6.

Policy for Medical Technology in France

Rebecca Fuhrer
Department of Health Services and Biostatistics
Harvard School of Public Health
Cambridge, Mass.

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FRANCE: COUNTRY DESCRIPTION

Physically the largest country in Western Europe, France has approximately 53 million inhabitants. Almost 75 percent of the population lives in urban areas, and 16 percent lives in the Paris metropolitan region. The average population density is 97 inhabitants per square kilometer, with a range from 44 inhabitants in the Limousin Region to 821 in the Paris area.

The active working population includes approximately 21.7 million people, of whom 13.3 million are men and **8.4** million women. Life expectancy at birth is 69.1 years for men and **77.2** years for women (41). The birth rate, which in recent years has been declining, is now 14 births per 1,000 inhabitants; the mortality rate is about 10.1 deaths per 1,000 inhabitants (41). As in other Western countries, the proportion of persons over the age of 65 has been increasing. In 1977, they represented 13.8 percent of the population. A summary of basic demographic data for France is presented in table 1.

Table 1.—Basic Demographic Statistics for France[a]

Population	52,973,000
Males	25,949,106
Females	27,023,887
Population density	97 inhabitants per km^2
Urban population	75 percent
Birth rate	14.0 per 1,000 inhabitants
Death rate	10.1 per 1,000 inhabitants
Life expectancy at birth	
Males	69.1 years[b]
Females	77.2 years[b]
Infant mortality rate	12.3 per 1,000 live births
Active working population	21,756,000

[a]1976 data from the Institut National de la Statistique et des Etudes Economiques (INSEE).
[b]1976 data from the United Nations.
SOURCE: Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1979 (41).

Like other countries in Western Europe, France has a parliamentary democracy. The present form of government was adopted in 1958 following a referendum which established the Fifth Republic. Executive power is exercised by the President, who is elected for 7 years and appoints the Prime Minister. The Prime Minister leads the government and makes recommendations concerning presidential appointments to other Cabinet positions.

The Prime Minister and the Cabinet are responsible to Parliament. Parliament, consisting of the National Assembly and the Senate, has legislative power. Deputies to the National Assembly are elected directly by their constituencies for periods of 5 years. Senators, whose term of office is 9 years, are elected indirectly by Deputies to the National Assembly, Departmental General Councilors, and delegates from municipal councils.

Most legislation is initiated by the Prime Minister.[1] The Prime Minister not only proposes new laws to Parliament, but, he/she has the exclusive right to initiate governmental expenditures. Parliament has censuring power over the Prime Minister's government, by its vote on the budget and 4- or 5-year economic and social development plans. Once laws have been approved by Parliament, the Prime Minister is responsible for ensuring their execution.

Government administration, with Ministries providing the infrastructure, is very centralized in Paris. France is divided into 95 Departments, each of which functions both as an administra-

1 The Prime Minister initiates about 95 percent of proposed legislation. Parliament itself initiates only about 5 percent.

tive unit of the Central Government and as a local unit administering its own concerns. In each Department, a Departmental Prefect is appointed by and represents the Central Government and all the Ministries. The Departmental Prefect is also responsible for executing policies established by the Departmental General Council, a directly elected body in each Department. Local units of governmental jurisdiction in France are the communes. Each commune has an elected municipal council and a mayor that the council elects.

Regions in France were given explicit new powers and functions by the Regional reform **law** of 1972, which became effective in late 1973.[2] The aim of Regional reform was decentralization, especially in the domain of economic and social development, so as to facilitate better response to Regional needs and more effective utilization of available resources. Economic and social development plans have guided major national development concerns since 1947. France is now in its seventh economic and social development plan and is working on goals for the eighth. In the past decade, plans have been increasingly oriented towards a Regional perspective.

There are 22 Regions, consisting of two to eight Departments each. Each Region is administered by a public corporation consisting of the Regional Prefect (the Departmental Prefect of the Department in which the Region's capital is located), the Regional Council, and an Economic and Social Commission. Advised by the Economic and Social Commission, the Regional Council is the policymaking body. Its decisions are executed by the Regional Prefect.

The French economy is a free enterprise system in which the State and public sector (i.e., industries and commercial establishments under State control)[3] play very important roles. Economic growth has been very rapid since World War II. In recent years, the gross national product (GNP) has continued to increase, although the inflation rate has been very high since 1974 (I5 percent in 1975), and unemployment, especially among the young, is a serious concern. Of salaried workers in France, about 10 percent are employed in the agricultural sector, 39 percent in the industrial sector, and the remaining 51 percent in the commercial and services sector.

[2]Unlike the Department, the Region is neither an administrative subdivision of the Central Government nor an independent administrative unit. It therefore has no authority other than that delegated by the Government.

[3]The public sector is comprised of: 1) government monopolies in industries such as transportation and energy, and 2) nationalized banks, insurance companies, automobile manufacturers, and oil companies that compete in the private sector.

THE HEALTH CARE SYSTEM

Brief History of the System

A dominating principle in the evolution and growth of the French health care system has been the continuing respect for the practice of "medicine liberale" (liberal medicine). Four basic principles, though somewhat modified in practice, still dominate the functioning of the French health care system: 1) the physician is free to prescribe as he/she wishes, 2) medical confidentiality is maintained, 3) the patient is free to choose his or her physician, and 4) the patient pays the physician directly.

Historically, French physicians cared for patients in their homes. Public hospitals were established by the church as centers for lodging the poor. Hospital services were free, and resources—human and material—were gifts. After the French Revolution of 1789, the hospitals' were accorded a civic rather than religious status, but their function and resources were not altered. In 1851, the civic responsibility was enforced explicitly, and each commune or municipality had to support its own hospital.[4]

The private hospital sector really developed along two different tracks. First, small, private "cliniques," for-profit hospitals offering limited

[4]In some cities, e.g., Marseilles and Paris, public hospitals today are still called "public assistance hospitals."

services to privately paying patients, most often were started by physicians. Second, private, nonprofit hospitals for workers were started by some large industries. Care at these institutions was free and physicians were reimbursed by the enterprise. Other private, nonprofit institutions were established to address specific health problems (e.g., tuberculosis, cancer, mental health).

Medical care in France today continues to be provided by both the private and public sectors. (See table 2.) Most ambulatory care is furnished by private practitioners. Some ambulatory care, however, is furnished by outpatient departments associated with large public hospital centers, by mutual fund societies run by industries or unions, and by neighborhood health centers.

Table 2.—Public and Private Health Care Providers in France (1979)

Provider	Public	Private
Physicians	30 %	70 %
General practitioners	(32)	(68)
Specialists	(28)	(72)
Institutions		73c
Beds	(72)	(28)d

[a]Physicians in public practice includes only full-time salaried practitioners (e.g., school physicians, industry-employed physicians, Social Security physicians).
[b]Physicians in private practice includes those who may have a part-time appointment in a public institution.
[c]Private nonprofit institutions constitute 23 percent; private for-profit institutions constitute 50 percent.
[d]Private nonprofit institutions constitute 11 percent; private for-profit institutions constitute 17 percent.

SOURCES: D. Ceccaldi, *Les Institutions Sanitaires et Sociales*, 1979 (15); and Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1979 (41).

Institutional care is provided by: 1) public institutions (including public hospitals) that are sponsored by the Department or commune, but are subject to administrative authority of the Ministry of Health (Ministere de la Sante); 2) private, nonprofit industry-related or special purpose facilities; and 3) private, for-profit, hospitals (called "cliniques") which usually offer surgical, medical, and/or obstetrical services. Most psychiatric hospitals, although originally private nonprofit or for-profit institutions, are now public facilities.

National health care expenditures' in France account for 7.36 percent of the country's GNP (42). In 1976, public and private hospitals consumed 43.8 percent of national health expenditures (42).

Health Policy, Administration, and Planning

Although government administration in France is highly centralized, along with efforts to decentralize economic and social development, there have been increasing efforts to decentralize the administration of health and social services.[6] Health policy is established nationally by the Ministry of Health.[7]

In each Department, there is a Departmental Directorate of Health and Social Services (Direction Departementale de l'Action Sanitaire et Sociale, DDASS), which serves as an external unit of the Ministry of Health (44). Heading the DDASS is the Departmental director of health and social services, who is directly responsible to the Departmental Prefect. He/she is assisted by various specialists (e.g., the Departmental medical officer, who is responsible for ensuring that institutions adhere to the decisions of the Prefect).

DDASS enforces both the regulations of the Ministry and the regulations of the local authorities. It has administrative authority over public hospitals in the Department, must approve the hospitals' budget and help establish the prix de

'National health expenditures includes only operating expenditures (not capital expenditures). Two categories of operating expenditures comprise national health expenditures: 1) medical care expenditures (i.e., expenditures for hospital care, ambulatory and home health care, routine and preventive medicine, affiliated medical activities such as industrial medicine, medical goods and devices); and 2) health expenditures (i. e., expenditures for medical research, medical education, administration of the health care delivery system, and community health).

[6]The organizational and administrative structure of the French health system is very complex. Full understanding of this structure is not needed to examine issues related to medical technology. Readers interested in other details, however, are referred to D. Ceccaldi, Les Institutions *Sanitaires et Sociales*, 1979 (15).

'The exact name of the Ministry concerned with health can change when a new Minister assumes power, or when the existing Minister feels that a socially relevant problem is of considerable importance that it should be included in the ministerial title. Since the establishment of the Fifth Republic in 1958, the name has changed numerous times. For the purpose of simplicity, though, the term Ministry of Health is used throughout this chapter.

journée[8] for the Departmental Prefect's approval, and has administrative control over technical standards for public and private institutions. DDASS also administers the various agencies responsible for numerous public health programs. It shares with the Regional Directorate (discussed below) some of the responsibilities related to Social Security.

Health facilities planning, coordination, and technical supervision are conducted at the Regional level. Responsibility for decisionmaking rests in each Region with the Regional Prefect, who is advised by the Regional director of health and social services, a Regional inspector-general, and a Regional hospital commission. The Regional director of health and services, who is responsible to the Regional Prefect, administers the Regional Directorate of Health and Social Services (Direction Régionale de l'Action Sanitaire et Sociale, DRASS) a coordinating body in each Region. This body performs management advisory functions for DDASS. It also has responsibility for enforcing Social Security regulations. (The Regional director of health and social services does provide consulting services, with technical input from the Regional medical officer, but has no authority over the Departmental director. With some exceptions, the Regional director does not have control over the institutions in the Region.)

Public and Private Hospitals

The Hospital Reform Acts of 1958 and 1970 (35,37,38) were enacted to foster coordinated planning of health facilities on a Regional basis.[9] Under these acts, France was divided into 280 health services districts (secteurs sanitaires) and 22 health services regions (régions sanitaires), corresponding to the Economic Development Regions. Each health services district is supposed to be able to meet the primary and secondary care needs of a defined geographic area and population (50,000 to 150,000 inhabitants); each health services region is supposed to be able to provide tertiary care.

The two hospital reform acts led to the expansion of the functions of the public and private hospital sectors, classified public hospitals according to the services they were prepared to render, and created a public hospital service. Although a description of ways in which the public and private hospital sectors can be integrated to form a public health service is contained in the 1970 Hospital Reform Act, the concept of an integrated service has been implemented slowly.[10]

Public hospitals throughout the country function in a fairly uniform manner, largely because they are subject to detailed Central Government laws, decrees, and regulations (arrêtés), which control and govern many of their fiscal procedures. Public hospitals are under the administrative authority of the Departmental Prefect, but receive recommendations from the Regional Directorate of Health and Social Services. They are public corporations with financial autonomy, which are administered locally or municipally. Each has a management committee (conseil d'administration), similar to a board of directors, and a hospital director, who is appointed by the Departmental Prefect.[11]

For the purposes of planning, the Ministry of Health classifies public hospitals on the basis of size and types of services they provide. Thus there are (classification revised in 1978 (33) but not yet applied):

- *Local hospitals (hôpitaux locaux).*—Local hospitals largely provide long-term and residential care, especially to the elderly. They also provide basic medical care, occasionally with limited maternity services. These hospitals, which do not have salaried medical personnel (i.e., physicians or midwives), allow local practitioners to care for their patients at the hospital.

[8]Prix de journée, the French term for a public service hospital's daily hospital charge, is used throughout the text. The manner in which the prix de journée is established is discussed in the section of this chapter entitled "Hospital Charges and Reimbursement."

[9]These laws, along with other regulations, decrees, etc., cited in this chapter can be found in D. Comet, *Legislation des Hôpitaux Publics*, 1974 (17).

[10]All nonprofit private hospitals can be accorded public service status. For-profit hospitals can provide agreed on services for the public service, but seldom do this because the procedure for obtaining agreement is rather complicated.

[11]The hospital director's responsibilities include ensuring the application of laws and regulations; the management committee's functions are primarily advisory and supervisory.

- *"Hospitals" ("hopitaux") or second category hospitals (hopitaux de deuxieme categorie).* — "Hospitals" are usually affiliated with hospital centers (see below) and collaborate in providing for the health care needs of a health care district. These institutions are supposed to provide at least one unit for each of the following: general medicine, general surgical, maternity, chronic care, pediatric, and infectious disease. They are also to have outpatient services, a clinical laboratory for basic analyses, and electroradiology. Medical personnel are salaried and are usually part-time employees.
- *Hospital centers (centres hospitaliers).* — Hospital centers are one jurisdictional entity, but may consist of several institutions. They are usually located in the capital city of the Department and are supposed to be able to provide for all the primary and secondary care needs of the health care district. Hospital centers offer a larger variety of specialty services than "hospitals" do. They also have more full-time medical personnel, especially in radiology, clinical laboratory, and anesthesiology. They sometimes participate in medical training and are often the base for a nursing school. *Specialized hospital centers (centres hospital iers specialises)* provide specialized care within a single medical area, e.g., psychiatry, tuberculosis.
- *Regional hospital centers (centres hospital iers regionaux, CHR),* called *university hospital centers (centres hospitaliers universitaires, CHU),* when they are in the same city as a medical school. The CHR is usually in the Regior's capital city. Not only must the CHR have the facilities to meet the basic needs of its health care district, but it must have the highly specialized facilities to provide the tertiary care for the entire Region. CHUS play a significant *role* in medical education and research.

Table 3 lists the number of different types of public hospitals (classified prior to 1978 revisions) and beds for France. Table 4 summarizes the distribution of types of beds for the public and private sectors.

Table 3.—Number of Public Hospitals and Beds in France (1975)

Type of facility	Number	Number of beds
General hospitals		
CHRs[a] (including CHUs[b])	28	120,601[c]
Hospital centers	99	105,513
Hospitals	400	156,626
Local hospitals	364	53,068
Total	891	435,808
Specialized hospitals		
Psychiatric hospitals[d]	89	83,954
Tuberculosis hospitals	55	9,163
Total	144	93,117

[a]CHRs—Centres hospitaliers régionaux (regional hospital centers).
[b]CHUs—Centres hospitaliers universitaires (university hospital centers).
[c]One CHR, Public Assistance Hospitals of Paris, has 38,547 beds.
[d]Most but not all psychiatric hospitals are public hospitals.

SOURCE: Centre d'Etude des Revenus et des Coûts (Center for the Study of Revenue and Costs), *Le Coût de Hospitalisation,* 1977-78 (16).

Physicians and Nurses

As shown in table 5, in 1977, there were some 91,000 physicians in France, or roughly 172 per 100,000 inhabitants. Of the total, one-third were private practitioners. 12 The number of nurses totaled 219,000, or 412 per 100,000 inhabitants.

Just as they do in the United States, physicians in France tend to cluster in urban areas, especially around university hospital centers. There is a 5:3 ratio of generalists to specialists, and the distribution of physicians throughout the country reflects and parallels this ratio.

In the period 1967-79, the number of physicians in France increased by approximately 80 percent (41,46). To stem this rapid growth, the government has instituted more restrictive medical school selection procedures.

The rapid increase in the number of physicians is affecting the number of physicians seeking salaried positions in order to guarantee a minimum level of income for themselves. In recent years, the number of salaried physicians in France has been increasing. Furthermore, an ever increasing number of salaried physicians

[12] When hospitals and universities started to collaboratein medical education, a university-hospital career track was created. The prestige associated with this career has made it competitive with private practice.

Table 4.–Number and Distribution of Facilities and Beds in Public and Private Institutions in France (1975)

Type of facility/bed	Public institutions			Private institutions			Total		
	Number of facilities	Number of beds	Beds per 1,000 population	Number of facilities	Number of beds	Beds per 1,000 population	Number of facilities	Number of beds	Beds per 1,000 population
Medicine/medical specialties	852	145,850[a]	2.8	680	29,262	0.6	1,532	175,112	3.4
Surgery/surgical specialties	489	70,569[b]	1.3	1,265	66,249	1.2	1,754	136,818	2.5
Obstetrics	614	16,374	0.3	716	14,695	0.3	1,330	31,069	0.6
Convalescent/rest.	218	7,099	0.1	452	21,217	0.4	670	28,316	0.5
Functional rehabilitation	53	3,426	0.1	134	12,007	0.2	187	15,433	0.3
Other: long stay.	24	2,314	0.1	–	–	–	24	2,314	0.1
Tuberculosis	55	9,163[c]	0.2	195	15,038	0.3	250	24,201	0.5
Psychiatry	78[d] 114[e]	16,913 105,519	0.3 2.0	222	15,103	0.3	414	137,535	2.6
Total	1,044[f]	377,227	7.2	2,534[f]	173,571	3.3	3,578[f]	550,798	10.5

[a]Including chronic beds.
[b]Including gynecology.
[c]Autonomous public institutions.
[d]Psychiatric units within general hospitals.
[e]Public psychiatric hospitals and private psychiatric hospitals in the public hospital service
[f]Does not represent the sum because there are beds that have a variable classification.

SOURCE: Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1978 (40)

Table 5.—Number of Physicians and Nurses in France (1977)

Profession	Number	Number per 100,000 inhabitants
Physicians		
Private practitioners~	63,531	119.4
General practitioners	39,262	73,8
Specialists.	24,269	45,6
Salaried physicians.	**27,911**	**52.5**
General practitioners	18,453	34.7
Specialist.	9,458	17.8
Subtotal—general practitioners	57,715	108.5
Subtotal—specialists.	33,727	63.4
Total	91,442	171.9
Nurses		
Registered nurses.	152,575	286.9
Nurses aides, nurses auxiliaries, nurses in sanatoriums.	17,364	32.6
Psychiatric nurses	49,143	92.4
Total	219,082	411.9
Midwives	**8,899**	**16.7**

[a]This includes both full- and part-time private practitioners.
[b]This includes only physicians who are salaried exclusively, i.e., it does not include part-time private practitioners.

SOURCE: Ministère de la Santé (Ministry of Health), *Annuaire Statistique de la Santé et de l'Action Sociale*, 1979 (41).

are working full time. The increase is especially impressive in the public hospital sector. In 1965, only 3.3 percent of all physicians were full-time salaried employees in public hospitals, compared to 13.6 percent in 1977 (15,46).

The nursing population has not increased to meet hospital staffing needs. Although the Government has made efforts to attract people to nursing by increasing salaries and career opportunities, results have not yet been observed. It may be that the low status of the nursing profession, combined with difficult working conditions, is retarding change.

Health Insurance

France has a comprehensive Social Security system (Securite Sociale), with a highly elaborate sickness insurance mechanism[13] that covers virtually the entire population. Between 99 and 100 percent of the French population is now

[13]The term health insurance would be a partial misnomer, because the orientation is definitely toward curative rather than preventive care. Only limited coverage for screening and periodic checkups is mandated by national policy. A national system for preventive services for mothers and children is established under systems not discussed in this chapter.

covered by one form of sickness insurance or another. The country's Social Security system had its formal origin in the law of April 5, 1928 (22), which was revised and became operational in 1930. At first, insurance was mandatory for certain groups of workers, but was administered through private social insurance and mutual aid funds. Reforms of 1945 and 1967 reorganized the administration of the Social Security system and also created a national health insurance system (3,22,48).

Administration and Financing

Because there was resistance on the part of the different worker groups to having one administrative system, different administrative "r%-gimes" were established under the Ministry of Health to cover different categories of workers. Currently, there are four large regimes within the Social Security system. These regimes and the workers for whom they offer health insurance coverage are:

1. *General Regime* (Regime *Generale).–All* salaried workers in industry, commerce, etc., not covered by "special regimes" (see below).
2. *Special Regimes (Regimes Speciaux).* — Salaried workers in special industries such as railroads, mines, electric and gas companies, and in the civil service.
3. *Nonagricultural Independent Professions (Professions Independents Nonagricoles).* —Autonomous, nonsalaried workers, including craftspeople, small business owners, private practitioners in medicine and law.
4. *Agricultural Regime (Regime Agricole).* — Salaried agricultural workers and independent farmers.

Social Security contributions are slightly different for each regime, but over the years have tended to move in the direction of increasing uniformity. Although contributions are the shared responsibility of the employer and employee, the employer pays by far the larger share (78 percent **(48)** or more) of the subscription rate. Social Security policy is set by the Ministry of Health, but the sickness funds administer independently.

All four regimes have similar hierarchical structures to facilitate service at levels close to the insured. In the General Regime, which covers approximately two-thirds of the population (and is expanding), the reimbursement system is operated by 122 primary sickness insurance funds (caisse primaire d'assurance maladie). These 122 funds—there is usually one such fund per Department—are fiscal intermediaries that provide reimbursement to hospitals or patients, as appropriate. A Regional sickness insurance fund (caisse reionale d'assurance maladie) operates in each Region, and is responsible for, among other things, developing and coordinating prevention activities in the area of occupational health and accidents. At the national lvel is the National Sickness Insurance Fund (Caisse Nationale d'Assurance Maladie, CNAM), a public institution under the trusteeship of the Ministry of Health and the Ministry of Economics and Finance. The National Sickness Insurance Fund receives insurance fund contributions from employers and employees and then disburses endowments to the primary and Regional funds. It ensures on a national level the fiscal solvency of the primary sickness insurance funds with regard to the provision of coverage for the two groups of risks: 1) sickness, maternity, disability, death; and 2) work-related accidents and occupational health (15).

Coverage

Although there are several health insurance administrations or sickness funds covering different categories of workers, the coverage the various funds provide is similar. Reimbursement coverage for the following is provided (3):

- fees for general and special medical care;
- fees for dental care;
- cost of drugs, prosthetics, medical devices or appliances, biological and radiological exams;
- cost of hospitalization in all public and private nonprofit health institutions, and in all private for-profit health institutions that have made an agreement with the national sickness funds and meet basic technical requirements (accreditation);

. cost of transportation by ambulance and other means; and
• cost of surgical operations.

The patient's copayment varies with the type of care received. Although there are minor insurance fund differences for the rate of reimbursement, the following percentages are the responsibility of patients covered by the General Regime (3):

- 10 percent of expensive and essential drugs;
- 20 percent of medical and paramedical fees and laboratory procedures in public or private nonprofit hospitals or hospital outpatient departments;
- 20 percent of hospital costs during the first 30 days;
- 25 percent of medical and paramedical fees for care provided at the physician's private office or for a home visit; and
- 30 percent of other expenditures, such as laboratory expenditures outside the hospital, drugs other than essential ones, outpatient dental care, eyeglasses, and small medical devices-or appliances.

The copayment often can be eliminated through various exceptions recognized by the social insurance system. For certain procedures and tests that are considered "high cost, " for example, computed tomography (CT) scans, the patient is fully covered and the sickness insurance fund reimburses at 100 percent.

Many individuals belong to independent mutual aid funds or purchase private insurance to cover copayment costs.[14] If the patient is a member of a mutual aid fund, care is provided by the mutual aid society or reimbursement for the copayment is provided through the mutual aid fund.

Hospital **Charges and Reimbursement**

It is important to note the continued impact in France of the principle of liberal medicine. Hospital charges in both the public and private sectors are calculated along two primary axes: 1) a daily hospital charge for institutional service, and 2) the quantity of different "medical actions" performed at the hospital by or under the supervision of a physician. Compensation for medical actions is provided in the form of honorariums for specific types of actions, either directly to the individual physician or indirectly through the institution.[15] (Honorariums are discussed in more detail in the section on physician reimbursement.)

The prix de journe (daily hospital charge) for each public hospital and private nonprofit hospital in the public service is fixed in each Department by the Departmental Prefect, who is advised on this matter by the Departmental director of health and social services. The prix de journe is calculated for each hospital by dividing the sum of the institution's real costs for the previous year plus its deficit by the number of bed days in that year, and then multiplying this figure by the inflation-related index recommended by the Ministry of Health.

$$\text{Prix de journee for year N + 1} = \frac{\text{(Real costs of year N + Deficit of year N)}}{\text{Number of bed days in year N}} \times \text{Inflation-related index}$$

The reimbursable daily hospital charge for each private for-profit hospital is based on an agreement or "convention" between the individual institution and the Regional sickness fund. If a hospital is not conventioned, its reimbursable daily charge is set by the Departmental Prefect, and the charge is considerably lower than it would be if the hospital were conventioned.

For the past few years, there has been an increasing interest in prospective reimbursement as a method for cost containment. Several public service hospitals are now using prospective reimbursement on an experimental basis.

[14] In 1975, there were more than 8,000 mutual aid societies with a membership of approximately 33 million. The number of societies is constantly decreasing, but total membership is constantly increasing.

[15] In the case of salaried physicians working for public hospitals (or in some nonprofit private hospitals), the principle of liberal medicine that the patient pays the physician directly is not fully respected. Honorariums for the physicians' actions are paid to the hospital, but the physicians themselves receive a set salary. Recent legislation allows full-time salaried physicians to have a ver, limited number of private beds, or perform certain medical acts on a private patient basis. For these acts, they are directly reimbursed.

Physician Fees and Reimbursement

Fees for medical care provided by or under the supervision of physicians are based on a system of valuation of medical actions. Assisted by the Permanent Commission on the General Nomenclature of Professional Acts (Commission Permanence de la Nomenclature Generale des Acts Professionnels), the Ministry assigns a key letter (i.e., C for consultation, K for medical manipulation, B for laboratory, Z for radiology) and a coefficient or relative weight to every medical action that must be done by or under the supervision of a physician (16). Thus, for example, an appendectomy is worth 50K, whereas an EKG is worth 12K (36). Monetary values are assigned to the key letters, and these can and do change over the years; the coefficients for specific medical actions, which presumably reflect the action's relative complexity, however, usually remain constant.

Upper limits on physicians' fees for office visits and medical actions—the monetary values assigned to the key letters—are determined either by conventions between physician groups or individual physicians and the national sickness funds, or if no agreement is reached, by an interministerial committee. As shown in table 6, fees for physicians' acts vary depending on whether services are rendered through private practice, private institutions, or public institutions. The key letters are assigned higher values for physicians' services provided in the public sector than they are for services provided in the public sector. The higher values in the private sector reflect the inclusion in the physician's honorarium of certain material costs, which for the public sector are included in the hospital's prix de journee.

Most private practitioners are conventioned with the sickness funds.[16] Physicians who are conventional are not supposed to charge more than the conventional fees.[17] In certain situations, specified below, the conventioned fees are waived:

1. the physician holds certain categories of university or hospital titles (e. g., the

[16] Those who are not are reimbursed at a much lower fee that is set by the Departmental Prefect.

[17] There are no data to indicate whether conventioned physicians violate this regulation.

Table 6.—Key Letters and Unit Values of Honorariums for Medical Actions Performed by Physicians in the Public and Private Sectors in France (1977)

	Unit values of physicians' honorariums (in francs)[a] [b]			
	In public hospitals		In private practice, private establishments	
Key letter and type of medical action	CHUs[c]	Other public hospitals[d]	Agreed tarification[e]	Authorized tarification[f]
Hospitalized patients				
C—Consultation	5.64	5.13	33.00	4.00
K—Medical intervention	2.06	1.88	7.40	2.00
Z—Radiology	1.84	1.77	5.90	1.60
B—Laboratory	0.22	0.20	—	1.15
Maternity care	148.00	135.00	450.00	96.00
Outpatients				
C—Consultation	16.15	16.15		
K—Medical intervention	4.34	4.34	Same as	Same as
Z—Radiology	3.06	3.06	above	above
B—Laboratory	0.77	0.77		

[a] 4.25 francs = $1.00 (United States).
[b] In specified instances involving certain patient characteristics, provider characteristics, or hospital stay, the unit values of honorariums that are shown may be modified.
[c] CHUs—Centres hospitaliers universitaires (university hospital centers).
[d] Excluding local public hospitals.
[e] Based on agreements (conventions) between private practitioners or establishments and the sickness funds.
[f] Set by the Departmental Prefect and applied when the private practitioner or establishment has not entered into agreement with the sickness funds.

SOURCE: Centre d'Etude des Revenus et des Coûts (Center for the Study of Revenue and Costs), *Le Coût de l'Hospitalisation*, 1977-78 (16).

equivalent of assistant, associate, or full professor, or clinical department head) or has passed highly competitive specialty exams;
2. the physician possesses medical authority accrued through research, publications, seniority, etc; or
3. a visit is excessively long or special treatment is provided.

For physicians who are in the first category, a waiver is granted automatically if requested. For those in the second category, a panel of peers and representatives of the sickness funds makes a judgment, which once attributed, is not rescinded. Waivers for long visits or special treatment are judged on a case by case basis. As of January 1, 1979, 15 percent of conventioned physicians had waivers for conventioned rates, 5 percent of general practitioners had waivers, and 29 percent of specialists had waivers. The fees of conventioned physicians who have waivers are not to be excessive and are to be set "with good measure and tact" (25).

POLICIES TOWARD MEDICAL TECHNOLOGY

France is a country with a highly traditional culture, and perhaps because of that, some ambivalence and skepticism underlie the attraction of modern medical technology. For the most part, however, technological innovation is greatly appreciated and sought after. Furthermore, with the economic growth of recent decades, medical technology has diffused very rapidly. There is strong national interest in—and financial support for—the development of French-produced technology for domestic and export use.

Numerous policies regulate the introduction, diffusion, and utilization of medical technologies in France. Discussed below are government policies in the areas of R&D, regulation of drugs and medical devices, health facilities and equipment planning, and reimbursement.

Research and Development

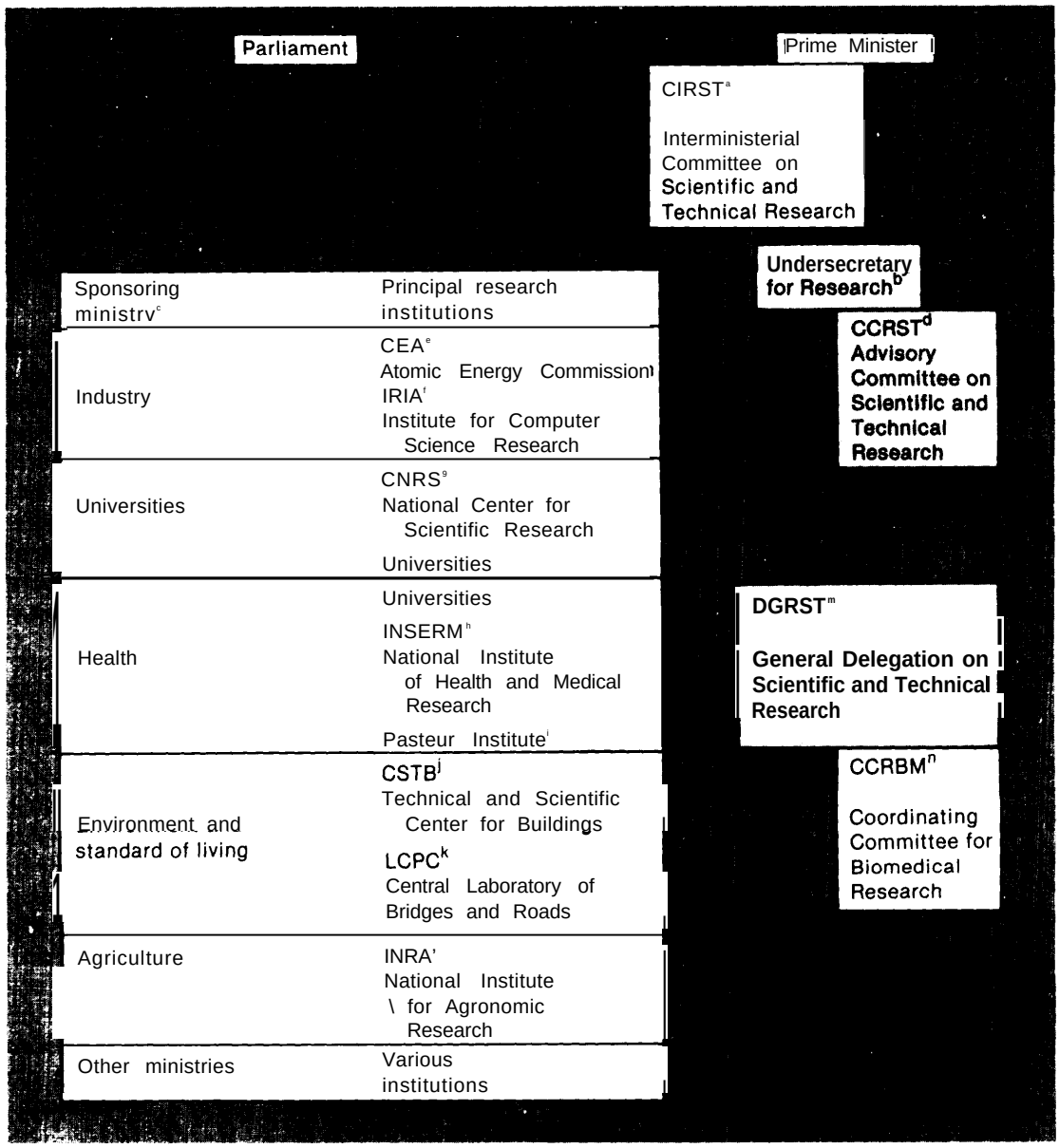
An Undersecretary for Research, attached to the Prime Minister's office, is responsible for the national publicly funded research budget. This research budget, or research envelope (envelope recherch~), includes the budgets of individual public research institutions.[18] Each public research institution is sponsored by the Ministry most closely alined to the subject area of research, and each institution's research funds come primarily from the state's budget to the sponsoring Ministry. (See figure 1.)

Responsibility for coordinating, stimulating, and monitoring all publicly funded scientific and technical research rests with the General Delegation for Scientific and Technical Research (Delegation Generale a la Recherche Scientifique et Technique, DGRST), which operates under the authority of the Undersecretary for Research. Advised by the Advisory Committee for Scientific and Technical Research (Comite Consultatif de la Recherche Scientifique et Technique), which is comprised of 16 prominent scientists from the public and private sectors, DGRST defines and implements, either directly or indirectly, any specific research policy in France (2,14). Its basic purpose is to ensure that short-term research goals are in accord with the longer term objectives of the economic and social development plan and national priority areas of interest.

DGRST attempts to coordinate collaboration between public and industrial research groups. In 1977, public funds accounted for 57 percent of R&D expenditures in France, but 61 percent of total R&D expenditures **was** utilized by private industry. The National Agency for the Promotion of Applied Research and Development (Agence Nationale de Valorisation de la Recherche), a recently expanded agency under the Ministry of Industry, stimulates innovation by partially subsidizing prototypes and by assisting in the subsequent development phase.

[18] The research envelop does not include all public research funds. For example, it does not include military research and telecommunications research. The research envelope coordinated by DGRST in 1977 represented 52 percent of all public research funds.

Figure I.–Simplified Organizational Chart **for** Public Research **Efforts in France (1978)**



[a]CIRST—Comité Interministeriel de la Recherche Scientifique et Technique (Interministerial Committee on Scientific and Technical Research).
[b]There is no Ministry for Research.
[c]Only the Ministries and institutions that do a fairly large amount of research related to health are shown.
[d]CCRST—Comité Consultatif de la Recherche Scientifique et Technique (Advisory Committee on Scientific and Technical Research).
[e]CEA—Commissariat a l'Energie Atomique (Atomic Energy Commission).
[f]IRIA—Institut de Recherche d'Informatique et d'Automatique (Research Institution for Computerization and Automation).
[g]CNRS—Centre National de la Recherche Scientifique (National Center for Scientific Research).
[h]INSERM—Institut National de la Santé et de la Recherche Médicale (National Institute of Health and Medical Research).
[i]The Pasteur Institute is a private, nonprofit foundation that receives government funding.
[j]CSTB—Centre Scientifique et Technique du Batiment (Technical and Scientific Center for Buildings).
[k]LCPC—Laboratorie Centrale des Ponts et Chaussees (Central Laboratory of Bridges and Roads).
[l]INRA—Institut National de la Recherche Agronomique (National Institute for Agronomic Research).
[m]DGRST—Délégation Générale a la Recherche Scientifique et Technique (General Delegation on Scientific and Technical Research).
[n]CCRBM—*Comité de Coordination de la Recherche Biomédicale (Coordinating Committee for Biomedical Research).*

SOURCE: Délégation Générale a la Recherche Scientifique et Technique, DGRST (General Delegation on Scientific and Technical Research), "France Recherche et Industrie," 1975 (20). (Modified by personal communication, May 1979.) (Reproduced with permission of DGRST.)

DGRST reviews and makes recommendations concerning all public research institutions' budgets to be presented to the Prime Minister and the Interministerial Committee on Scientific and Technical Research (Comite Interministerial de la Recherche Scientifique et Technique, CIRST) for annual budgetary approval. In addition to the budgets of individual public research institutions, the research envelope includes funds for DGRST to allocate to concerted actions (actions concertees) in areas of research which DGRST has identified as having priority (e.g., biomedical engineering, biology and myocardial function, computers and social sciences, reproductive and developmental biology, nutritional and agricultural technology, immunology, organ transplants). Funds for concerted actions are given to university research groups, research units of the research institutes, and to industry (18).

The Coordinating Committee for Biomedical Research (Comitee de Coordination a la Recherche Biomedicale, CCRBM) of DGRST supervises the activities of the various organizations that conduct or sponsor biomedical research. As shown in figure 1, the principal public institutions are: 1) the National Institute of Health and Medical Research (Institut National de la Sante et de la Recherche Medicale, INSERM), 2) National Center for Scientific Research (Centre National de la Recherche Scientifique, CNRS), and 3) the universities. The Pasteur Institute, a private, nonprofit foundation that also does biomedical research, is partially subsidized by the state.

INSERM and CNRS both allocate research funds to their own in-house research laboratories and to research units at the universities; both can also identify priority areas for research and request research proposals that are called programed thematic actions (actions thematique programme, ATPs). ATPs are 3-year contracts to support the operating expenses, equipment, and temporary personnel for assistance with items such as data collection or interviewing. [19]

[19]The salaries of reseachers at public institutions, who after a 4-year probationary period are tenured employees, must be paid with general research funds and cannot be met with funds for ATPs.

The scientific merit of research proposals is judged by different advisory commissions within INSERM and CNRS, depending on whether the proposals are self-generated grant proposals or are submitted in response to ATPs. INSERM receives a certain amount of money to help subsidize ATPs from the National Sickness Insurance Fund. INSERM judges the proposals for scientific merit, but if the ATP is based on a priority area of the National Sickness Fund, the Fund makes the final decision about whether to allocate funds.

Evaluation studies have been subsidized by ATPs, concerted actions, and the sickness funds. Most evaluation studies conducted are either clinical trials or efficacy studies of one form or another. A recent reorientation to include cost effectiveness is illustrated both by the inclusion of cost-effectiveness studies as an INSERM research priority and by the allocation of ATP funds to evaluate radiologic examination methods and determine their cost-effectiveness ratios (20).[20]

The state and its central policy guidelines have played an important role in scientific development since the creation of the Fifth Republic. A 10-year research policy (1980-90) has been proposed and is now (January 1980) being refined and elaborated by scientists. Among the various long-term priority areas that have been identified are biomedical technologies (microbiology, genetics, biomedical engineering), medical care evaluation research (nutrition, medication), and health economics (19). For the past few years, France's total public and private investment in R&D has been 1.8 percent of the gross domestic product. There is a plan to increase the public sector's investment in R&D

[20]In the late 1960's and early 1970's, cost-benefit analyses were very much in vogue within the Ministry of Health. For example, the maternal and child health program was implemented after a cost-benefit study (rationalisation des choix budgetaires, RCB). A similar study was conducted for deciding whether psychiatric catchment areas were advantageous or not. It is difficult to ascertain whether the psychiatric study had an impact on the decision-making process or was used to justify a decision already made. In both cases, the studies were coordinated by the Ministry with substantive input from experts in the specific medical area. In more recent years, there has been growing disenchantment with this approach, and no such studies appear to be underway at the present time.

during the 1980's, so that the country's total public and private investment in R&D amount to 2.2 percent of the gross domestic product—the same percent as in West Germany and Japan at present.

Evaluation and Regulation of Drugs and Medical Devices

Medical technology in France is regulated directly, indirectly, or not at all, depending on the technology in question. New medical procedures are not regulated at all, because one of the principles of liberal medicine which is still respected in France is that the physician is free to prescribe or treat as he/she wishes. If a new procedure is not in the nomenclature of medical acts reimbursed by the sickness funds, however, reimbursement to the patient for the procedure may not be provided. (In some cases, though, a new procedure can be integrated into an existing category of acts for which reimbursement is provided.)

Medications are regulated both directly and indirectly. Decisions regarding which drugs can be sold in France are made with the assistance of expert commissions by the Directorate of Pharmacy and Medications (Direction de la Pharmacie et du Medicament) at the Ministry of Health. Drugs to be sold in France are required to meet fairly stringent standards of experimentally demonstrated efficacy, safety, etc. A recent legislative change by the European Economic Council (EEC) may eventually provide an alternative for market approval: If a drug has been approved for sale in any two EEC countries, then the other EEC countries are expected to grant permission fairly automatically (26,33, 34). This legislative change will not actually be enforced for a few years.

Although there are no advertising or price restrictions on drugs that have been approved for sale (including most over-the-counter drugs), such restrictions are imposed on drugs that are included on the reimbursable list of the Social Security System. In order to be placed on this formulary, a new drug must be shown to be more efficacious, have fewer side effects, or cost less than another drug which is already on the formulary. Once the drug has met these criteria and been placed on the formulary, its price is set by the Ministry, and advertising must conform to certain restrictions. At the same time, however, the market for the drug is greatly expanded.

Medical devices are not regulated for efficacy before being placed on the market. Sometimes, however, the evaluation of a new medical device is stimulated by the National Sickness Insurance Fund. Since the Fund provides reimbursement for medical devices, it can decide to provide reimbursement for a limited quantity of a new device on the condition that INSERM or a university group be permitted to evaluate the new device's efficacy. This evaluation provides information that can be used in deciding whether or not the device should be placed on the list of devices for which reimbursement will be provided (47). To obtain reimbursable status, a device must be shown to be efficacious. The evaluation of medical devices that is required by Social Security can be considered an indirect form of regulation.

Health Facilities and Equipment Planning: The Carte Sanitaire[21]

The carte sanitaire, the system of health facilities and services charts that is used for health planning, was created by the Hospital Reform Act of 1970 (35). Since 1972, various decrees and circulars have detailed how the system should function (see, e.g., 4,5,6,7,8,10,26,27, 28,29,30,31,34,35). Creation of the carte sanitaire was aimed at stimulating reorganization and equalization of the distribution of health care facilities and services. By regulating their expansion and redistribution, the carte sanitaire regulates the availability of resources for geographic areas and population groups. Expansion or creation of services must be approved regionally or nationally to ensure that growth relates to need.

[21]*Carte sanitaire, the French term for the system of health facilities and equipment charts that are used for health planning, is the term used to refer to that system throughout the remainder of this chapter.

A method for needs determination is established nationally. The Ministry of Health, advised by the National Commission on Medical Equipment (Commission Nationale de l'Equipment Sanitaire), recommends norms for equipment/population ratios. [22] The charts that constitute the carte sanitaire are prepared on either a population or specific equipment basis by the Regional Prefect, and they list existing and authorized-for-purchase equipment and locations, population projections, and where applicable, the discrepancy between actual supply and projected supply and projected need.

The Ministry of Health reviews and approves the charts prepared regionally; except in specified cases, however, he/she leaves actual needs determination (and the local request and approval process) to the Regional and Departmental authorities. Health facilities planning for individual Regions and districts within the Region is coordinated by the Regional Prefect, who is assisted by the sectorial interhospital group, the Regional interhospital group, and the Regional Commission on Medical Equipment (Commission Regionale de l'Equipment Sanitaire). [23] Interregional planning and decisionmaking for certain facilities or equipment that are considered to be assessed best from a national perspective are the responsibility of the Ministry of Health advised by the National Commission on Medical Equipment. The carte sanitaire must be reviewed by the Ministry each time a new economic and social development plan is being prepared, about every 5 years. At the initiative of the Ministry or Regional Prefect, it can be reviewed at other times, as well.

The Ministry of Health has issued a list of "heavy equipment" (equipements lourds), and each of the specific medical technologies on this list has its own chart, and usually an index of need. Authorization for acquisition from the Minister of Health, the Regional Prefect, or the Departmental Prefect, depending on the technology and type of facility, is required for any item on the list. [24] In the case of a public institution, if authorization for purchase of an item is granted, the state may—but is not obliged to—subsidize part of the purchase cost. If authorization is not granted, purchase by a public or private institution would be illegal .25 The cost of unauthorized equipment could not be included in a public or private hospital's capital or operating costs, nor could it be included in calculating a public hospital's prix de journee,

At the present time, there are 11 technologies on the "heavy equipment" list of the carte sanitaire that applies to both public and private institutions. [25] [26] They are (modified May 1976) (31):

1. autoanalyzers,
2. heart-lung machines,
3. hyperbaric chambers,
4. linear accelerators with sources greater than 10 MeV (million electron volts),
5. radiotherapy machines: cobalt bombs and linear accelerators with sources less than or equal to 10 MeV,
6. scintillation cameras,
7. radioisotope scanners,
8. artificial kidneys,
9. information-processing equipment whose cost exceeds 150,000 francs (13,530) [27] for purchase, or 5,000 francs ($1,175) per month for rental and operation,
10. laser photocoagulators, and
11. CT scanners.

[22] These have been established for surgical, medical, obstetrical, and extended-care-facility beds, and also for certain medical technologies.

[23] The members of the Regional Commission on Medical Equipment are recommended by the Ministry and include representatives from various organizations and institutions who are directly or indirectly involved with hospital care. These include representatives from the Regional and Departmental government agencies, from elected representatives, from private practitioners, from both the public and private hospital sectors, from the medical university, from the sickness funds, etc. The membership of the National Commission on Medical Equipment is analogous to that of the Regional Commission.

[24] The approval process for private for-profit hospitals is different from that for institutions in the public hospital service. When a private sector institution requests approval for equipment acquisition, replacement, or expansion, the appropriate approval body must respond within *6* months of the demand. Otherwise, approval is granted by default. Public service hospitals are granted a *6*-year authorization, whereas for-profit hospitals are granted a *2*-year authorization.

[25] Enforcement of th, prefect's decisions is the responsibility of the Departmental or Regional medical officer.

[26] Additional technologies are included on the heavy equipment list that applies to the private sector.

[27] For conversion of French francs to U.S. dollars, the exchange rate used throughout this chapter was *4.25* francs = $1.00 (U.S.).

The Regional Prefect has jurisdiction for autoanalyzers, heart-lung machines, hyperbaric chambers, artificial kidneys to be used only for acute kidney failure, and information-processing equipment in private facilities. All equipment in public facilities, [28] excluding CHRS and CHUS, are in the jurisdiction of the Departmental Prefect. The remaining items are the responsibility of the Minister. The Minister is advised with respect to items in the private sector by the National Commission on Medical Equipment.

Indexes of need are recommended by the National Commission on Medical Equipment. To help determine an index, the Commission may call on experts, including physicians and manufacturers, in the specific area of interest. Given the diverse representation and expertise of the National and Regional Commissions, indexes of need are presumably unbiased or balanced and based on the latest available information and methodology for needs determination. If the indexes are perceived by the General Directorate of Health or others at the Ministry of Health to be inadequate or inappropriate, however, efforts to revise them are initiated.

The carte sanitaire can affect the capital expenditures of an institution and determine the availability of specialty units and beds, and indirectly, personnel. By explicitly indicating that certain districts are "underequipped" the carte sanitaire can and has induced health costs. The system also brings to light the fact that certain districts are "overequipped. " Until December 1979, the carte sanitaire regulations allowed the appropriate authorities to close down "unneeded" beds and heavy equipment—for the private sector. In practice, however, little if anything, was done to redistribute equipment from "overequipped" districts.[29] The power to close down unneeded facilities has now been extended to public hospitals. Individuals responsible for the carte sanitaire at the Ministry anticipate that this change, combined with the present emphasis on health care cost containment, will provide the impetus to enforce this regulation.

The Hospital Reform Act creating the carte sanitaire was passed in 1970. In a circular on July 13, 1976, however, the Minister indicated that the carte sanitaire's regulations were not being taken seriously and were therefore having no apparent impact (12). At the time of the circular, the carte sanitaire system had been functioning for only 3 years, and its work had been mostly descriptive and hardly at all normative. Since then, the situation has been improved by more concerted efforts. The latest available data for the private sector 1977 (43) indicate that not only are fewer beds being requested, but that a lower proportion of the requests are being authorized. What is important to observe, however, is the lag between the declaration of policy, the presumed implementation of policy via regulatory mechanisms, and the expected impact of the policy.

Reimbursement and Medical Technology

Reimbursement for professional fees and technology charges is provided for differently in the public and private sectors. For public service institutions, technology capital and operating costs are included in the hospital's prix de journee. For private facilities and practitioners, part of these costs is included in the reimbursable daily hospital charge and part is included in the honorarium fee.

As has already been mentioned, the percentage of reimbursement to the patient depends on the technology in question. More complex technological procedures engender a higher rate of reimbursement, i.e., the patient pays less or nothing at all. Prior to the use of certain high-cost procedures, authorization should be obtained from the sickness funds. If authorization is denied, the patient is liable for the cost. (The mechanism of prior authorization is discussed below in conjunction with cobalt therapy.)

[28] Except dialysis machines for chronic kidney failure.

[29] Thus, for example, although there are districts that do not have a cobalt machine that they "need," France as a whole has more machines than the cobalt/small-linear-accelerators total population index specifies.

SPECIFIC TECHNOLOGIES

As described in the preceding section of this chapter, France **has** numerous policies that regulate the introduction, diffusion, and utilization of medical technologies. Some of these policies are fairly recent, and it is too early to assess their impact. The following examples of experience with specific medical technologies, however, provide insights into the existing relationship between the policies and the technologies.

CT Scanners

A highly expensive capital investment, the CT scanner was subject to regulation by the carte sanitaire even before it was specifically added to the list of heavy equipment by the decree of September 1975 (31). Because of the computer component of the machine, the CT scanner was regulated as technology in the category of information-processing equipment exceeding specified cost limitations. This category was in the jurisdiction of the Prefect. As soon as the Minister placed the CT scanner on the list of heavy equipment, however, she indicated her intention to obtain ministerial jurisdiction for this technology. Ministerial jurisdiction for CT scanners in the private sector was obtained shortly thereafter (32).

The first CT scanner in France was purchased with assistance from the Ministry of Health by the Public Assistance Hospital of Marseilles. That purchase was made in March of 1975, before a CT scanner facilities chart and government-recommended indexes of need had been issued.

The current index of need, one CT scanner per 1 million inhabitants, is a combined index that includes both head and total body scanners. This index was agreed on by an expert committee of renowned physicians, researchers, and manufacturers called together by the National Commission on Medical Equipment. The committee recommended that scanners be approved only for institutions associated with research units; it also recommended that brain scanners be approved only for those facilities with neurosurgery departments and that body scanners be approved only for facilities with clinical oncology departments.

The rate of diffusion of CT technology, as controlled by the index of need, was affected by an important factor—the desire to foster the development of a French-fabricated scanner. The scanner had been included in a priority area for development identified by DGRST: computer science technology. In addition, government subsidies for developing CT equipment had been provided to the French manufacturer CGR. The index of one scanner per million inhabitants was chosen so that there would not be a rapid saturation of the CT market and room would be left for CGR to compete. The index was not medically restrictive, because the relative diagnostic value of the scanner had not been fully established. The first perfected CGR scanner was installed in January 1977.

Using the current index of need, France should have 54 CT scanners by 1983. As of January 1, 1979, 30 CT scanners (20 head, 10 body) were installed in France, and 26 more (13 head, 13 body) have been authorized (43).[30] Nine of the twenty-two Regions do not have scanners, although they have been authorized, and Corsica's population size does not justify one. Other Regions have attained their limit and would like more.

The high level of interest in the diagnostic value of the scanner has stimulated the awarding of grants and contracts through INSERM, the National Sickness Fund, and DGRST for research on the value of this technology to medical decisionmaking. The impetus and efforts to evaluate a medical technology in terms of the impact of the information it provides are a rather new phenomenon in France, but one which has persisted. When the National Commission on Medical Equipment was requested to reassess the index of need in light of the in-

[30] Fifteen scanners (5 head, 10 body) purchased without government subsidies have been installed since *1975 (43)*, Most of these scanners are in private (for-profit and nonprofit) establishments; some are prototype machines for evaluation, All 15 were authorized.

production of body scanners, researchers working on the subject of diagnostic value of the scanner were also invited to participate. Further evidence of the persistence of the phenomenon was the recommendation that total body scanners be installed where research could be conducted to evaluate the machine. Requests for proposals (ATPs) from INSERM followed this requirement. In addition, the National Sickness Fund is currently supporting several scanner evaluation projects.

Requests for scanner purchase authorizations have been coming in more slowly than expected by the Ministry and CGR. The supposition is that the political problems involved in determining which radiology service in a Region or hospital center gets a machine have slowed down the process. In the United States, each hospital within a medical or hospital center that includes several hospitals usually has independent administrative authority; in France, though, a hospital center is one jurisdictional entity. Since each hospital can have its own radiology department, or several smaller departments, each of which is headed by a chief of radiology, reaching agreement as to which radiology department within the hospital center will get the machine can sometimes be difficult. This problem is thought to have affected the requesting process.

The CT scanners that have been installed are operating at capacity. Inpatients have an average delay of 3 to 4 days between the request for a scan and the performance of the procedure. For outpatients, the delay is closer to 4 weeks. All scans are reimbursed by Social Security at 100 percent, because they are considered high-cost procedures.

Whether the scanner is being utilized appropriately is not known. Most physicians perceive a need for more installations, however, and this perception, combined with CGR'S capacity to supply the demands, fosters the expectation that the present index will be revised with the next 3 or 4 years.

Renal Dialysis

Research on renal dialysis apparatus was going on in France in the late 1940's, but the clinical use of hemodialysis machines did not begin until 1965. Since kidney disease fell into the category of chronic diseases, Social Security funds covered the entire cost related to the treatment. Considerations of the patient's ability to pay, therefore, were not a determinant of the choice of patients for treatment. This choice was left—and remains—entirely up to the clinician.

The very early indicators of need for dialysis equipment, which affected the diffusion of this technology, were based on the availability of trained professionals and the purchase of equipment, as well as the increasing prevalence of kidney failure. These early indicators came from a group of experts representing INSERM, specialists in nephrology, and the Ministry of Health. The goal in the mid- to late 1960's was to have enough renal dialysis facilities to treat 10 new cases per 1 million inhabitants. The treatment goal was revised in 1968, for the sixth economic and social development plan (1971-75), to 30 cases per million. The current goal, 50 new cases per 1 million inhabitants, has been achieved in practice, and the present intention is not to increase the number of facilities. The demand for facilities should start leveling off by 1985 because of advances in nephrology that are expected to prevent chronic renal failure (39).

The carte sanitaire includes renal dialysis machines as heavy equipment that must meet interregional planning objectives (11). The Ministry of Health has jurisdiction for the carte sanitaire for dialysis machines used for chronic renal failure in hemodialysis centers; and the Regional or Departmental Prefect has jurisdiction for machines used in such centers to treat acute renal failure. The current carte sanitaire index prescribes 30 dialysis machines per 1 million inhabitants for chronic renal failure (24). (This includes machines to train people for home dialysis, and surveillance to ensure that machines are being used for this purpose is called for.) That index is qualified by an additional index that guarantees at least five machines for each CHR. This means a possible in-

dex of 35 machines per 1 million inhabitants. The directives specify the desired minimum number of machines per center (eight), and they assign the power to the Region to determine the locale so that patient convenience is planned for. Each machine is supposed to be used to treat four patients.

Although the carte sanitaire does not include home dialysis machines, present policy is to encourage the expansion of home dialysis and kidney transplants when medically and socially appropriate. The expectation is that stopping the expansion of dialysis machines in centers will increase the use of home dialysis and transplants. The goal is to treat approximately 50 percent of new cases at centers and to treat the other 50 percent by other methods (e.g., home dialysis, peritoneal dialysis, transplants, etc.) (39). A ministerial circular in January 1977 specified a goal of 25 percent home-dialyzed patients among chronic renal disease patients (13).

Statistics on the prevalence of dialysis use and related information are maintained by the Division of Hemodialysis and Transplantation within the General Directorate of Health at the Ministry. This Division is advised about hemodialysis equipment by the Commission on Hemodialysis and Transplantation. There are 151 hemodialysis centers in France (9,13,43). As of 1977, there were 7,096 individuals with chronic renal failure on dialysis (9,13,43). Within this group, 83.4 percent (5,920 persons) were treated at the 151 dialysis centers, and 16.6 percent (1,176) were on home dialysis. The percentage of patients on home dialysis tends to vary inversely with the rate of transplant operations. Furthermore, this percentage varies in different parts of the country: In the Paris Region, for example, 38 percent of dialyzed patients are on home dialysis, whereas in the Rhones-Alpes Region, only 9.8 percent are. Approximately 650 kidney transplants were performed in 1978 (39). Data on the number of machines to treat acute renal failure were not available.

INSERM supports several research projects on the subject of the treatment of chronic renal failure. One collaborative venture, originally supported by the Ministry of Health, the National and Paris Region Sickness Insurance Funds, the Association for Artificial Kidney Utilization (Association pour l'Utilisation du Rein Artificiel), and the National Commission on Hemodialysis (Commission Nationale d'Hemodialyse), is now completely supported by participating dialysis centers. This project involves the development and operation of a computerized data bank on dialysis patients (at present in 40 centers). Data from the project are being used to evaluate the effectiveness, impact, and epidemiology of hemodialysis.

Coronary Bypass Surgery

Coronary bypass surgery was first performed in France in 1969. Since then (up to 1979), approximately 5,000 bypass procedures have been done, 1,000 of them in 1978 alone (21).[31] Only cardiac surgery departments can perform bypass surgery, because only they have the necessary equipment. At present, 23 active cardiac (open-heart) surgery units in CHRs and CHUs and several (5 or 6) private institutions perform this procedure.

The carte sanitaire for the authorization of heart-lung machines does place some indirect limitations on the surgery rate, but because the government has no jurisdiction in the area of regulating individual physicians' decisions concerning the use of medical interventions, it cannot regulate physicians' use of coronary bypass surgery. The initial response of French physicians to this new procedure was rather skeptical. Practitioners wanted more evidence of its effectiveness. Because of ethical objections, the French have not conducted, and do not plan to conduct, their own randomized trials of the procedure. When French physicians make therapeutic decisions, however, they do use the results of trials conducted elsewhere.

When coronary bypass surgery was introduced in 1969, it did not have to be specifically added to the nomenclature of medical acts with an associated K-coefficient (medical manipulation), because it could be subsumed under the existing category of open-heart surgery. Thus, neither the government nor Social Security was involved in the introduction of this technology.

[31] Subjective estimates provided by informed sources.

Since the charges for coronary bypass surgery are the physician's honorarium as reflected by the total number of K's, in fact, neither the Ministry nor the sickness funds can even provide accurate data on the number of procedures performed.

The general belief among physicians seems to be that coronary bypass surgery is used cautiously, and the rate of coronary bypass surgery seems to support that belief. The rate of coronary bypass surgery in France, about 19 procedures per million inhabitants, is far lower than that in the United States, about 370 per million inhabitants (21). One possible reason for the lower rate in France is the channeled access to the surgery there. Referrals for surgery are made by cardiologists only after treatment failure with medications. Generally, surgery is prescribed only for those patients, usually fairly young (35 to 45 age group), who have had certain types of myocardial infarctions or for whom medications have not been effective in treating cardiac pains. The rate of surgery has been increasing (21), however, and one cannot predict if the rate has reached a plateau or will continue to increase.

Cobalt Therapy

The first cobalt treatment machine was installed in France in 1955. In the beginning, cobalt machines were mostly in the private sector. Figure 2 illustrates the rate of diffusion of radiotherapy equipment (i.e., cobalt bombs and small linear accelerators combined).

The carte sanitaire specifically lists linear accelerators and cobalt bombs as heavy equipment needing special approval (31). Both are subject to approval of the Ministry of Health. The first indexes of need were one linear accelerator and five cobalt treatment machines per 1 million population. In May of 1976, these were revised to reflect utilization patterns. The present indexes are one large linear accelerator (capable of more than 10 MeV) and five cobalt bombs and/or small linear accelerators (capable of 10 MeV or less) per 1 million inhabitants.

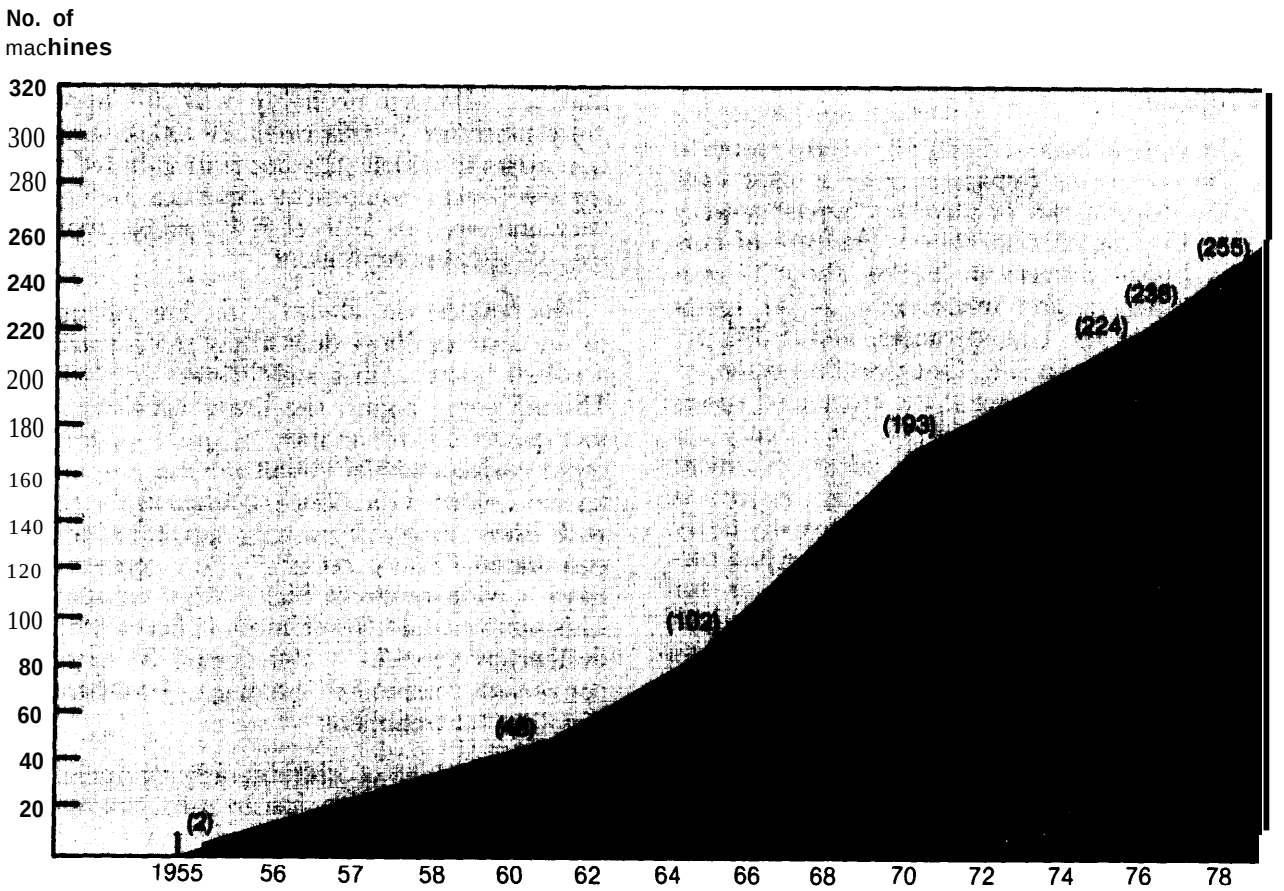
The carte sanitaire for radiation therapy made explicit in three Regions the unmet need for the large linear accelerators. With the reclassification of small linear accelerators into the cobalt bomb category, there is a small excess of this category of equipment (278 authorized machines instead of 263) (43). This excess means that the Ministry probably will not approve more machines in this category unless a situation arises in which: 1) a population-based need for additional equipment develops (which is very unlikely), or 2) there is a need for replacement of existing equipment.

The replacement clause of the law pertaining to the carte sanitaire does allow replacement of a cobalt bomb with a small linear accelerator. Though some regard the linear accelerator as therapeutically preferable, in order to impede rapid replacement of cobalt bombs, the Ministry has qualified the clause to allow replacement with linear accelerators only in establishments considered "heavy centers, " i.e., centers that have a wide range of high-energy equipment. This action could foster more concentrated radiotherapy services, which would be more inconvenient for patients having to travel longer distances for treatment.

For each piece of radiotherapy equipment it possesses, every facility has an authorization for ownership from the Ministry of Health. If an institution does not really use its machine, or uses it infrequently, as may be the case for some private clinics that had cobalt machines early, it sells its machine and associated authorization to another institution within the health services region or Department. This procedure is not one that the Ministry recommends, but it is not really illegal and is tacitly accepted.

In addition to the aforementioned measures for regulating the acquisition and existence of this technology through the carte sanitaire, there does exist a Social Security System mechanism which presumably is intended to regulate its use. When radiation treatment is prescribed, a request for prior authorization of the treatment is submitted to the sickness fund. If a response is not provided within 10 days, tacit approval is implied. (Although prior authorization is supposed to be granted before treatment is provided, in practice it is often granted after

Figure 2.—Diffusion Curve for Installed Cobalt Machines and Linear Accelerators < 10 MeV in France (1955-78)



SOURCE: F. Bachelot, *Cancer et Radiothérapie* (Paris: Firmim-Didot, 1977) (1). Updated by the Ministère de la Santé (Ministry of Health), 1979 (43).

treatment.) In the event that authorization is denied, the patient who has received treatment is liable for the cost and there is no reimbursement. It was not possible to obtain data on how frequently reimbursement is denied. Few documents discuss the procedures for prior authorization, and the procedures are not often mentioned by physicians as being part of the treatment/reimbursement process. This suggests that prior authorization is not widely perceived as a powerful regulatory mechanism. Whether its weakness results from inadequate staff at Social Security to fully review authorization requests, or from a small proportion of inappropriate requests, cannot be determined on the basis of available data.

Several years ago a study commissioned by the Ministry produced results that indicated to the Ministry that the coefficients for radiotherapy (Z key-letter) were inflated (45). Despite criticisms of this study, the coefficients were reduced. Radiotherapy is considered a high cost therapeutic mode, and the sickness insurance funds cover the cost completely.

At the present time, possible changes of the carte sanitaire indexes for radiotherapy equipment are under discussion. The discussion has arisen for two reasons. First, preparation of the eighth economic and social development plan requires review of the carte. Second, the experience of using the linear accelerators, large and

small, for several years has changed the treatment protocols again and may have altered the equipment needs.

Automated Clinical Laboratories

The first autoanalyzer installed in France was a Technicon product installed in 1959-60. Since 1972, autoanalyzers have been included on the heavy equipment list of the carte sanitaire. This equipment is under the jurisdiction of the Regional or Departmental Prefect. For the carte sanitaire, autoanalyzers are defined as bioassay equipment capable of performing 250 analyses or exams per hour, or more than 5 analyses or exams simultaneously. The equipment can be one apparatus or an assembled apparatus of several components.

The index for determination of need is not based on population, but based on the volume of tests performed by the laboratory. A clinical laboratory must perform a total number of tests valued at a minimum of **2** million B (key-letter category for laboratory honorariums) in order to purchase automated equipment. This carte sanitaire index is for public and private hospital laboratories, as well as for freestanding laboratories.

Following the 1972 decrees identifying heavy equipment, the Ministry of Health requested an inventory of existing equipment. Data concerning the distribution of autoanalyzers in 1973 should therefore be fairly accurate. Any subsequent figures, however, underestimate the number of autoanalyzers. This is because the Prefect's approval for purchase is required only if a laboratory wants to purchase a large machine, or wants to obtain *several* small ones simultaneously for integration into a unified apparatus. It is not uncommon—and according to some, it is quite frequent—for a laboratory to build up sophisticated apparatus by purchasing small independent components in a sequential and planned fashion. In this manner, a laboratory is able to obtain a more sophisticated and powerful machine, while avoiding government regulation and thereby not having its equipment appear in the Ministry's statistics. Even when a technology's diffusion is closely regulated, it appears, ingenuity can sometimes circumvent the regulatory process in a very legal fashion.

CONCLUDING REMARKS

The carte sanitaire system has been operational for close to a decade. Experience has improved judgment and clarified the problem issues. With the present preparations for the eighth economic and social development plan, and the concomitant review of the carte sanitaire, two major issues are being raised at the Ministry of Health.

One issue is revision of the authorization process. The **1970** law establishing the carte sanitaire and the many decrees and circulars that describe, define, and redefine its procedures have created a system that is bureaucratically heavy, confusing, and at times counterproductive. Under the existing authorization process, for example, a private institution and a public institution (other than a CHR or CHU) that want a heart-lung machine would submit their requests to, respectively, the Regional Prefect and Departmental Prefect. Each Prefect could make a decision independent of the other's, thereby undermining the intended coordination of the carte sanitaire. To improve overall coordination, some individuals at the Ministry want to have one decisionmaker for a given type of equipment in both private and public institutions.

The second major issue being raised at the Ministry is revision of the carte sanitaire indexes. Health care providers consider many of the indexes overly restrictive. Individuals with responsibility for the carte sanitaire at the Ministry of Health consider it advantageous not to revise the population-based indexes for equipment,[32] however, until there is better information about the use and the utility of the equipment.

[32] Other than the scintillation camera.

The carte sanitaire system has the potential for ensuring that the French population's health needs are being met and that health care facilities are not overabundant. Its early effects are now being observed, but it is too soon to say whether the system will be effective over a longer period. As noted above, because of the sanctioning process, the carte sanitaire system does have loopholes. Further, it appears that stricter enforcement of the carte sanitaire authority is necessary to the correct the system's functioning. Finally, it should be noted that although the carte sanitaire was introduced to foster coherent health services planning and to redistribute services so that the needs of local populations are met, in some cases the carte sanitaire can be counterproductive. The concentration of facilities at technology heavy centers that have evolved in part because of some of the criteria for authorization, for example, may limit some patients' access to these facilities by necessitating their having to travel farther for treatment. It is too early to say whether the carte sanitaire system has had an impact on health care costs. These costs have been rising at the rate of 17 to 20 percent each year for the past few years. Whether efforts to limit the supply of available technology resources will stem the increases, however, is still not known.

The carte sanitaire is a good example of French social laws. The policy is simple, clear, and flexible: Regionalization of health services planning, indexes of need based on the consensus judgments of experts, required review of the indexes. The regulations, by contrast, are both very detailed and subject to frequent modifications and additions, which often makes their implementation complex bureaucratically. As the carte sanitaire illustrates, the legislative system's flexibility in terms of permitting frequent changes can at times lead to a situation that is confusing and somewhat less rational than the rational policy which fostered the legislation. The result is a system that has many positive attributes that are counterbalanced by defects and other problems.

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