved or rejected by the board of directors (although rejection is of no particular consequence if the government representative—the prefect—approves it). One-twelfth of this allocation is paid to the hospital each month by a "lead fund" (*caisse-pivot*), usually the local branch of the National Sickness Fund. Financial reparation is made to the different funds involved.

Since 1991 this procedure of payment has been extended to the private hospitals. Every year, a “national quantitative goal” is determined according to national agreement; it expresses a level of activity not to be exceeded during the following year. In 1992, a maximum, agreed-upon level of expenses was negotiated as well with representatives of laboratory physicians; negotiations are ongoing with representatives of radiologists.

Pharmaceutical prices are set by the government after extensive negotiations with representatives of the industry (*Syndicat National de l'Industrie Pharmaceutique*, or SNIP). A general agreement with SNIP is followed by specific contracts with each firm or laboratory. The negotiations focus on several goals, including rationalization of the use of drugs in France (which is considered too high), cost containment, and protection of the French pharmaceutical industry, which is highly competitive (with 80,000 employees and annual sales of 90 billion francs).

Financing the introduction of new technologies in hospitals is differently regulated for private and public hospitals. For private hospitals a specific procedure called the interministerial tariff for health devices (*Tarif interministériel des prestations sanitaires*, or TIPS) determines the conditions under which hospitals may be reimbursed following the acquisition of medical equipment or drugs for individual care. This procedure, based on a list of prices, is implemented by the Ministry of Health with input from other officials in other ministries involved in the setting of prices. Public Hospitals, in contrast, invest in needed equipment and drugs by using requests for proposals (when the amount is over 100,000 francs).

If the equipment to be procured is subject to premarketing approval, the hospital must go through this procedure in order to be reimbursed. In any case, three other conditions must be fulfilled: 1) registration with the pricing list (*nomenclature*), 2) conformity to legal manufacturing standards, and 3) an existing set fee for the medical procedure involved. For certain equipment considered especially costly or of nationwide interest, advance purchasing authorization by the Ministry of Health is also required (see below).

## CONTROLLING HEALTH CARE TECHNOLOGY

The regulation of health care technology in France is different with respect to pharmaceuticals and equipment or devices. The regulation of pharmaceuticals is based on a time-tested, pre-marketing approval approach designed to assess the safety and efficacy of drugs. The regulation of equipment entails approval of the location of services and pre-market approval of the equipment itself—two distinct processes. Since 1970, placement of services have been decided by a planning system for hospital beds and major equipment that is aimed largely at guaranteeing equal coverage across the country. The pre-market approval procedure, which was reinforced in the 1980s, remains weak.

### Regulation of Pharmaceuticals

Control of pharmaceuticals is based on a procedure of “authorization to market” (*autorisation de mise sur le marche*, or AMM). Created in 1972, the AMM procedure controls verification of the therapeutic value of pharmaceutical products and their correct use. The companies bear the major responsibility for testing products for efficacy and safety in fulfillment of the authorization requirements. Until 1992, the AMM process was administered by the Ministry of Health; the minister himself signed each AMM after reading the findings of the *Commission de l'AMM*. After the AMM is signed, cost-effectiveness is considered (along with conditions for placing a drug on the pricing list for reimbursement) by another committee, the *Commission de la Transparence*.

Since 1980, surveillance of adverse effects of pharmaceuticals has been part of drug regulation. Physicians and pharmacists are supposed to report any unexpected and harmful effects of medications to a network of “pharmaco-vigilance” centers. Warnings and even the withdrawal of a medication by the Ministry of Health can ensue after advice from the National Pharmaco-Vigilance Commission. Up to now, however, only a few drugs have been reported to this Commission.



Despite some red tape, the system for assessing medication has been considered a model system. Recently, several experts have pointed out that there are insufficient funds and staff for implementing the AMM procedure. To solve this problem, in 1992 the government decided to create a new body, the Agency for Medicine (*l'Agence du médicament*), an independent agency financed by grants from the government and industry oversee the AMM procedure. The agency may also receive private funding. The Agency of Medicine has a staff of 320 experts, one-third of whom are physicians and chemists. During its first year, this agency dealt with more than 1,000 authorization requests. Its board of directors includes, together with Ministry of Health representatives, individuals from the Ministries of Research, Industry, and Finance and from Social Security, along with seven experts (including a representative of industry).

The agency's director, not the Minister of Health, signs the AMM for drugs. It is expected that this new procedure, which involves all the players, will be more consensual. One of its main goals is to define the ways and means of its cooperation with the European agency created by the European Union in London.

### ***Pre-Marketing Approval Process***

The pre-marketing approval process (*homologation*) aims at assuring safety for patients as well as machinery operators and at assessing new technologies' technical and clinical efficacy (25). (Efficiency prospects, comparisons, or cost evaluations are not part of this procedure.) A manufacturer applies for pre-marketing approval by submitting results of tests carried out by one of the official laboratories listed by the Ministry of Health, as well as clinical trials. The procedure takes six months on average. Until 1990, the pre-marketing approval process affected only public hospitals. Like private clinics, private hospitals were free to buy any equipment of their choosing.

Since the decree of October 1990, manufacturers have been held responsible for the marketing of any new technology. As a consequence, pre-

marketing approval is now required for both public and private medical practice. Only about 70 technologies have in fact been governed by this procedure to date. These are listed on an official decree as "technologies implying a risk for the patient or for the user of the machine."

A National Pre-Marketing Approval Commission advises the Ministry of Health. The 30 members of this commission include 12 representatives from the concerned ministries (e.g., Health, Industry, International Trade, Defense, Consumer Interests, Research) representatives from Social Security, nine representatives of stakeholders (e.g., representatives of public and private hospital associations, industry, insurance companies), and nine individuals personally nominated by the Minister of Health.

Extension of the pre-marketing approval process to private hospitals and local practitioners, combined with the temporary consequences of internal administrative organization, has caused dramatic delays in the system. The National Commission as well as the bureau in charge of the process at the Ministry of Health appeared initially unable to handle the volume of requests, even though less than 10 percent of all technologies were governed by the process. The logistics remain problematic, and manufacturers complain about the costs and delays involved.

### ***Post-Marketing Quality Control***

Since July 1986 a post-marketing procedure has been established for medical equipment, aimed at observing the conditions of use and modification of equipment in order to detect any risk, incidents, or accidents and, ultimately, to minimize risks. Users of approved equipment must fill out a form when taking possession of the equipment and whenever an incident occurs or may be foreseen. Inquiries are then held when incidents are reported, with various possible consequences: canceling approval of the equipment either temporarily or permanently; definition of new directions for use, modification of norms, setting up of new trials, etc.

Although theoretically significant, the system is of little practical use. Only about 50 forms were completed in the first year and even fewer thereafter. In 1991 only 19 forms went through the entire procedure, and half were rejected by the National Commission.

### ii9 Health Care Planning

As noted earlier, the French health care planning system, based on a national health map, was setup in 1970 (4,28). The system was modified by the 1991 law on hospitalization to consider the qualitative aspects of medical services. In every region the health map quantifies equipment and beds required in the future, as evaluated by “need indexes.” In addition, the “regional scheme of health organization” (SROSS), which is defined through an extensive negotiation process, is established in every region and qualitatively describe various common goals for health care and health equipment supply.

Definition of needs is technically very complex. The definition of needs for beds and heavy equipment is the technical base for health care mapping; until 1991, this was the task of the Ministry of Health (though it involved groups of experts at different levels). In its conception, this procedure aimed at stimulating the reorganization and equal distribution of health care facilities and services. It was intended to guarantee the availability of resources for all geographic areas and population groups during a period when facilities were being built and technological innovation was strong.

National bed-to-population ratios for medicine, surgery, and obstetrics, as well as equipment-to-population ratios for some heavy equipment listed in a national decree, were established as reference points (mostly guided by existing capacities in 1973). A reference health map was then drawn that described desirable health care facilities for the entire territory. The document was finalized in 1977 and revised once (in 1980).

In each health sector, the calculation of a needs index makes it possible to ascertain whether

health care facilities are adequate. When the needs index shows an excess in existing local capacity, creation of a new facility is deemed legally impossible.

This process has suffered from a lack of expertise and funding. The reference ratios have remained inexact, having taken little account of epidemiologic, demographic, and local characteristics. In the case of diagnostic equipment, such as computed tomography (CT) scanners or magnetic resonance imaging (MRI) equipment, establishing an appropriate reference ratio based on objective assessments or data has been especially difficult. The temptation to politicize the process—either by allowing perceived “needs” to drive the purchase of new equipment or by increasing the size of the population considered in the equipment-to-population ratio in order to restrict equipment capacities—has apparently been a problem. Although the system was designed to guarantee equitable health care across the entire population, other criteria—such as the balance between the public and private sectors, competition with other countries, industrial motivations, or cost containment—have entered into the picture. Moreover, the intended universality of the approach did not in fact come to pass, as authorization processes differed with respect to requests by public versus private hospitals.

Ultimately, it became clear that most of the health sectors were overequipped and that the health map system was operating strictly as a quantitative limitation tool. Not only increases in the number of hospital beds but also the restructuring and reorganizing of existing facilities became impossible. As a result, the law was revised to allow a more evolutionary approach. In 1991 the health map was extended to cover every technology and setting necessary to meet the population needs. For example, same-day care (e.g., at-home hospitalization and ambulatory surgery), costly medical activities, and other activities ‘of special importance to public health are now covered by the health map. Moreover, the authorization process is now the same for private and public hospitals. The list of activities and procedures

governed under the agreement system (hence requiring a specific governmental license) includes the following:

- implementation of services (e.g., opening of new departments as well as extensions, reorganizations, or conversions) in one of the basic disciplines, including medicine, surgery, obstetrics, psychiatry, rehabilitation or convalescence care, and long-term care;
- heavy equipment, including extra-corporeal heart-lung machines, hyperbaric chambers, hemodialysis apparatus, blood product separators, centrifuges, cyclotron, nuclear medical devices, CT scanners, digitalized angiography, MRI, radioactive monitoring, lithotripsy, and imaging networks; and
- major care, including organ and bone-marrow transplants, bum treatment, cardiac surgery, neurosurgery, emergency care and trauma centers, intensive care, radiotherapy, nuclear medicine treatment for cancer, neonatal centers, chronic renal failure treatment, reproduction treatment and research centers, and rehabilitation.

The law requires that the Ministry of Health determine national goals for the health system as well as national need indexes for each program and each piece of equipment or group of activities, after being advised by a national committee (*Comite' National de l'Organisation Sanitaire et Sociale*). This committee has 40 members, including representatives of the Ministry of Health, two Congressmen, one representative from each type of local assembly, and representatives of the different Social Security funds, public and private hospital unions, various unions of physicians, patients, and health professionals' unions.

Regional mapping is undertaken by regional authorities for each of the 247 "health zones" (which are different from the administrative regions), and SROSS (health and social organization scheme) is designed prospectively for every zone. (Zones are intended to be internally coherent with regard to medical facilities, economic and social activities. geography. transportation fa-

cilities, and cultural traits.) Regional committees of representatives work as advisers to the regional directorates; members are comparable to those of the national committee at the regional level. According to the law, the SROSS and health map are designed to fulfill the needs of the population while taking into consideration local disease patterns, demographic trends, improvements in medical technology, and present available supply.

The 1991 law concerning the authorization process has six main characteristics:

- unification of processes for the private and public sectors;
- compatibility of individual authorizations with the goals of the SROSS;
- requests for authorization must include a commitment from the applicant regarding the level of activity involved and future costs to insurance funds;
- permits are given for a limited period of time, and can be revoked;
- regular assessments for all permits; and
- permitting by the regional prefect, with the exception of permits for certain equipment and health care facilities listed by special decree, including extracorporeal heart-lung machines, centrifuges, cyclotrons, nuclear diagnostic equipment, MRI, organ and bone marrow transplants, treatment for serious bums, cardiac surgery, neurosurgery, nuclear treatment for cancer, and reproduction treatment centers.

Permits are issued by the local representative of the government for a period of five years or less. Renewal is subject to the same conditions, including that of evaluation. If fully used by the government, this mechanism might have important consequences for future technology assessment—because evaluation is involved at every stage of the planning process—and for general health care regulation in France. The system remains quite new, however. It is too early to evaluate the future impact of the 1991 law, although it is obvious that a major attempt to rationalize the health care system and to make it more responsive to the needs of

the population has been launched, and an important negotiation process has begun at local levels.

### HEALTH CARE TECHNOLOGY ASSESSMENT

Concerns about the quality of health care began appearing in France in the 1970s (21,32). At the same time, efficiency issues became central for the health care financing system due to increases in health care costs. The deficiency of medical technology assessment was stressed by the Minister of Health in 1983. At that time, only the director of the Hospitals of Paris benefited from the advice of a proper, permanent group of experts (the CEDIT) with respect to purchasing and siting new technologies. To plan, set tariffs, and perform quality control responsibilities, neither the Ministry of Health nor the CNAMTS had any means of evaluating medical practice or medical technology; thus, decisionmaking relied mainly on negotiations or arbitrary evaluations. A leading university physician was commissioned by the Minister of Health to investigate ways of implementing a system that would allow for the development of medical technology assessment at the national level. His 1985 report recommended the creation of a multipartner, financially self-sufficient foundation to hold consensus conferences. The report was accepted, and a contract was signed by all the partners for the creation of this foundation. Unfortunately, a change of majority in the Parliament occurred, and the project was canceled by the new government. Nevertheless, in 1987 the government set up an institution called the National Committee for Medical Evaluation in Health Care. This committee involved leading personalities and official representatives of the health care system, but had neither a budget nor an official schedule. Its task was mainly to discuss ethical issues and methods of evaluation in health care and to develop priorities.

In 1989, after the return of a socialist majority in the Parliament, a leader of the continuing medical education association was commissioned by the Minister of Health to undertake another study. His report involved most of the experts in the field

of medical technology assessment. It led to the creating a national agency to launch medical technology evaluation as a national project.

The emphasis on technology assessment must be placed in the wider context of the French government's concern about a lack of evaluation of public programs in general during a time of economic difficulties. The need to assess public policies and programs was indicated by several reports as a much-needed goal. Specific bodies, including a National Evaluation Committee (*Comite' National de l'Evaluation*) and a Scientific Board (*Conseil Scientifique de l'Evaluation*), were created close to the Prime Minister, and some grants were allocated for starting evaluation projects. (Fifteen projects have been financed by the National Evaluation Committee, none of them dealing with health policy.)

This concern about evaluating public programs reached its zenith in 1990, when reform of the law on hospitalization was discussed by the Parliament. The new 1991 law finally included not less than 14 articles treating evaluation as a major theme—thus lending medical technology evaluation the status of a legal requirement for every hospital manager and for every health care professional.

This entirely new situation is to be realized through a new set of norms and practices in the health care system. Yet this field must be created, as the law has expressed requirements and goals but has not defined ways and means. The concept of evaluation itself remains undefined and health professionals recognize the need for expert help. Expertise and training are in major demand. Professional training and seminars offered through the National School of Public Health, university courses, use of private experts, and cooperation with public researchers for specific evaluation programs are all growing. The years to come will show if this approach has been successful in building greater expertise into the decisionmaking process.

In 1994, the main bodies involved in health care technology assessments are as follows:

1. the Department of Evaluation of the Hospitals of Paris, which includes the CEDIT, the oldest and the most experienced French technology assessment program, and a new bureau in charge of evaluation of health care;
2. ANDEM, a recently created national agency financed equally by the Ministry of Health and the National Sickness Fund, in charge of developing medical technology evaluation in France, building adequate methods, assessing medical practice, and training students and practitioners; and
3. a group of institutions inside the Ministry of Health or close to it at the national or local level, created by the 1991 law to use the concepts and tools of evaluation as a way of regulating health care.

### 9 Committee for Evaluation and Diffusion of Medical Technology (CEDIT)

CEDIT is part of the Department of Evaluation of the Hospitals of Paris, which also includes a new bureau in charge of evaluation of health care. CEDIT was established in 1982 as an advisory board for the General Director, mainly to help the Director buy and site new and costly medical technologies.

The General Director, the president of the Medical Council, and any chief physician of a clinical department or hospital director may ask CEDIT to investigate implementation of a new technology. The staff will study the case and present its conclusions to the scientific board, which will make recommendations to the General Director regarding diffusion, placement, financing, and assessment of the technology.

The staff of the committee includes 10 experts from various disciplines. Also involved are physicians trained in economics, a hospital manager, and an engineer. The Scientific Board has 18 members; half are top physicians, and the other

half represent hospital managers of the Hospitals of Paris.

Methods of assessment include synthesis of relevant medical literature, consultation with experts, and economic evaluations. Roughly 50 technologies have been investigated by CEDIT the past 10 years (see appendix table 4-1).

In 1991, CEDIT became a branch of the new Department of Health Care Evaluation of the Hospitals of Paris. The other branch of this department is dedicated to the evaluation of health care. Its first missions have included:

- conceiving follow-up tools for topics selected as indicators of malfunction (e.g., waiting time in emergency care departments or for outpatient care; drug delivery; surveillance of falls of patients; surveillance of nosocomial infections; followup of complaints, etc.);
- launching multicenter studies on the quality of health care; and
- cooperating on evaluations of the management of planned and integrated care.

The department also has built a network of medical practitioners specializing in medical evaluation. An assessment of its activities will be carried out after three years.

### Agency for the Development of Medical Evaluation (ANDEM)

Generally speaking, ANDEM is in charge of leading any program of technology and health care assessment with an impact on public health (with the exception of pharmaceuticals). ANDEM was established by law in 1989 as a nonprofit, independent association with the following goals:

- to develop internal projects in technology assessment,
- to validate the methods and means of external projects,
- to disseminate the results of assessments, in cooperation with concerned professionals,

TABLE 4-1: Guidelines Issued by CEDIT

Year	Topic
1990	<ul style="list-style-type: none"> <li>▪ Implantable insulin pumps</li> <li>▪ Cochlear implants</li> <li>▪ Treatment with intravenous polyvalent immunoglobulins</li> <li>• Treatment of prostatic adenoma by hypothermia</li> </ul>
1991	<ul style="list-style-type: none"> <li>• Stereotaxic radiotherapy with gamma rays</li> <li>• High-resolution digitalization of angiographic images and reducing use of film</li> <li>• The digital system for transmission of digital images</li> </ul>
1992	<ul style="list-style-type: none"> <li>Endovascular treatment of intracranial aneurysms by platinum microcoils</li> <li>Measuring the attenuation of ultrasound by bone</li> <li>▪ Novacor Phase II</li> <li>▪ Chronographic diagnosis of endotoxemia</li> </ul>
1993	<ul style="list-style-type: none"> <li>• Ventriculocysternostomy under endoscopic control</li> <li>• High-speed rotational coronary angioplasty (Rotablator)</li> <li>▪ The treatment of tremors by thalamic stimulation</li> <li>• Extracorporeal photochemotherapy</li> <li>▪ Endovascular hepatic echography</li> <li>• Digital echography</li> <li>▪ Minitransplants of bone marrow</li> <li>▪ Applications of the Charpak wire chamber in radiology</li> </ul>

SOURCE C Weill, 1994

- to build a resource center of documentation on French and foreign assessments,
- to build a network of assessment specialists,
- to develop a proper curriculum for the training of medical evaluation specialists, and
- to measure the impact of specific assessments on health professionals and laypeople.

ANDEM is assisted by a scientific council and is supervised by a board of directors. Its budget, originally \$US1.5 million in 1990, was raised to \$5US million in 1992. (Funds come equally from the Ministry of Health and the CNAMTS.) The agency has a full-time staff of 24 people, mostly physicians, who work with the help of many scientific experts and health professionals. The board of directors (whose chairperson is a civil servant) comprises representatives of the ministries of Health, Education, Research, and Agriculture. Other members are appointed from the CNAMTS, the National Insurance Fund for non-salaried physicians, and the complementary insurance Fund. The National Committee for Medical Evaluation is also represented. Scientific council

members (18 in total) are commissioned by the Minister of Health and are nominated personally on the basis of their expertise.

Topics for assessment may be suggested to ANDEM by the board of directors, the scientific council, or any other partner or professional group. Selecting and launching an assessment requires the consultation of the scientific council and the board of directors. ANDEM has produced syntheses of scientific knowledge on various technologies and a booklet on the methodology of consensus conferences. Its resource center for documentation has become very efficient. Many expert teams are working in parallel on diverse fields and topics. A network is being built that connects private office practitioners interested in medical evaluation. This network develops methods and research studies in collaboration with university experts. A guide to the methodology of technology assessment is being prepared for publication.

The topics and technologies studied by ANDEM are shown in table 4-2.

**TABLE 4-2: Topics and Technologies Studied by ANDEM**

Year	Topic
1990/91	<ul style="list-style-type: none"> <li>▪ Prevention of hepatitis C</li> <li>▪ Heat treatment of prostatic adenoma</li> <li>▪ Osteodensitometry</li> <li>▪ Screening blood with p24 antigen to reduce transfusion-related AIDS</li> </ul>
1992	<ul style="list-style-type: none"> <li>▪ Pre-operative routine testing</li> <li>▪ Bone marrow transplants</li> <li>• Blood transfusions</li> <li>• Lasers in ophthalmology</li> <li>▪ Vascular angioplasty</li> <li>▪ Dental implants</li> <li>▪ Fetal telemonitoring</li> </ul>
1993	<ul style="list-style-type: none"> <li>• Oral Implants</li> <li>▪ Bone marrow transplants</li> <li>▪ Endoluminal revascularization of lower limb arteries</li> <li>▪ Digestive echoendoscopy</li> <li>▪ Gynecologic laparoscopy</li> </ul>

SOURCE C Weill, 1994

Consensus conferences have always been a major ANDEM concern. A 1985 attempt to create a federal foundation to promote a national program of consensus conferences was unsuccessful. Nevertheless, the concept of such conferences quickly created interest among various specialist societies and public health professionals. Many such conferences have been held in France with many different sponsors, such as scientific associations, the National Sickness Fund, the Complementary Insurance Fund, hospital physicians, and so forth. "Consensus conferences" came to refer to any grouping of experts expressing a common point of view, regardless of their methodologies. This resulted in some confusion between scientific consensus based on a proper methodology and other types of consensus. Taking as one of its priorities the need for clearer definitions and guidelines, in its first year ANDEM published a guidebook used for validating consensus conferences. It has also helped organize (and has assisted financially) a limited number of conferences each year, selected by the scientific council. ANDEM participates by

collecting scientific references, defining major issues or questions referred to the consensus panel, disseminating recommendations, and assessing relevant medical practices and the impacts of conferences. It can also work as an advisor, or review various methodological aspects of the process. In 1991, 1992, and 1993, ANDEM was involved in eight consensus conferences, and it has allowed its name to be used in connection with eight others (see table 4-3).

In parallel, ANDEM, together with concerned professionals, has begun working on developing clinical practice guidelines. So far, three have been completed. At the beginning of 1994, the ANDEM was asked by CNAMTS and the Ministry of Health to validate the "medical references" in the context of the national agreement with private practitioners' representatives—a task assumed by the organization's scientific board.

### The 1991 Law on Hospitalization

The new law is based on the need for evaluation, respect for patients' rights, and the concept of universal health care. Evaluation, an important yet undefined concept, has become through this law a leading channel for health care regulation, management, and planning in France. New institutions have been set up to implement evaluation methods in health care management at various levels: regional evaluation committees and an evaluation bureau in the Department of Hospitalization of the Ministry of Health.

#### *Regional Committees for Medical Evacuation of Hospitals (CREMES)*

The 1991 law requires all public and private hospitals, "in order to deliver quality care," to evaluate its activity. This mandate includes evaluation of medical practices, hospital management, nursing care, and "any activity aiming at providing patients with total care particularly in order to guarantee its quality and efficiency."

This new requirement is monitored at the administrative regional level. The CREMES established by law as methodological resources, advise local authorities on:

TABLE 4-3: Consensus Conferences: ANDEM

Year	Topic
<b>Direct involvement of ANDEM</b>	
1991	<ul style="list-style-type: none"> <li>▪ Medicalizing the menopause</li> <li>▪ Urinary lithiasis. therapeutic strategies</li> </ul>
1992	<ul style="list-style-type: none"> <li>▪ Monitoring the extension of non-small-cell bronchial cancer</li> <li>▪ Prophylaxis of endocardial infections</li> </ul>
1993	<ul style="list-style-type: none"> <li>▪ Diagnosis, prognosis, treatment and surveillance of polyglobulinemia</li> <li>• Indications for hepatic transplant</li> <li>• Use of red blood cells to compensate for blood loss during adult surgery</li> </ul>
1994	<ul style="list-style-type: none"> <li>▪ Long-term therapeutic strategies for schizophrenia</li> </ul>
<b>Methodology endorsed by ANDEM</b>	
1991	<ul style="list-style-type: none"> <li>▪ Stopping mechanical ventilation in the adult patient</li> <li>▪ Dealing with infertility For whom? How? For what results?</li> <li>• Selective digestive decontamination during resuscitation</li> </ul>
1992	<ul style="list-style-type: none"> <li>▪ Evaluation of adult ventricular function at the sick bed</li> <li>▪ Digestive cleaning during severe intoxication</li> </ul>
1993	<ul style="list-style-type: none"> <li>▪ Sedation and resuscitation, concept and practice</li> <li>▪ Sexually transmissible disease in the woman, the mother, and the child</li> <li>▪ Predicting outcome in ICU patients</li> </ul>

SOURCE C Weill, 1994

- medical and technical implications of the planning process;
- methods and results of medical evaluations of hospital management, technologies, and practices in health care; and
  - “any question concerning medical evaluation and databases run by public and private hospitals.”

These committees have not been set up as permanent organizations. They do not have autonomous agendas, permanent staff, or means of operating routinely. According to the law,

CREMES intervene only if requested by the prefect or the hospitals; they are not supposed to develop independent projects. Thus, their efficacy in disseminating proper technology assessment methodologies is unpredictable.

Each CREME comprises 11 members nominated by the local government representative (i.e., the prefect) “according to their expertise in the field of medical evaluation and technology assessment.” CREME members must include two hospital practitioners (one of them from a university hospital), one physician from a private clinic, one matron, one public hospital director, one biomedical engineer, and two other individuals commissioned in consultation with ANDEM. CREMES are not legally coordinated at the national level (although such coordination could in theory be provided by the Ministry of Health to bring about coherence in methods and projects). A National College of Experts has, however, been set up for national issues concerning health care evaluations. In this context, the law has given a more official role to ANDEM, which has a legal mandate to validate evaluation methods in the planning process.

ANDEM is thus the methodological support of the entire system, but its tasks are huge, and it is hard to predict if and how this system will actually work. As it stands, each CREME is trying to find its own way toward fulfilling an imprecise mission; no specific resources, human or financial, have been dedicated to this task. Moreover, CREME members are typically local representatives rather than experts in evaluation. Their activity appears to be legally dependent on other local institutions, as the CREMES have to be asked by these groups to work with them.

### ***Evaluation Bureau of the Department of Hospitals***

To implement the 1991 law, a new bureau was created as part of the Branch of Planning of the Ministry of Health under the Hospitals Department. This bureau has a large assignment but limited staff, with one public health physician as a permanent member of the team. The bureau is in



charge of defining “adequate and acceptable methods” for the following:

- evaluating health care organizations policies with reference to public health goals (to be defined by the National Committee of Public Health in concert with the Minister);
- assessing the health care system performance prior to planning at various levels: local, regional, inter-regional, and national;
- stimulating the hospitals to set up programs for quality assurance with the help of assessment specialists (partly through the definition of guidelines).

In June 1993 another bureau dedicated to health care evaluation was created in the Ministry of Health under the general director of Public Health. This bureau is in charge of defining the goals of a policy of evaluation of medical practice. The staff is now working on developing its first projects.

### **Other Activities**

With the new law, a wide field of activity has now opened for experts. Several groups including researchers, clinical physicians, medical-school public health departments, and private consultants compete for evaluation markets.

### **The Researchers**

INSERM, the French national research institute specializing in biomedical and public health research, established in 1990 a special (but temporary) multidisciplinary committee to undertake research in health care prevention and evaluation. This committee may provide grants and contracts, using research funding or with the financial support of the National Sickness Fund. Epidemiologists, economists, and social scientists are involved more than ever before in evaluation projects. A new research unit dedicated to health care economics has been created in Paris and another unit that evaluates innovation and technologies has been created in Marseille. The National School of Public Health, until now dedicated chiefly to management and legal topics, has begun developing research activities in hospital

management and economics, and the quality of health care assessment.

### **Physicians**

The French Society for Evaluation in Health Care and Technology Assessment (SOFESTEC) was created in 1986 as a French version of the International Society for Quality Assurance. Its main goal is to gather experts in the field from various institutions to disseminate the methods and results of both French and foreign assessments.

### **Private Consultants**

A number of private consulting companies (especially audit firms) have “applied physicians” trained in economics, statistics, or informatics and have set up specialized departments for health care and hospital management evaluation. They establish databases, audit hospitals, and report on medical projects for establishments made legal by the 1991 law.

Two consulting firms are of special interest: the Centre National de l’Equipe Hospitalier (CNEH) and SANESCO. CNEH was until 1990a semi-public organization with governmental duties in the field of medical informatics and technology assessment. It has now become an independent, private association whose main clients are the Ministry of Health and public hospitals. SANESCO was created in 1989 by the former director of the Hospitalization Department of the Ministry of Health. Its activities cover technology assessment, databases, auditing, and prospective studies. SANESCO also handles logistics for consensus conferences run by the main complementary insurance Fund (*Mutualite Francaise*).

### **The Departments of Public Health of the Medical Schools**

Departments in various universities are now creating courses in evaluation. More physicians are now trained in such subjects as informatics, statistics, and economics, and they are obtaining postgraduate degrees in health care evaluation. At the same time, hospital informatics and statistics departments have started developing quality-of-care assessment projects in connection with clini-

cians. It appears that the level of expertise in evaluation methods will increase rapidly in the health care system.

### ***CNAMTS Medical Board***

The medical officers of the National Sickness Fund (CNAMTS) are now working to change traditionally control-oriented activities and to develop evaluation projects based on the construction of a medico-economic database. In 1992 the medical board of CNAMTS carried out a huge survey of obstetrics; future possible projects include a comprehensive study of anesthesia. In September 1993 CNAMTS started working on the establishment of reference protocols (*re'fe'*

*rences me'dicales*) in the context of the annual agreement with physicians' representatives. This project includes reviews of published scientific literature and negotiations with medical representatives.

It is not easy to evaluate the future developments and impacts of this type of activity for CNAMTS. This body has been extensively criticized in the past for its preference for control rather than evaluation methods. Considering the importance of this group of public health physicians in the management of health care in France, it will be very interesting to see if it can adapt to new conditions.

---

## Case studies<sup>1</sup>

---

### **TREATMENTS FOR CORONARY ARTERY DISEASE**

A national survey carried out by the National Society of Cardiologists, published in 1991, along with a report to the Ministry of Health by the General Inspectorate of Social Affairs (*Inspection G'enerale des Affaires Sociales* or IGAS) in 1988, provide an assessment of the diffusion of coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA), and other methods (20). Some of the data, especially in the IGAS report, are now as old as 1986, and only some can be updated using the 1990 census of the Ministry of Health. A new survey by the National Society of Cardiologists and a CNAMTS study were carried out in 1992 and 1993, respectively. These studies are part of the negotiation process for new pricing of cardiology procedures, however, and their results are not available to the public.

PTCA was introduced into France in 1978, but not fully developed until after 1983, when the guided coaxial system was introduced. PTCA diffused first in teaching hospitals and then mostly in the private sector, which now appears very active, despite general dissatisfaction with rate of payment for PTCA. Media coverage was considerable, and patients immediately demanded this technique—as they still do.

The 1988 IGAS report noted the following:

The treatment of coronary artery diseases has benefited greatly due to the improvement of drug treatments, of heart-lung machines, of improvements in surgical strategies and, above all, of the introduction of PTCA. Treatment using beta-blockers and calcium inhibitors has now been improved and is better mastered. Intensive care through the veins allows for a better response from the patient. Emergency revascularization surgery in the different stages of

---

<sup>1</sup>The case studies, with the exception of the one on neonatal intensive care, are based on previously published literature. As a result, some of the information may be outdated. More recent data were unavailable when this report was prepared.

unstable angina does not exist any more. Now, surgery is in most cases postponed for scheduled surgery, and takes advantage of the possibility of using a membrane oxygenator for extracorporeal blood circulation. ... before, coronary investigations were restricted by the fear of possible incidents with no other possible conclusion than surgery. Today, PTCA offers a possible treatment to patients over 70, chronically ill patients, or younger adults with an early diagnosis of coronary stenosis.

As a result, the patient population for PTCA has increased dramatically, including older and sicker patients. In addition, coronary artery surgery rates have increased, as has the mortality rate after bypass surgery (from 1.5 to 2 percent in 1970 to 4-6 percent in 1987). The existing studies show that the development of PTCA in particular has led to more angiographic investigations and to major qualitative changes in cardiac surgery. Thus, rather than substitution of a new procedure for an old one, cardiac surgery has been extended (33).

A Ministry of Health census established that in 1990, there were 73 authorized cardiac surgery units, 49 in public hospitals and 24 in private clinics. The growth in these units is significant; there were 44 units in 1979 and 63 in 1987. In 1990, the total number of centers performing PTCA was estimated at 145 and included 55 private centers, which revealed a number of PTCA centers outside cardiovascular surgery units. Hospitals in the south, southwest, and Paris regions are over-equipped, whereas those in the west and north appear under-equipped.

In 1986, 27,000 cardiac surgeries were performed; of these, 24,334 involved extracorporeal blood circulation (EBC) and about half of these (11,675) were coronary artery surgeries. In 1990, according to the Ministry of Health census, 32,702 EBC procedures were performed, an increase of 30 percent.

According to the Society of Cardiologists, about 20,000 PTCAS were carried out in France in 1990, and 30,000 were performed in 1991. Half were carried out in the private sector. The procedure is now available to all potential patients. ap-

parently with no waiting list in most regions. PTCA has replaced conventional bypass surgery in about half of all cases, but the expansion of indications for the conventional procedure has led to the general extension of cardiac surgery.

The indications for PTCA have expanded since 1980. Coronary artery dilatation was initially restricted to single, noncalcified proximal lesions but is now performed in multiarterial lesions, arterial bifurcations, tandem or distal stenoses, and stenotic bypasses. PTCA also may be offered by some operators for the elderly or children, but there is no complete consensus in France on these patients.

Today, PTCA is considered established; various techniques are available, the "gold standard" being the balloon. PTCA with the balloon is a perfected technique, involving tools considered completely reliable. After five years, the results for single-lesions PTCA are the same as those for conventional surgery.

### Concerns with the Technology

A high restenosis rate with PTCA remains a problem. Researchers are now investigating the possibility of finding drugs to treat cell proliferation. They are also working to develop intercoronary support springs, rotary probes to dislodge atheroma plaque, and laser treatment (2).

In 1987, according to IGAS, eight out of 56 surveyed centers had performed more than 30 percent of the total PTCAS in France. More recently, a higher level of dissemination has been observed in smaller centers and in institutions with no in-house cardiovascular surgery, which has been considered problematic. This points up the fact that as the technique is developed, the concept of "surgical cover" has become followed less rigidly.

### Government Policy

Cardiac surgery units are subject to authorization by the Ministry of Health, whose policy implies that every university hospital must have one such department. Moreover, EBC machines are considered heavy equipment requiring ministerial authorization.

The needs index for cardiac surgery identifies the need as one department for every 850,000 inhabitants. However, PTCA is freely diffused, with no government license or specific price setting. In particular, there has been no administrative requirement or control to limit PTCA to, or close to, cardiac surgery units. Setting global policy vis-à-vis cardiac surgery is not straightforward. Today, the pricing of PTCA appears problematic; providers believe that the actual price does not take in account the real cost of the procedure. Negotiations between cardiologists and the Ministry of Health have been difficult during a time when cost containment receives top priority.

## MEDICAL IMAGING (CT AND MRI)

### Regulation

Acquisition of CT and MRI scanners, which are classified as heavy equipment, is dependent entirely on authorization from the Ministry of Health or its local representatives. Need for these devices is evaluated on the basis of an equipment-to-population ratio; if there appears to be no need in a given area, then no hospital in that area, either public or private, can buy such equipment.

Under the 1991 law, the need for CT scanners is evaluated locally, whereas for MRI scanners, it is evaluated nationally (24)—probably because of the high cost of MRI, which means that government financial support is required to purchase MRI equipment. Many experts have stressed that this situation will pose a major obstacle in the event that a particular region seeks to develop a coherent policy for medical imaging.

There are no data on the numbers of CT and MRI scanners in place in France, but only on the numbers authorized, which may not reflect the actual situation. For example, the purchase of a scanner may have been authorized, yet for some reason the purchase was never made. It also is possible (even though this would be hard to prove) that some machines that should be replaced by a new, approved one are being kept in use by hospitals.

### Needs for and Distribution of CT and MRI Scanners

According to the first needs index for CT scanners, one machine was needed for every million inhabitants. At that time, the ratio was 1:250,000 in the United States and 1:450,000 in West Germany. A modified needs index was published in 1981 allowing one machine per 600,000 to 900,000 inhabitants.

Between 1976 and 1981 the main goal of the Ministry of Health was to delay the introduction of foreign CT scanners in France. In fact, the *Compagnie Française de Radiologie* (CRG) was working on a prototype French CT scanner. In 1976 and 1977 CRG distributed two cranial scanners, but the company underestimated the demand for CT scanners. The French total body scanner was ready for marketing only in 1981, which is when the needs index was modified allowing more equipment (15).

The distribution of CT scanners accelerated through annual public programs after 1984, including subsidies from the government to public hospitals for their purchase. By 1987 a new needs index allowed one machine for every 140,000 to 250,000 inhabitants. By 1992, the authorized ratio was 1:122,000. Since the introduction of CT scanning technology in France in 1976, 476 licenses have been granted: 63 percent to public hospitals, 9 percent to nonprofit hospitals, and 28 percent to private for-profit clinics. As a result, France has now attained the population to machine ratio of other European countries.

The national (authorized) stock of MRI equipment in 1989 was of one for every 850,000 inhabitants, which represented the sixth-highest density among the industrialized countries. Sixty-six new imagers were authorized between 1983 and 1989, 74 percent to the public sector. This shows an accelerating trend, confirmed by the current number of authorizations (103, or one MRI for an average population of 564,000 inhabitants).

Since 1984, CT scanning has become accessible to the entire French population without waiting. Every teaching hospital has been equipped

with MRI. Remaining disparities among regions reflect no more than existing disparities in the numbers of hospital beds and of other equipment in the different regions. The Centre and Pays de la Loire regions have been for a long time the least equipped with regard to CT scanners: one machine for every 188,000 people in the Centre region and one for every 225,000 in the Pays de Loire. For MRI, the Centre region has one machine for every 2,264,000 inhabitants; Picardie has one machine for every 1,740,000. Conversely, the Ile de France, Provence-Alpes-Cote-d'Azur, and Midi-Pyrenees regions are the best equipped in terms of MRI and CT scanners, as well as all other facilities. These are also the regions where the equipment rates at private, for-profit facilities are the highest.

The private for-profit sector's equipment rates (for CT and MRI scanners) appeared after 1986 to be somewhat higher than this sector's level of hospital beds. Indeed, 70 percent of the licenses given after 1986 for CT scanners and 42 percent of those for MRI were for facilities in the private for-profit sector. Recently, traditional private x-ray centers have begun to transform into autonomous diagnostic centers. This may now be the case for one-quarter of those centers that own CT scanners.

The private sector can take advantage of easier loan conditions (private hospitals do not have to wait for government agreement) as well as the fee-for-service pricing system, which allows for quicker profitability. Generally, the greater flexibility of the private sector has become evident since the 1980s, especially regarding adoption of new technology. Moreover, after 10 years of cost containment, the public sector suffers from an increasing lack of skilled medical imaging professionals.

### Concerns with the Technologies

Even if knowledge of medical imaging activity remains incomplete, most experts feel that use of imaging is excessive in France (16). According to the Ministry of Health, in the mid-1980s the private for-profit sector performed 8,500 scans per

year, as opposed to 4,350 yearly in the public sector. According to the INSERM survey, the private sector in the Provence-Alpes-Cote d'Azur region performs more than 10,000 scans per year. A CNAMTS survey of one day of imaging activity has shown that the private sector, which owns 28 percent of all CT scanners in France, performs 33.5 percent of the procedures. (The reimbursement rate for the procedure was considered too profitable and was revised downward.)

Medical imaging activity in the public sector has also increased greatly over the past decade. At facilities of the Hospitals of Paris, the total number of radiological procedures (key letter Z) increased 13.7 percent between 1982 and 1988, while payments for these services increased 21 percent. Use of each Hospitals of Paris scanner increased 18.5 percent per year between 1985 and 1988; at the same time the number of machines increased from 10 to 17. Some experts have raised the possibility of inappropriate use.

New need indexes published in February 1993 greatly increased the allowable number of CT scanners and MRI in France. After years of restriction (due mostly to the cost containment priority), this step was taken after intensive negotiations among the Ministry of Health, CNAMTS, equipment makers, and hospitals. The date of the decision, very close to the elections of May 1993, can be interpreted as a sign that political rather than health goals were key.

For CT scanners, the new need index authorizes one machine per 110,000 persons in each health sector, plus one machine for every 1,500 university hospital acute beds. As a result, 72 new CT scanners could be purchased in the years to come, thereby allowing under-equipped regions to reach the levels of the others (which, with the saturated needs index, cannot acquire any new equipment).

Ten regions are now fully equipped for MRI, but others are waiting for machines. The February 1993 needs index authorizes one MRI for every 600,000 inhabitants, which would allow 18 new imagers.

### Government Policy

The policy of the Ministry of Health concerning CT scanners and MRI has been characterized by a desire for a rather slow diffusion for several reasons: 1) the technical complexity of defining needs for diagnostic equipment; 2) the long-range cost implications; and 3) the duration of the learning curve. The desire to promote French industry was involved, too, in choices to distribute CT scanners between 1976 and 1981. The rather slow equipping of French hospitals was harshly criticized by professionals and the media. Waiting lists in France were very long, and the more fortunate patients were for a time sent to foreign hospitals, especially in Belgium or Switzerland. It was seemingly very difficult for France to maintain a level of equipment that was notably inferior to the level of its nearest European neighbors even if at that time the French government could legitimately deem the technology not yet fully assessed. Indeed, this situation illustrates one of the limits of an independent national approach to the diffusion of medical technology. Although currently the number and distribution of CT scanners is considered quantitatively satisfactory and possibly over-used, medical professionals emphasize that the quality of the French equipment maybe poor and en route to obsolescence.

### LAPAROSCOPIC SURGERY

The leading role of French physicians in the major innovative field of coelioscopy (laparoscopy) is well known in scientific and clinical communities, and is a source of national pride (33). The first pelvic coelioscopy was attempted in 1943 by Dr. Raoul Palmer in Paris. In 1973, Professor Bruhat of the teaching hospital of Clermont-Ferrand carried out the first treatment of an abscess of the fallopian tubes through a coelioscope. The same year, Bruhat performed the first coelioscopy for the treatment of an extra-uterine (ectopic) pregnancy. The first treatment of an ovarian cyst was published by Bruhat in 1976.

In 1980 the first appendectomy using a laparoscope was carried out successfully in Germany. The "French first" was performed in Lyon in 1983

in the private Clinique de la Sauvegarde. In 1981 Professor Bruhat was the first to attempt use of a laser in coelioscopic gynecological surgery.

Arthroscopy, a technique imported to France in 1969 remained unusual for many years and was carried out only by rheumatologists. Orthopedic surgeons gradually adopted the technique from 1980 on, and it became widely available (especially in the private sector) after 1986. In 1987, a French doctor carried out the first cholecystectomy through a laparoscope, and the first hyperselective vagotomy for duodenal ulceration was carried out by Professor Dubois at the Clinique de la Porte de Choisy in Paris in 1989.

### Coelioscopy in Gynecology

The diffusion of this technique was stimulated by Professor Bruhat and his medical team at the teaching hospital of Clermont-Ferrand (17,19). Numerous international symposia were held there, as was the World Congress of Gynecological Coelioscopy in 1989. Clermont-Ferrand took the lead as a training center, with the creation of a European certificate and an international training center for endoscopic surgery. According to the equipment manufacturers, virtually all public and private gynecologists, whether or not they are surgeons, are now equipped with endoscopes. Forty percent are said to undertake surgical laparoscopy.

Gynecological laparoscopic surgery was studied between January 1987 and December 1991 by seven leading French centers (30). The 17,521 procedures followed fall into three categories of coelioscopy:

1. "traditional coelioscopy," which includes the current indications: diagnostic; and "minor laparoscopic surgery" such as minor adhesiolyses, destruction of first-stage endometriosis, biopsies and treatment of ovarian cysts, tubal sterilization, and reproduction treatment;
2. "major laparoscopic surgery," which includes procedures that have become "classical:" major adhesiolyses, destruction of ovarian cysts, and treatment of extra-uterine pregnancy; and
3. "advanced laparoscopic surgery," which defines a field of new procedures: including hys-

terectomy, myomectomy, ovariectomy, treatment of prolapsus, cure of incontinence, and pelvic and para-pelvic ganglion curettage. (This is the field of “research and future possibility for practice.”)

Activity in laparoscopic surgery has increased in the seven centers studied; 52.5 percent of the 17,521 procedures studied were performed during the three first years of the survey, and 47.5 percent during the last two years. Advanced surgery accounts for most of this increase, comprising 1 percent of the indications in 1989 and 10 percent in December 1991. The rate of incidents leading to an emergency laparotomy was 3.25 per thousand (1.7 for diagnostic procedures and 5.3 for surgery). One death occurred during the five years of the survey.

No administrative obstacle has either hindered or promoted dissemination of the technique, which has taken place in departments already equipped for diagnostic coelioscopy. There has been no specific reimbursement rate for performing a coelioscopy rather than classical surgery; the financial scaling incorporates no incentive to carry out one procedure over another.

According to the experts, a small proportion of coelioscopic surgery may be performed in ambulatory care facilities, but there are many obstacles with respect to the internal organization of hospitals, and CNAMTS as well as the Ministry of Health appear to be reluctant to endorse this practice. They fear that it would result in more procedures with possibly debatable indications and increasing costs, rather than leading to a substitution of practice.

In the past, gynecological laparoscopic surgery faced strong hostility from cancer treatment centers and from many academics. The method was denigrated as a “blind” procedure that could not provide gynecologists with a proper pelvic and histological assessment. Recently, however, coelioscopic surgery in gynecology has become quite fashionable. More surgeons came to this technique after the diffusion of the laparoscopic cholecystectomy technique. French gynecology is therefore entering a new learning phase that, ac-

ording to observers, may result in increased surgical risk (although no figures are available to support this observation).

Laparoscopic surgery in gynecology is a field of ongoing diffusion. Its indications are increasing, and there is strong acceptance by patients. With “advanced laparoscopic surgery,” a new area has now opened, following the developments of digestive laparoscopic surgery. This has fueled a need for risk-benefit evaluations.

### Digestive Laparoscopic Surgery

This technology (6,33) has been strikingly quick to spread and has also been the subject of a major media campaign. (Some media have even called for “the end of surgery.”) *The American Journal of Surgery* has called the spread of this technique the “second French revolution” (9). Interestingly, laparoscopic surgery did not appear first in university hospitals but in two private clinics in Paris (11).

According to digestive surgeons, laparoscopic cholecystectomy is a consumer-driven technology; some patients are now refusing the classical invasive procedure. The competition between digestive surgeons and gastro-enterologists has also played an important role: digestive surgeons may regain some of the patients who are drawn toward physicians because of new drug therapies and, to a certain extent, lithotripsy.

Laparoscopic appendectomy was first performed in France in 1983. Although this procedure is considered efficient, its diffusion remains rather slow. The classical procedure is considered satisfactory by both surgeons and patients.

A 1992 unpublished survey exhaustively described the practice of laparoscopic digestive surgery (6). Two-thirds of the relevant facilities in the public sector and three-quarters in the private sector now perform laparoscopic surgery. The Hospitals of Paris appeared to be slightly behind; in public hospitals, diffusion of the technique appears greater in university hospitals than in others. Diffusion occurred particularly early in private for-profit hospitals, and the smallest of these were the pioneers; nevertheless, only 55 percent performed coelioscopies by the end of 1992. The

public sector reached the same level of **activity as** the private sector in late 1989. The public sector nonetheless proved less dynamic, and the lead continues to be held by the private sector.

In January 1992 laparoscopic surgery in the public sector accounted for 53 percent of the total number of cholecystectomies, with a higher concentration in the university hospitals compared to other public hospitals. A tendency to expand referrals toward treatment of asymptomatic stones was noticeable. (In December 1991, a European consensus conference stated that cholecystectomy is not justified in the absence of specific symptoms.)

By the end 1992, 79 percent of the digestive surgeons in public hospitals had performed laparoscopic surgery; in one-quarter of the departments, residents could be trained on a routine basis. Thirty-two percent of the nonuniversity and 46 percent of the university ones were involved in some trial or register. Seven ongoing studies were registered by the survey.

In university hospitals, 35 percent of the departments perform laparoscopic appendectomy; 46 percent treat perforating ulcers; 32 percent treat hiatal hernias; 27 percent perform abdominal vagotomy; and 23 percent perform colectomies (at least once).

### Concerns with the Technology

For hospitals, the diffusion of laparoscopic surgery creates significant problems because of new working conditions (6,33). Patients' stay in the intensive care units is shorter, but the entire stay is more costly because it involves more procedures. The large patient turnover creates a burdensome task for the personnel. Moreover, the equipment is delicate and carries high maintenance costs. Finally, defining indications, evaluating procedural risks, and training operating personnel are major challenges with this technology.

The economic advantages of the technology for French society at large are linked to the simplicity of post-operative sequelae, the reduction in hospitalization time, and the more rapid recovery of activity experienced by patients. However, these

benefits are arguably more theoretical than real. There has been a noticeable increase in tests prior to actual operations, especially in the areas of cholangiography and ultrasound endoscopy, which are especially invasive and costly. The widening of the indications for cholecystectomy is also a source of increased costs.

Since 1990, laparoscopic cholecystectomies have been registered by the French Society of Digestive Surgery. Of 1,200 procedures reported during one year by 67 surgeons, the figures show that 8 percent of patients had peri-operative cholangiographies, 8 percent had laparotomies, 6 percent had post-operative complications, 2 percent had early re operations, and 0.1 percent died (14). As in gynecology, the method has been diffused freely without administrative controls or pricing processes. There were no financial limits, either, as the endoscope is moderately priced, and can be easily borrowed by digestive surgeons from gynecologists (or even from manufacturers). Moreover, the equipment has not been subject to pre-marketing approval. In less than two years, laparoscopic cholecystectomy has become a standard technique. Nevertheless, concerns have been raised about the quality of the training of surgeons performing coelioscopies; many surgeons learn while actually performing the operation.

In 1993 CNAMTS asked ANDEM to study the risk-benefit ratios of coelioscopy, both in gynecology and in digestive surgery, to help define proper pricing for the procedures. This assessment is ongoing.

### TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Since 1990, a national register has been maintained by the National Society of Nephrology with the support of the Ministry of Health. This register extended to all of France for the first time in 1991, and comprises more than 20,000 patients treated either by dialysis or by renal transplant. Of the 240 existing facilities that provide the treatment, 210 have reported information on their patients.

Fifty-nine percent of ESRD patients are male and 41 percent are female. Thirty-two percent of



the patients were living with a functional transplant, 56 percent had been treated by hemodialysis at a center or by auto dialysis, 7 percent by hemodialysis at home, and 6 percent by peritoneal dialysis. Nearly 40 percent of all patients are retirees; 20 percent are disabled, 20 percent are jobless and on welfare, 8 percent have full-time jobs, and 4 percent have part-time work. Statistics indicate an aging population in this program.

The prevalence of patients treated for chronic renal failure at the end of 1991 was 355 per million inhabitants; 46 new patients per million inhabitants were treated for the first time. Glomerulonephritis now represents 25 percent of all of ESRD; renal polycystic disease, 10 percent; and diabetic renal disease, 7 percent.

“Chronic nephropathy and the pure primitive nephropathic syndrome” as well as “post-transplant surveillance” are on the list of ailments said to be “long-term afflictions” for which care is 100 percent reimbursed by the National Sickness Fund. Moreover, a sick individual can benefit from state welfare revenues if his or her physical status leaves him or her unemployable.

### Renal Dialysis

The first French renal experiments date from September 1960. These first trial experiments took place in high-technology hospitals. The first experiments in at-home dialysis were carried out in 1967 in Lyon. The placement and maintenance of patients in their homes proved more difficult; thus, at the beginning of the 1980s, auto-dialysis was developed for autonomous patients aided by nurses. As at home, with this technique patients are responsible for maintaining their own personal material. This formula rapidly developed, and the number of patients quickly increased from 760 in 1985 to 2,374 in 1990 (10,34). In 1991 around 4,300 new patients (77 per million inhabitants) were cared for using the entire gamut of available techniques; about half were treated outside of centers.

Renal dialysis equipment requires authorization from the Ministry of Health. Theoretical needs were established in 1984 at 40 to 45 stations

per million inhabitants. However, the rules have never clearly fixed actual limits on the zones of the health map, nor has dialysis outside a center been considered. Also not considered is the technical evolution of handling patients (e.g., the wider diffusion of renal transplants due to the use of cyclosporine). In the technical arena, moreover, nothing determines the working rules of the public sector nor of dialysis outside the established centers. As a result, the rules today appear to be singularly obsolete, making any attempt at global policy inefficient. Experts are calling for their modification.

The current state of dialysis in centers is virtually unknown. No precise inventory has been made of this practice or of patients in residence; an official census exists only for public establishments. In 1989 there were 116 public centers at which 937,770 dialysis sessions took place (for 6,011 full-time patients). The situation in the private sector is even less well known. The number of patients using private establishments is around **9,000** (10,34).

### Renal Transplant

Renal transplants were successfully performed in France in 1951; a year later, the first renal transplant involving a living donor was performed at Necker Hospital in Paris (5,7). French doctors continued to be pioneers in this domain: a successful transplant operation was performed on identical twins in 1955, and attempts made with related nontwin donors multiplied until 1970. Transplants were then practiced by means of initial grafting, with organs taken from subjects in a state of brain death; between 1970 and 1986, approximately 13,000 renal grafts were performed. By 1980, France was fifth in Europe with regard to the number of grafts accomplished, having slowed somewhat in its advances with this technology.

As of 1984, the use of the immunosuppressive drug cyclosporine (undertaken in France as early as 1981 and diffused by 1984 to all clinical research teams) prompted considerable progress. Increased activity and interest were supported by specifically defined concessions provided by pub-

lic budgetary allocations for transplants (as of 1986). Surgery and followup care benefits of 100 percent were provided by the Sickness Fund. Studies have established the cost of this surgery in France at between \$US3,515 and \$US3,630, and the cost of the followup care for an individual between \$US6,150 and \$US9,000, depending on the hospital and region (28).

Between 1977 and 1983, the number of medico-surgical groups practicing transplants (for all organs) remained at about 35 teams. However, after the diffusion of cyclosporine and the allocation of public funding, this number rose. There were 44 teams in 1984 and 104 in 1988. Simultaneously, the steadily improving rise in the numbers of grafts performed was remarkable within every category of transplant. Between 1984 and 1988, 1,808 renal transplants were performed.

To match donors and recipients, French transplant surgeons have created an interesting organization (13). *France Transplant* is a nonprofit association founded in 1969 to:

1) Develop the deduced organs by their number and quality; [promote] the use of all those available; promote and coordinate the extraction of multiple organs; 2) . . . perfect the necessary skill of extraction of all the various organs; [and] 3) Organize the distribution of the organs according to ethical and scientific norms, as well as the modes of distribution proper to each organ on the local, regional and national level.

This association cooperates with teams receiving authorization to perform transplants as well as with histocompatibility laboratories. The association functions in a decentralized manner in seven regions, each of which has a coordinator who informs both professionals and the public at large of the need for organs and designates local coordinators.

The power of *France Transplant* remains, however, limited. When an organ is removed from a subject in a state of brain death, only one kidney is furnished to the association; the other is assigned to the team that has removed it. *France Transplant*, unlike UNOS (its American equivalent), does not have the legal right to claim the second kidney. Moreover, some teams have felt that the

system has favored the major Parisian teams. This has led to discord between the medical groups and to the creation of regional independent associations (*Paris-Transplant and Rhone-Mediterranean Transplant*).

The rate of renal transplants remained at about 35 per million inhabitants from 1989 to 1991. Waiting lists are lengthening; an estimated 4,886 patients were waiting in 1991. (Average waiting time is estimated at three years.) Long waiting lists are the result of several factors, including reduced numbers of transplantable organs because of a reduction in road accident traumas; a seeming recent reluctance on the part of the French people with regard to donating organs; and more restrictive ethical rules resulting from various donation scandals reported by the press.

### Erythropoietin (EPO)

No French company produces EPO, which first became available in France in January 1989. After its introduction, public authorities, considering EPO too costly, sought to restrain its use (the annual cost per dialyzed individual is as high as the minimum legal income). Nephrologists protested publicly, as did those doing transplants; and the public authorities ended up overturning previous restrictions.

According to the national register of chronic renal failure, EPO was used at the end of 1991 in 38 percent of patients treated by hemodialysis in centers or by autodialysis. There are important regional variations, with more than 45 percent of patients benefiting from EPO in Ile de France and Aquitaine, as opposed to 16 percent in Rhone-Alps. EPO seems to be markedly less frequently used for patients having peritoneal dialysis (only 22 percent).

### Government Policy

The Ministry of Health is responsible for guaranteeing the equity and general balance of the system, using legal requirements and conditional financial support to accomplish those ends (26). By 1986, confronting an increase in transplant activity and rising costs, the Ministry took excep-

tional administrative steps to coordinate diffusion of transplant activity throughout the country. That year, a ministerial instruction defined (for certain categories of grafts) national, quantified objectives as well as a methodology for their implementation. Each transplant unit was to define a medical goal that integrated an analysis of the current situation, a definition of therapeutic protocol, and the modes of evaluation to be put into practice. By 1987, a quantitative “balance sheet” and annual financial scheduling were required from each transplant unit.

Although newly formed teams were in theory free to undertake transplants, only the pilot centers or some of the more “encouraged” centers (i.e., the allo-graft centers) could benefit from public funding (14 renal grafting centers benefited). The pilot centers were selected by the Ministry of Health from among the oldest and most prestigious transplant teams. Their role is now to set norms of practice that can be transferred to the other centers, which must compete in order to improve their practice and become pilot centers themselves (as determined by the Ministry of Health).

As of 1988, organ transplants, in both the public and the private sector were subject to ministerial authorization; any hospital unit that had not begun a program of organ grafting as of this date could not begin without authorization.

In 1992, reform of the system of organ and tissue transplants was initiated. Its aims were rationalization, published guidelines, and security. The *Comite de Transparence* was formed by a legal order in 1992 to develop requirements for different associations in the field, to counsel the Minister of Health, and to identify all cases of malfunction. The committee chairperson is a state counselor (civil servant), not a specialized doctor.

Active transplant units (fixed at 40 for renal units) are defined by a 1992 health map, and health norms are established for the centers, which are now required to declare any organizations involved in imports, conservation, and transformation of organs and tissues and to guarantee the highest quality of technical and human know-how. Reports from the general inspectorate and

the committee cover the scheduling of transplant activity as well as financial guidelines (e.g., setting of payment rates and payment of costs).

## NEONATAL INTENSIVE CARE

Little information exists on neonatal intensive care in France as it relates to demographic, equipment-related, or technological issues, despite the fact that Neonatal Intensive Care Units (NICU) require a Ministerial license. Neonatology itself does not exist in France as a formal specialty, but pediatricians who specialize in neonatology are grouped together in a Neonatal Study Group (*Groupe d'Etudes Neonatales*, or GEN). Information in this case study derives from private interviews with two leaders in the field and from GEN.

In the Ile de France region, GEN uses its unpublished census on various neonatal services to organize summer shifts of services on a permanent basis. Thus, the GEN figures give an accurate assessment of the number of beds and units in the Paris area. In the permanent summer-shift organization, GEN accounts for 196 beds in 15 units. Only three hospitals have wards exclusively for neonatology. There is one unit in a private hospital. Most of the beds are in NICUS, but some are part of general pediatrics.

Most units are costly in terms of both equipment and personnel. The situation has become more tense recently, particularly in relation to problems with nursing personnel, which has meant that beds are unavailable at certain times of the year, and experts feel that the situation may worsen in the near future. The NICU population is now growing as a result of several factors (mostly connected with improvements in the technologies):

- increases in birth rates of radically premature infants (delivery between 33 and 37 weeks) whose survival was previously impossible;
- the consequences of medical interventions in procreation, which lead to an increase in multiple pregnancies (3 percent triple pregnancies after medical intervention) and ultimately to very low birthweight premature infants;

- the consequences of prenatal diagnosis, leading to therapeutic in utero care and continued care in NICUS; and
- complications in pregnancy (e.g., low fetal growth) leading to fetal problems during birth, and neonatal emergencies of term infants who are systematically placed under surveillance and quasi-systematically resuscitated.

### Concerns with the Technology

Experts emphasize a great disparity in the ways and means of neonatal services as well as in medical and nursing staffs. The high level of technical skill, heavy equipment, and burden of care for the nursing staff in NICUS implies that such units should be restricted to university hospitals and carefully assessed by ministerial authorities. Lack of proper beds for NICUS in university hospitals, combined with the lack of specific qualifications for personnel, has meant that new wards are being created in general hospitals (the smallest with only three or four beds). Even though GEN experts find these small units insufficient to satisfy safety criteria and lacking in specialized services with the proper environment, technology, and staff, they cannot be closed.

According to GEN experts, the main problem of the NICUS (other than the absolute lack of beds) is linked to nursing jobs. NICU nursing is very demanding and not socially rewarding. Nurses working in the NICUS do not receive career or salary advantages or professional recognition. These units must expend increasing energy on maintaining their nursing personnel, and they rotate shifts excessively.

In May 1991 one expert submitted to the Prime Minister a report on French problems in bioethics. One chapter and several appendixes of that report discuss the question of neonatal intensive care. The report underlines questionable areas as well as positive aspects of neonatal resuscitation, and it raises several ethical questions (23). On the positive side, the report points out that France has a strong tradition of organizing specialized services for newborn infant care. Such services are closely coordinated with centers for prenatal diagnosis,

which can thus anticipate and prepare to receive newborns with problems. However, on the negative side, France's infant mortality rate is 7.3 per 1,000, which places it eleventh in the world. Moreover, although the frequency of premature births in France has been diminishing (from 7 percent in 1981 to 5 percent in 1991), the rate is not negligible. The rate of highly premature births (i.e., delivery after less than 33 weeks) is 0.7 percent of the births, or 5,000 per year, which raises immense problems for localities treating these infants.

Ethical questions concern, on the one hand, the problem of resuscitating newborns, and on the other, the harvesting of organs from brain-dead infants for transplantation. The decision to abstain from therapy or to pursue resuscitation lies mostly with physicians rather than parents. Proponents of resuscitation feel that newborns must be systematically resuscitated if this is possible—a position that has been a focus of criticism, particularly because the criteria used for deciding on whether to resuscitate vary with different proponents.

Demand for grafts from newborns—heart and lungs in particular—has been increasing, and both harvesting of organs and transplantation require NICU services. If a baby is alive, it is theoretically and ethically possible to extract bone marrow for transplantation to a sibling, but only with the consent of parents and of three doctors not involved in the operation. Removal of an organ from a deceased child (covered by the Cavaillet Law of 1976) is subject to parental consent as well as that of the recipient. Above all, the law calls for doctors to take all precautionary measures for the benefit of the recipient.

### Extracorporeal Blood Circulation

The French technique of extracorporeal blood circulation and artificial lungs in newborns was first undertaken in 1987. The American technique (extracorporeal membrane oxygenation, or ECMO), which requires two nurses per patient, appeared overly burdensome, and the hospital that first used the technology therefore developed a less invasive technique: the AREC, a “veino-venous” tech-

nique permitting the ward to perform AREC with three units for 14 beds using only five nurses (8). An association known as GRAREC was created to ensure the dissemination of this particular technique in France and Europe (3). Five centers now function in France: two in Paris (one with three machines and one with one machine); one in Line with one machine: one center and one machine in Dijon; and two machines in Marseille.

AREC is not subject to specific regulations, reimbursement rates, or analytical accounting. As a technology within neonatology, AREC receives financing from relevant administrations (e.g., the CEDIT in Paris) as a technological innovation. At present all the French centers use the AREC technique rather than ECMO. This technique is connected to the use of a French invention, a pump developed by Rhone-Poulenc, readapted, and now produced by other, smaller companies.

Around 200 French newborns with an estimated 80 percent risk of mortality have been placed on AREC: the average duration of treatment is five days. A followup of results over two years demonstrates that 86 percent of the infants are normal. A frequent complication can be intracranial hemorrhaging due to heparin (12).

The AREC technique is less invasive than ECMO. It uses only the jugular vein and does not suppress natural circulation inside the lungs. It also permits much less intensive surveillance. The expense compared to that of maintaining an average patient in an intensive care unit is estimated to be slightly lower. An estimate of potential need for this technique was made by CEDIT and GRAREC (held to be 40 cases annually in the Paris region, or about 200 overall in France).

AREC is not considered by all French neonatologists to be a priority but rather one technology among others. Currently, GEN gives most of its attention to the ethical issues of neonatal intensive care, to problems of the burden of care in the units, and especially to the status and position of NICU nurses.

### SCREENING FOR BREAST CANCER

In 1982, early screening for breast cancer by mammography was virtually nonexistent in France.

Mammographies were exclusively a diagnostic activity undertaken after the appearance of a symptom or as a surveillance practice. Between 1982 and 1988, the use of mammography increased rapidly (there were 650 machines in 1982 and about 1,700 in 1988), and the field underwent a veritable explosion—from 350,000 to nearly 1,890,000 annual tests (about 90 percent of which were done by the private sector) (22).

In 1988, 60 percent of mammography were medically prescribed for the purpose of early detection, but outside organized screening programs, and a considerable number of mammograms still are done outside of formal programs.

In recent years, about 1.15 million exams have been done annually. Unfortunately, the percentage of the population screened is only around 8 percent of women aged 45 to 54 and 10 percent for those between 55 and 64—age ranges for which epidemiologic studies show that screening is the most beneficial. A structured national system of early detection thus appears necessary.

### Government Policy

In 1988 the Ministry of Health entrusted the National Sickness Fund with the responsibility of setting up and evaluating programs of prevention and health education. A new financial tool was founded for the promotion of this mission, with a specific fund (*Fonds National de Prevention, d'Education et d'Information Sanitaires*, or FNPEIS) managed by CNAMTS. Programs to be funded are selected by the CNAMTS board of directors and annually approved by the Minister of Health (1,29). Some of these grants were dedicated in 1989 to the organization and evaluation of departmental campaigns to reinforce screening for breast and colorectal cancer in several research *departements*.

Programs for breast cancer screening have only lately seen the light in France. In 1988, before financial action from FNPEIS, eight structured programs were being set up and eight others were well established. These programs are characterized by enormous diversity within the institutional and financial framework, reflecting the

organization provided for by the 1983 Law of Decentralization that gives responsibility for cancer screening and for post-treatment surveillance to the departments. In conformity with the law, the screening program provided for and supported by FNPEIS was organized by departments; local hospitals and local Sickness Funds did not take the lead but were associated as full partners. A total of 48.5 million francs (\$US8 million) or 5 percent of the FNPEIS budget was dedicated to cancer screening in 1990. The Ministry of Health intervenes principally to give a technical endorsement to provide the legal basis for disbursing funds, and it participates in program followups.

The CNAMTS prevention program is aimed at women 50 to 69 years old. The strategy is based on sensitizing practitioners; advertising campaigns; drafting contracts with radiologists responsible for examining mammograms; creating contracts with a center for "secondary x-ray readings;" making contacts with local partners (e.g., departmental leagues for the fight against cancer); and developing mailing lists.

Women are invited to be screened in a letter from the local Health Insurance Fund. After the x-ray is completed, the fee is directly paid by the local fund to the radiologist (\$US40 per examination), so that the service is free to the patient. The radiologist sends the results to a center for secondary x-ray readings.

Financing is budgeted by size of the populations targeted by each department, which means (for breast cancer exams) that about 2 million francs are allocated for every 50,000 people. The cost of the entire program is estimated at 234 million francs per year, around 100 million francs less than the estimated cost of the actual (predominantly spontaneous) exams conducted in France (22).

This program still is defined as "experimental," and a "medical, social and economic" evaluation is required to change its status. In 1992, 20 or so departments were receiving financing for screening; mass screening, however, has not yet been carried out.

---

## CHAPTER SUMMARY

Compared with the situation at the beginning of the 1980s (18), the assessment of health care technology in France has achieved the status of a major concern. The 1991 law made extensive use of the concept of evaluation, associated with notions of quality, management, planning, and cost-effectiveness assessment. For decades, French experts have stressed the lack of basic studies of the decisionmaking process. It is striking that now legal requirements, specific institutions, and public grants dedicated to evaluation exist at every level of the health care system and the government.

Public health care managers are learning how to deal with the new requirements, which are based on a demand for greater expertise as well as improved communication and cooperation among the different actors. Nevertheless, needs for consensus and guidelines on medical strategies as well as for primary data on diagnosis-related med-

ical activities and prescriptions remain the stumbling block. This is not news to the experts, but it seems to be widely publicized and accepted now—in particular by physicians, which makes a great difference.

Experts feel that medical representatives (if not the entire medical community) have now become less reluctant to accept the concept of medical technology evaluation. Many groups of professionals have for some years been involved in consensus processes or in assessments of some sort. However, the main change derives from the fact that physicians' representatives have negotiated contracts with the Ministry of Health and the National Sickness Fund that involve medical evaluations and medical guidelines stipulating possible sanctions for physicians who infringe these rules—a situation that would have seemed impossible 10 years ago.

It is thus fair to say that the need for cost containment (because of the dramatic increase in health care costs), rather than objective interest in improving health care quality, has played the major role in pushing technology assessment in health care into the spotlight. Successive Ministers of Health, calling for reduced health care expenses, have promoted the concept of “medicalized management of health care,” which implies that improvement of quality and cost containment can go hand in hand. The public at large is now well informed about this concept. Moreover, the possibility of drastic changes in the health insurance and welfare system is also generally grasped. The medical community thus cannot remain outside this national debate. Evaluation in health care is beginning to be viewed by every professional involved as the key to a stronger position at the inevitable negotiating table.

It must be said too that this now familiar technical debate took center stage at the very moment when important national debates were occurring in France about medical ethics and about governmental and physicians’ responsibilities in ensuring health care security and quality after the recent tainted blood scandal (which led four top physicians and administrators to court and two to jail). The responsibilities of experts, medical advisors, practitioners, industry, and the government have been publicly and dramatically discussed. It is hard to forecast the historical consequences of these events, yet it is possible to speculate that the blood scandal may have opened a new era in which experts, journalists, and the courts might play an increased role.

As for the experts, it has been widely noted (especially during the blood scandal) that their knowledge has not played and generally does not play (as far as health policy is concerned) the role it should. Lack of expertise has been pointed out for many years by different observers of public health policy. Proposing solutions to this problem was one of the goals of successive missions on the development of medical evaluation in the 1980s. One of the consequences of the blood scandal has been to drive the government itself toward a better

understanding of the need for expertise to assist the Ministry of Health. Money and positions have become available, and a number of new experts have now started to work in various teams close to the Ministry of Health.

As for the various media, they had mostly (until the 1990s) intervened to praise and promote medical innovation and had frequently promoted technologies that were not yet fully assessed. Journalists are now appearing in a different role, as protectors of patients against the high risks of medical technology and poor quality health care. Apart from the transfusion issue, other medical and health care issues have been highlighted by the press (e.g., the unequal and generally poor situation of emergency care).

As for judges and the courts, in 1993 three high-profile scientists and administrators were charged for bearing responsibility for the occurrence of 25 cases of Creutzfeld-Jacob disease among children treated by extractive growth hormone. This decision was publicized as a new blood scandal—an attempt by the press (and others) to go beyond the limits of the transfusion issue and to find a new and perhaps more demanding definition of medical and governmental responsibilities in the diffusion of medical innovations. This new attitude will probably have important consequences for the future of clinical research and the management of innovation.

Above all, the government now appears to consider cost containment its top priority. The reforms of the 1980s and the 1991 law strengthened the quality control processes for medical equipment and health care; now the focus at the central governmental level is on costs.

Compared to the 1970s and the 1980s, the French health care system is going through a crisis. The longstanding balance among the powers and parties involved (physicians, industry, Sickness Funds, government, courts, patients, and press) has become unstable. Quality of care and excessively rising costs have become open, urgent, and nationwide concerns, and technology assessment one of the key tools for addressing the problem.

## REFERENCES

1. Abaléa P., Csaszar-Goutchkoff M., Jouet V., Anguil S., Foray C., and Belhadi S., "Evaluation des Campagnes de Dépistage des Cancers Colorectal et du Sein Prévue par les Arrêtés de Septembre 1989, Juillet 1990 et Avril 1991 Concernant les Travailleurs Salariés," Ecole Nationale de la Santé Publique-Séminaire interprofessionnel, ENSP, Novembre 1991.
2. Agence Nationale pour le Développement de l'Évaluation Médicale, Service des Etudes, "Nouvelles Techniques d'Angioplastie Coronaire, état des Connaissances," Septembre 1992.
3. "Assistance Respiratoire Extra Corporelle, de la Théorie à la Pratique," La Lettre du GRA-REC, numéro spécial, N 2 et 3-Mars et Juin 1992.
4. Bigotte, C., Harari, J., and Montaville, B., "Dual Plurality: the French Health System—Policies for Health in European Countries with Pluralistic Systems," (Copenhagen: World Health Organization Regional Office for Europe, 1991).
5. Bitker, M.O. and Luciani, J., "Transplantations Rénales et Pancréatiques," IV-Impact Médecin, les dossiers du Praticien n 169-Les greffes, 1992.
6. Bouvier V., "Analyse de la Diffusion de la Cholecystectomie par Coelioscopie en France," ENSP, travail dirigé par G. de Pourville, unpublished, 1993.
7. Cabrol C. (Pr): "Les Greffes," Editorial-Impact Médecin, les dossiers du praticien n 168, 1992.
8. Chevalier J. Y., Durandy Y., Batisse A., Mathé J. C., and Costil J., "Preliminary Report: Extracorporeal Lung Support for Neonatal Acute Respiratory Failure," *Lancet* 335: 1364-1366, 1990.
9. Cuschiéri, A., Dubois, F., Mouiel, J., Mouret, P., Becker, H., Buess, G., Trede, M., and Troidl H., "The European Experience With Laparoscopic Cholecystectomy," *Am. J. Surg.* 161 (Special Issue): 385-388, 1991.
10. Dixsaut, G., "Situation du Traitement de l'Insuffisance Rénale par Dialyse en 1992," Ministère de la Santé et de l'Action Humanitaire, Direction Générale de la Santé-Note Interne, communication personnelle, 1992.
11. Dubois, F., "Cholecystectomie sous Coelioscopie 330 Cas," *Chirurgie (Mémoires de l'Académie)*, éd. Masson, Paris, 116, 248-250, 1990.
12. Durandy, Y., Chevalier, J.Y, and Lecompte, Y., "Single-Cannula Venovenous Bypass for Respiratory Membrane Lung Support," *J. Thorac. Cardiovasc. Surg.* 99, 404-409, 1990.
13. Ecole Nationale de la Santé Publique, "La Transplantation d'Organes en Europe, Aspects Juridiques, Éthiques, Logistiques et Financiers," Séminaire de Recherche ENSP, 1991.
14. Escat, J., "Le Registre des Cholecystectomies par Coelioscopie de la Société Française de Chirurgie Digestive," Paris, Jan. 1991.
15. Fagnani, F., Charpak, Y., Maccia, C., and Meyer, C., "L'Évolution de la Radiologie Conventionnelle en France Entre 1982 et 1988," *Revue d'Imagerie Médicale* 2: 663-667, 1990.
16. Faure, H., and Le Fur Ph, "Evaluation de la Consommation Radiologique en 1989, Evolution 1974- 1989," Centre de Recherche et de Documentation en Economic de la Santé, 1991.
17. Fédération des Gynécologues et Obstétriciens de Langue Française, 33ième congrès, Line, "La Coelioscopie Opératoire, le Point en 1990," deuxième rapport, (Clermont-Ferrand), 5-8 Septembre 1990.
18. Fuhrer, R.
19. Hauuy, J. P., Madalenat, P., Bouquet de la Jolivière, J., and Dubuisson, J. B., "Chirurgie Percelioscopique des Kystes Ovariens, Indications et Limites à Propos d'une Série de 169 Kystes," *Journal de Gynécologie-Obstétrique et de Biologie de la Reproduction*, 19: 209-216, 1990.



20. Inspection Générale des Affaires Sociales, "La Chirurgie Cardiaque en France, Résultats d'une Enquête Nationale," Rapport au Ministre des Affaires Sociales, coll Rapports IGAS, MSAH internal publications, Juin 1988.
21. Lacronique J. F., "Technology in France," *Inter. J. Technology Assessment Health Care* 4:385-394, 1988.
22. Le Galès, C., Fagnani, F., and Lefaure C., "Le Dépistage Mammographique du Cancer du Sein: Explosion des Pratiques, Multiplication des Programmes," *Bulletin Epidémiologique Hebdomadaire*, N 1/1990, 8 Janvier 1990.
23. Lenoir, N., and Sturlesse, B., "Aux Frontières de la Vie: Pour une Démarche Française en Matière d'Éthique Biomédicale," Rapport au Premier Ministre. Ed. La Documentation Française. Coll: rapports officiels, Mai 1991.
24. Meyer, C., Lefaure C., and Fagnani F., "L'Investissement en Imagerie Médicale en France: la Montée des Technologies Nouvelles," *RBM*, Volume 8, Numéro 6:377-1987.
25. Ministère de la Santé et de l'Action Humanitaire, Direction des Hôpitaux: "Guide Général de l'Homologation des Matériels Médicaux," MSAH internal publication, Mars 1993.
26. Ministère de la Santé et de l'Action Humanitaire: "Réforme du Système de Transplantation d'Organes et de Tissus, Troisième Vole," Dossier Santé, MSAH internal publications, 4 mars 1993.
27. Ministère de la Solidarité, de la Santé et de la Protection Sociale, "L'Hospitalisation en France, Données et Chiffres Repères," MSSPS Information Hospitalières, Numéro Spécial, édition 1990.
28. Moat(i, J. P., and Mawas, C., "Evaluation des Innovations Technologiques et Décisions en Santé Publique," Editions INSERM, Collection Analyses et Prospective, 1993.
29. Montaville, B., and Lefaure, C., "Le Dépistage du Cancer du Sein en France: Programmes et Projets," Rapport n 53-INSERM Unité 240, 1988.
30. Querleu, D., Chevalier, L., Chapron, C., and Bruhat, M., "Complications de la Coeliorurgie Gynécologique," *JOBGYN* Vol. 1, No 1, pp.57-65, 1993.
31. Service des Statistiques, des Etudes et des systèmes d'information, "Annuaire des Statistiques Sanitaires et Sociales," Ministère des Affaires sociales et de l'intégration, la Documentation Française, 1992.
32. Weill, C., "National Policies in the Domain of Medical Technology Assessment," *Assessment of Medical Informatics Technology*, Proceedings of a joint working conference of the International Medical Informatics Association, the International Society for Technology Assessment in Health Care and the Ecole Nationale de la Santé Publique C Flagle, F. Gremy, and S. Perry (eds.) Montpellier, Oct. 22-26, 1990.
33. Weill, C., "Minimally Invasive Therapy: the French Case Study," *Health Policy* 23: 31-47, 1993.
34. Zmirou, D., Benhamou, P. Y., Cordonnier, D., Borgel, F., Balducci, F., Papoz, L, and Halimi, S., "Diabetes Mellitus Prevalence Among Dialysed Patients in France (UREMIDIAB study), Original Article," *Nephrology Dialysis Transplantation* 7: 1092-1097, 1992.