Chapter 6

The National Cancer Institute

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The National Cancer Institute

INTRODUCTION

In 1979, cancer killed more than *400,000* Americans *(47)* and 815,000 new serious cancers were diagnosed (1) (see table 14). Over 3 million Americans alive today have had a diagnosed cancer. Cancer accounts for about 20 percent of total U.S. mortality, second only to heart diseases, which are responsible for about 38 percent of deaths.

Cancer has a major impact on the Nation's economy, both from the personal costs of treatment and lost income, and from public expenditures for screening programs, public education, and cancer research. In 1977, the most recent year for which information is available, direct costs for all cancers, including hospital care and physicians' services, amounted to about 7 percent of these costs for all illness (33). Indirect costs, based on a lost earnings approach (discounted at *6* percent), amounted to approximately 19 percent of total indirect costs (33), The fiscal year 1982 budget for the National Cancer Institute (NCI) is $986 million.

The costs of cancer are not exclusively economic. Social costs have taken on increasing prominence in recent years, and include more than the obvious pain and suffering of the victim, Relatives and friends of victims and caregivers may suffer direct consequences of the victim's morbidity and mortality. Social isolation, economic dependence, lost personal and business opportunities, and many undesirable alterations in lifestyle are inevitable. Serious emotional and psychological problems requiring professional attention are not uncommon among victims and their family members, often producing irreversible changes in family structure and relationships.

A common measure of disease impact is the number of years of life lost due to premature mortality. This index takes into account both the number of deaths and the age at which people die. Therefore, the death of a younger person will contribute more person-years lost than will the death of a person who is closer to having

Table 14.—Estimated New Cancer Cases and Deaths by Sex for Major Sites, 1981

	Total cases		Total deaths		Females				Males			
					Cases		Deaths		Cases		Deaths	
Site	Number	Percent of total	Number	Percent of total	Number	Percent of total	Number	Percent of total	Number	Percent of total	Number	Percent of total
Lung	122,000	15.0	105,000	25.0	34,000	8.3	28,000	14.5	88,000	21.8	77,000	33.8
Colon-rectum	120,000	14.7	54,900	13.1	62,000	15.0	28,700	14.9	58,000	14.4	26,200	11.5
Breast	110,900	13.6	37,100	8.8	110,000	26.7	36,800	19.1	900	0.2	300	0.1
Prostate	70,000	8.6	22,700	5.4	—		—	—	70,000	17.4	22,700	10.0
Uterus	54,000[a]	6.6	10,300	2.5	54,000	13.1	10,300	5.4	—	—	—	—
Urinary	54,600	6.7	18,700	4.5	16,600	4.0	6,500	3.4	38,000	9.4	12,200	5.4
Oral (buccal cavity and pharynx)	26,600	3.3	9,150	2.2	8,200	2.0	2,850	1.5	18,400	4.6	6,300	2.8
Pancreas	24,200	3.0	22,000	5.2	11,500	2.8	10,500	5.5	12,700	3.2	11,500	5.1
Leukemia	23,400	2.9	15,900	3.8	10,400	2.5	7,000	3.6	13,000	3.2	8,900	3.9
Ovary	18,000	2.2	11,400	2.7	18,000	4.4	11,400	5.9	—	—	—	—
Skin	14,300[b]	1.8	6,700	1.6	7,300	1.8	2,700	1.4	7,000	1.7	4,000	1,8
All others	177,000	21.7	106,150	25.3	80,000	19.4	47,750	24.8	97,000	24.1	58,400	25.7
Total	815,000		420,000		412,000		192,500		403,000		227,500	

[a]Invaslve cancer only.
[b]Melanoma only.

NOTE. Estimates of new cancer cases and deaths are offered as a rough guide and should not be regarded as definitive

SOURCE. Office of Technology Assessment, 1981 from American Cancer Society data,

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lived to full life expectancy. Cancer accounted for approximately 19 percent of all deaths in 1975, and about 16 percent of all years of life lost (104), indicating that the average age of those who die from cancer is greater than the average age of those who die from the aggregate of all other causes of death.

The importance of cancer in U.S. policies about disease is illustrated by the attention focused on cancer research. NCI, established in 1937, was the first institute of the U.S. Public Health Service to be devoted to a single disease. Initially a freestanding institute, it was incorporated into the National Institutes of Health (NIH) which was organized in the 1940's. In 1971, 34 years after NCI's establishment, an intensive effort was mounted in Congress to separate NCI from NIH and to establish a National Cancer Authority.

While the National Cancer Act of 1971 was unsuccessful in establishing a new authority, it elevated NCI to bureau status, a higher organizational level than any other institute at NIH until the National Heart, Lung, and Blood Institute (NHLBI) was also made a bureau. The act also resulted in remarkable growth at NCI (see addendum A).

This chapter was developed by a review of selected literature and through a number of telephone interviews of experts. The questions that were mailed to the experts and a list of the addressees are included as addenda B and C. OTA staff talked with 22 individuals on the list and to another group of about 15 experts who were suggested by those on the list.

Throughout this chapter, attribution to named individuals refers only to published papers or quotes from news sources. Information obtained during conversations with experts is so identified, but no specific attributions are made. Care has been taken to make plain those **cases** in which an opinion was heard from more than one person as opposed to only one person.

CANCER MORTALITY AND INCIDENCE

Nationwide mortality data are used to answer questions about the number of deaths caused by cancer in the United States. Without doubt, the number of Americans dying from cancer has increased during the last century. Paradoxically, a major part of this increase has resulted from improvements in public health and medical care. In years past, infectious diseases killed large numbers of people in infancy and during childhood. Now that advances in health care have softened the impact of those diseases, many more people live to old ages when cancer causes significant mortality.

Deaths from cancer are not evenly distributed among all body sites; the lung, colon, and breast account for over 40 percent of the total (see table 14). Discussion of cancer rates at particular body sites is more revealing than discussion of overall trends which mask changes at individual sites. Moreover, some cancer-causing substances act at specific sites, and more information about opportunities for prevention is obtained from the analysis of trends at particular sites. Likewise, survival rates and improvements in treatment vary at different anatomical sites.

The trend that has dominated all others over the past 50 years is the increase in lung cancer mortality, largely a result of the widespread adoption of cigarette smoking earlier in this century. Male lung cancer rates have been rising steadily for at least half a century. Female lung cancer rates started to rise about 25 years ago and are now increasing rapidly. All other changes are small in comparison with the large increases in smoking-related cancers, although the decreases in cancer of the stomach and uterus are also important.

Currently, there is a general tendency for the rates of change at each cancer site to be slightly more favorable for people under 65 than for those over *65:* If the site-specific rate for all ages is increasing, it is increasing at a slower pace among the younger group; if the rate is decreasing, the decrease is more pronounced in those under 65. Two clear exceptions stand out. First,

skin cancer is increasing much more rapidly among males under 65 than among those over 65. Second, mortality rates of brain tumors appear to be moving in opposite directions; despite falling death rates in middle age, there are large increases in old age, perhaps because of better diagnosis for older people which improves the efficiency of case reporting.

If attention is restricted to those younger than *65,* for almost all types of cancer except those strongly affected by smoking (cancers of the respiratory and upper digestive tracts), the most recent trends in mortality are downward. The chief exceptions are pancreatic cancer in women, and melanoma in whites of both sexes.

Incidence rates differ from mortality rates because not all people who contract cancer die of it. Rates are calculated by relating the number of cases or deaths to the "population at risk" of either contracting cancer or dying from the disease. "Crude rates" are the total number of cases or deaths divided by the total population. Crude rates are affected by changes in the age structure of the population, i.e., the fact that there are more older people in the population today, and hence more people contracting and dying of cancer, means that the crude rates will increase. All of the overall comparisons in this report are based on rates "age-standardized" to the composition of the population determined in the **1970** census. Changes in these rates occur because of changes in the risk of cancer among people of a given age; increases or decreases in the proportion of old people in the population do not affect age-standardized rates. When a figure or comparison refers to a specific age class, the rates are based on the cases or deaths as a proportion of the total number of people in that class.

Apart from whether or not cancer rates are changing, many variables contribute to the greater prominence accorded the disease today as compared to even a few decades ago. A major factor in its emergence is the sharp decrease in deaths from infectious diseases such as tuberculosis, dysentery, and diphtheria over the past 100 years. Before the mid-19th century, these diseases killed far more people than did chronic diseases. General improvements in living conditions, public sanitation, and nutrition **began to** reduce the rates of infectious diseases, and the decline was hastened by advances in biology and medicine early in the 20th century.

As the decades passed, these improvements have shifted the age structure of the population upward; as a result, there is a larger proportion of people over *65.* Cancer risks have always been 10 or 100 times greater among older people than among younger people. The change in age structure increases the actual number of cases and deaths (crude incidence and crude mortality) but not necessarily the age-standardized cancer rates.

Second, cancer has become *relatively* more common as a cause of death because of the prevention or cure of other diseases. This phenomenon is illustrated by the mortality data for females in 1935 and 1975 (see table 15). Nonrespiratory cancer death rates decreased substantially, but the death rates from all other causes decreased even more. Therefore, the percentage of female deaths attributable to nonrespiratory cancer was greater in 1975 than 40 years earlier, even though female nonrespiratory cancer deaths had declined during that period.

Third, many cancers, which might previously have gone unnoticed or unreported; are now

Table 15.—Death Rates per 1,000 Females, 1935 and 1975

Year	All causes except cancer	All nonrespiratory cancers	Respiratory tract cancers	All causes
1935 (1933-37)	11 .92[a] (87.6 %)b	1.65 (12.1 %)	0.03 (0.2%)	13,60 (100%)
1975 (1973-77')	4.96 (78.8%)	1.17 (18.6%)	0.16 (2.50/o)	6.29 (100%)

[a]All ages, age.standardized to the U S 1970 census Population
b p$_{ercentage}$ of rate for all causes

SOURCE. Off Ice of Technology Assessment, 1981.

diagnosed both during medical treatment and in death certification. This change is especially pronounced among the elderly who today receive more medical attention than in premedicare years.

Finally, cancer is discussed more openly in the media and among friends and relatives of cancer patients; public figures no longer try to conceal their diseases. Previously, such matters were often hushed up and the diagnosis perhaps withheld even from the victim. The jump in the reported incidence of breast cancer in 1974 and 1975 is attributed to the publicity surrounding Happy Rockefeller's and Betty Ford's breast cancer surgery. Greater public awareness led to more women being examined, the detection of more cancers, and more accurate reporting, but the reported increase in those years is not considered to reflect a real increase in incidence.

REDUCING CANCER'S IMPACT

There are three approaches to reducing cancer's impact: prevention, the ultimate goal; earlier detection; and improved treatment. The general consensus that most cancers are caused by extrinsic forces (86) has led to the view that many cancers are preventable. Estimates of theoretically preventable cancers have reached as high as 90 percent of the total, though the practical limits undoubtedly will be lower.

Once identified, exposures to carcinogens may be reduced either through voluntary or regulatory methods. There has been one notable success among efforts to influence personal behavior—the reduction in cigarette smoking among adults. The decrease is most notable among adult males, and can confidently be attributed to the publicity and attention given to adverse health effects of tobacco. Between *1965* and 1979, the proportion of adult male smokers dropped from 51 to 37 percent. The decline among women over the same period was much smaller, from 33 to 28 percent,

Antismoking efforts on the part of NCI and other organizations, notably the American Cancer Society, are considered partially successful. However, many people still smoke and smoking initiation rates may still be rising in teenage girls. A number of the people OTA spoke with, in basic and applied research and administration, expressed the opinion that, because this is one area in which there is virtually no serious disagreement about the cause of a major cancer, continued smoking is the greatest failure in cancer control.

It is generally believed that American eating habits are healthier than they were early in this century and that some of the changes, though not specifically identified, have spurred the decrease in stomach cancer rates. Future cancer-reducing changes in dietary habits may result from research into mechanisms by which dietary components cause or prevent cancers, or from epidemiologic observations of associations between dietary components and cancers.

In the last year, NCI approved its first large-scale "chemoprevention trial, " from the Division of Resources, Centers, and Community Activities (DRCCA), based on the hypothesis that beta-carotene, the precursor of vitamin A, reduces cancer rates for at least some sites. The study is being funded jointly by NCI and NHLBI, and will also test the effects of aspirin as a prophylaxis for heart disease.

Early detection of cancers may improve overall survival rates when efficacious treatment is available. Localized cancers detected before they metastasize can be excised completely, leaving the patient with an excellent chance for survival. The proportion of cancers detected at "early" v. "late" stages has increased over time. For example, between the early 1950's and the late 1960's, the proportion of prostate cancers diagnosed as "localized" increased from 48 to 63 percent. Over that period, the 5-year relative survival for prostate cancer climbed from 43 to 57 percent. The overall relative survival rate is the ratio of the observed survival rate of the treated group to the expected survival rate for persons of the

same age, sex, and race in the general population. Three elements may contribute to the apparent improvement. Part of the improvement may be artifactual and result from detecting and reporting less serious tumors in the late 1960's, that, had they occurred in the early 1950's, would not have been reported. Some of the improvement probably resulted from better treatment. However, a major component of the gain resulted from detection of tumors at earlier stages, when they could be more successfully treated *(61)*. The same pattern has occurred in some, though not all, body sites.

Surgery, radiation therapy, and chemotherapy are the mainstays of cancer treatment. There have been advances in all three areas. Refinements have been made in surgery and in radiation therapy as technologies have improved. There have been no quantum leaps in surgery and radiation therapy at least since the 1950's. This is not necessarily a criticism of NCI, but a sign that perhaps, particularly for surgery, there are diminishing returns in efforts to improve survival. In particular, disseminated cancers cannot be treated by excision of all tumor cells. Improved surgical procedures generally emphasize doing less surgery with no loss of survival benefit, a move toward improved quality of cancer treatment.

Some "quantum leaps" have been made in chemotherapy, and in terms of treatment, this area still holds the greatest potential, particularly in integrating chemotherapy, surgery, and radiation into better treatment regimens. Chemotherapy has had a major impact on Hodgkins and non-Hodgkins lymphomas, childhood leukemias, testicular cancers, and osteogenic sarcoma, and choriocarcinoma. There is evidence that, in coming years, survival for certain groups of breast cancer patients may be improved by the use of postsurgery chemotherapy.

Presently, NCI (19) estimates that 46,000 patients yearly are helped by chemotherapy. Scientifically and medically, the successes represent promising advances. With longer followup periods, more studies might indicate substantial gains. However, because many people who receive the drugs (which are often accompanied by undesirable side effects) experience no substantial gain in life expectancy, concern about the use of chemotherapy has developed in some parts of the medical profession and in the minds of the public.

YARDSTICKS FOR MEASURING THE SUCCESS OF CANCER RESEARCH

The Cancer Control Program at NCI is mandated by the National Cancer Act *(69)*. In addition to that program, the Cancer Centers Program and clinical trials of treatment regimens promote and facilitate technology transfer. The basic requirement of any technology transfer program is a scientific base of knowledge.

NCI research is directed at increasing knowledge about cancer; development, demonstration, and transfer activities, dependent on research, are aimed at reducing incidence and mortality.

Increases in Knowledge

In *1973,* an Institute of Medicine (IOM) committee (44) suggested that the following avenues of research were likely to be fruitful in the years ahead: "DNA replication, the cell cycle, regulation of transcription, regulation of membrane assembly and function, cell differentiation, regulation of protein synthesis, and all aspects of cellular immunity. "

The next paragraph cautioned, however, "The list should be regarded as flexible, subject to additions or changes depending on the progress of cancer biology itself. "

Nine years later, in 1982, a number of experts contacted by OTA suggested areas of research most likely to yield important results. Often mentioned were recombinant DNA research, hybridomas and monoclonal antibodies, and better methods for risk assessment. None of

these were listed by the IOM committee. Although the basic discoveries about recombinant DNA were published in 1971, their impact had not been fully appreciated in early 1973; hybridomas were simply unknown; monoclinal antibodies a hypothesis. Risk assessment was little discussed and of little perceived importance.

A decade ago, understanding of the possible mechanisms by which genes regulate and control cells and how cells synthesize gene products was based on elegant experiments in bacteria and the viruses that infect them. The last 10 years have seen that some of those ideas have much less application to human cells than was expected. Although some scientists have claimed that they had inklings of the extraordinary differences between production of gene products in bacteria and mammals, those claims are dismissed. The new ideas about mammalian cells were forced on scientists by experimental results. At the same time, without the bacterial models as a baseline, little progress would have been made in understanding mammalian cells. Several experts who talked with OTA emphasized the importance of NCI'S support of basic research, both intramural and extramural, in these discoveries.

These examples illustrate the impossibility of predicting the direction, results, and applicability of basic research. Basic knowledge about mechanisms important in cancer and in biology in general has increased greatly in the last decade, but the productive approaches of the last 10 years may not be the only ones to pay off in the years ahead.

There is no yardstick to hold up to basic research progress that is similar to the actuarial measurements of cancer incidence and mortality that are discussed below. The awards of Nobel Prizes and other trophies are in recognition of excellence, but they may come soon after or much after the important discoveries and they reward only a fraction of outstanding basic research. Scientists often describe progress in their own fields, but they face a difficult problem in conveying their excitement and approbation to more lay audiences. Experimental technicalities, laboratory jargon, arcane mathematical measures, immersion in a sea of details interfere with the expert's communication to others not so expert. (A refreshing contrast to those difficult-to-understand measures is provided by Lederberg (41). Even without these problems, some scientific concepts are difficult to understand. For many people, the most convincing evidence of the importance of basic biological research has been the formation of genetic engineering companies with large amounts of capital provided by financial organizations that have made a great deal of money in the past.

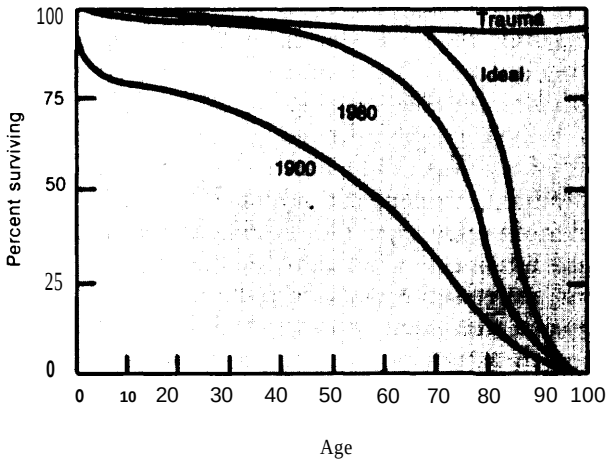
A measure of progress in basic research more directly related to cancer are the reports of experts who teach courses about cancer. The content of those courses has changed dramatically during the last decade. Such teachers rely on articles in recent scientific publications. Neither last year's notes nor textbooks are sufficiently current,

Reduced Mortality From Some Cancers

The ultimate desired effect of health research and development programs is longer lives and more disease-free years. Extending maximum human lifespans by many years seems unlikely, but extension of more people's lifespans to the biological limit seems attainable. The idea that humans' lifespans are fixed by some biological clock is discussed by Fries (22) and Fries and Crapo *(23).* Very, very few people live to ages much greater than 100; the percentage of centenarians in England's population has not increased since 1837 despite great changes in average life expectancy. Disappointingly, reports of people living to very great ages, 110 or more, are largely from less developed countries. The number of those reports varies directly with the illiteracy rate, and it is reasonable to conclude that these reports are the product of faulty recordkeeping.

Fries and his colleagues find that while there has been little change in the maximum expected lifespan, more and more people are living to or almost to what appears to be a maximum expected age (see fig. 3). The maximum expected age seems to be about 85, with a distribution of people dying within a few years of that age.

Figure 3.—Changes in the Percentage of People Living to Specified Ages, 1900 and 1980



The increasingly rectangular survival curve About 80 percent ( ) of the difference between the 1900 curve and the ideal curve ( ) had been eliminated by 1980. Trauma is now the dominant cause of death in early life.

SOURCE: Fries, 1980.

Cancer accounts for about 20 percent of U.S. mortality (86). Despite that large percentage, eliminating cancer as a cause of death would have only a small effect on the average U.S. lifespan, because cancer is largely a disease of advanced age. About 90 percent of cancer deaths occur in persons over 65. While average life expectancy might be little affected by preventing cancer deaths, preventing cancer at whatever age improves the quality of life.

OTA'S *Assessment of Technologies for Determining Cancer Risks From the Environment (86)* and Doll and Peto (20) discuss mortality rates from cancer. Significant decreases have been seen in mortality from some types of cancer—stomach, uterine cervix, lung cancer in men younger than *so* during the last two decades, and Hodgkin's disease, other lymphomas, and some childhood cancers.

The causes of the declines in the first two remain largely matters of speculation. Higher standards of living, more varied diets, and better food preservation techniques have been associated with decreases in stomach cancer mortality, which became noticeable in the 1930's and have continued. The downward trend in uterine cancer mortality over the past 50 years is a major factor contributing to the steady decrease in death rates from nonrespiratory cancers in females. Again, the causes are not clear, but improved personal hygiene associated with higher standards of living may be involved in the decrease. Decreases in uterine cancer mortality preceded the development and widespread introduction of cervical cytology screening for the disease by at least 25 years. The importance of the screens in the continuing decline is difficult to assess. In the case of stomach and uterine cancers, for poorly understood reasons, there have been decreases in incidence that are translated directly into decreased mortality.

The observed decreases in lung cancer incidence and mortality in young men are directly related to changes in smoking. Hodgkin's disease, other lymphomas, and some childhood cancers differ from the others; mortality from them has decreased because of better treatment and increased survival rates.

The examples of declining mortality from these cancers illustrate the two types of intervention that can reduce cancer mortality: reducing cancer incidence and improving treatment. The National Cancer Program Plan recognized the preferability of reducing incidence. Four of the seven objectives of the Plan focus on cancer cause and prevention (69).

Changes in Cancer Incidence

Recent years have seen much progress in identifying environmental agents and personal behaviors that are associated with higher cancer risks. A thorough examination of epidemiologic studies of the occurrence of cancer in the United States (20,86) reaffirms the impression of many experts that, to a major extent, we have only clues about what causes cancer. The few positive exceptions, in which causes are clearly identified, are relatively well known—smoking, exposure to asbestos, radiation, sunlight, some chemicals, and some drugs. More typical of our level of knowledge is the case of food. Through various methods, a number of different estimates have been made that suggest that as much as 50 percent of all cancer is associated with elements

in the diet. This observation provides a tantalizing lead for further study, but so far few specifics are known (20, 71,86). Finally, there are some cancers for which there are still no hypotheses about their causes.

As more specific knowledge is obtained and prevention activities are increased, measurements of their success in the general population will depend on obtaining reliable incidence data. Each new case of cancer, whether it is subsequently cured or results in death, is recorded in incidence data; mortality data record only deaths. As is described elsewhere (20,86), mortality data have been collected on a nationwide basis since 1933. No nationwide incidence data are collected. The NCI Surveillance, Epidemiology, and End Results (SEER) program now collects incidence data on about 10 percent of the U.S. population (see below).

Incidence data have been used in the recent past, 1980 and 1981, to support arguments that cancer is rapidly increasing in the U.S. population (112). The most recent summation of SEER data, released to the press in late 1981, does not support the idea of rapid increases in cancer occurrence at any major sites except lung.

Prevention, which precludes illness and the rigors associated with treatment, is highly desirable in cancer. Measuring the effects of prevention programs will require accurate, comparable incidence data collected from (probably) large segments of the population.

Changes in Survival

The third actuarial measure of success for the National Cancer Program are improvements in treating cancer as measured by more people surviving the disease. This measure, generally expressed as the percentage of newly diagnosed patients surviving years after treatment, after adjustment for "normal" life expectancy, is called "5-year survival rates." These data have taken on more importance with recent announcements of treatment success from NCI. The most recent report from NCI (19) depends on incidence data collected by the SEER program.

One of the seven objectives of the National Cancer Program (16,44,69) was directed at treatment. As this chapter discusses, and is commonly agreed, NCI has emphasized treatment and curing cancers. To a major extent, this emphasis is understandable, because it offers opportunities to help people in need of care now. At the time of the National Cancer Program Plan's development, therapeutic advances were in hand and more were expected *(28,64).* Exploitation of those advances is certainly justified, but questions are raised about the balance being struck between treatment research activities and other research activities at NCI. An additional, tiger by the tail, reason for the emphasis on treatment is congressional pressure. As NCI lauds its treatment advances, the public, through Congress, demands access to them. In response, NCI bends more effort to treatment research and cancer control.

Cancer Treatment and Curing Cancer

At the time the National Cancer Act was being considered in 1970, the National Panel of Consultants on the Conquest of Cancer reported (28, quoted in 66).

> The cure rate for cancer is gradually improving. In 1930 we were able to cure only about 1 case in 5; today we cure 1 case in 3; and it is estimated that the cure rate could be brought close to 1 case in 2 by a better application of knowledge which exists today, i.e., detection at an earlier stage through the more widespread use of existing techniques (such as the Papanicolaou test for women and mammography), coupled with an extension to all citizens of the same quality of diagnosis and treatment now available at the best treatment centers.

The last part of this quote touches directly on cancer control, which includes efforts to move the best treatment from specialized centers to all citizens. Increased survival rates are the expected results from such efforts, and, in fact, by all measures, survival has increased, albeit not so much as expected in 1970.

Some of the reported improvements in cancer treatment survival have stemmed from general improvements in radiotherapy and surgery in

the post-World War II years. Improved radiotherapy and surgical techniques, better aseptic procedures, antibiotics, and better postoperative and supportive care have contributed to the improving cure rates.

Beginning somewhat later, and well underway by the late 1960's, chemotherapy has brought significant improvements to the treatment of some cancers. From a compassionate standpoint, these improvements, which were and are especially pronounced in the treatment of childhood cancers, are gratifying.

The triad of cancer treatments is completed by radiation therapy. A recent survey (108) shows that the presence of a radiation therapy unit is the second most important factor (after having an American College of Surgeons-approved program) in determining the number of cancer cases treated by a hospital.

The most encouraging projection about cure rates has been made by the NCI Director (19). From examination of data collected through the SEER program, he concludes that during the period 1975 to 1979, 46 percent of diagnosed cancers among whites and 45 percent among all races were "cur able." A "more optimistic calculation from the same data results in a 50 percent 5-year survival for white patients and 49 percent for all races. " To date, the cure rate for specific sites has not been published. Furthermore, this is the first calculation of survival rates using SEER data, and the reported rates may not be directly comparable to data collected earlier under other systems.

The American College of Surgeons has collected information about cancer cure in community hospitals. Upon presentation of appropriate information about a hospital's cancer treatment program, the American College of Surgeons will approve the program, Approved programs are found more frequently in larger hospitals: 14 percent of all acute-care hospitals have approved programs, and those contain 32 percent of hospital beds (see table 16). The approved hospitals treat a disproportionate number of cancer cases: 60 percent of all newly diagnosed cases are treated in the 14 percent of hospitals with American College of Surgeons-approved programs.

Estimated 5-year survival rates *were* reported from four types of hospitals (see table 17), The rates for community and university hospitals are quite similar; lung cancer remains intractable to treatment, and its higher frequency in the Veterans Administration (VA) and military hospitals

Table 16.—Distribution of Commission on Cancer of the American College of Surgeons-Approved Hospital Cancer Programs According to the Size of Community Hospitals in the United States

Bed size of hospital	Number of hospitals in United States	Number of approved cancer programs
501 and over	385	216 (560/o)
301-500	717	317 (44%)
101-300	2,152	359 (16°/0)
Under 100	3,285	51 (>1%)
Totals	6,539	943 (14%)

SOURCE. Smart, 1981

Table 17.—Five-Year Estimated Survival Rates After Treatment of Cancer in Community, University, Veterans Administration and Military Hospitals, and Children's Hospitals

	Community	University	VA and military	Childrens
Number of hospitals	555 (840/o)	28 (4°/0)	67 (100%)	9 (2%)
Number of cancers	1,420,213 (820/o)	196,483 (11 °/0)	114,639 (7°/0)	14,292 (1 °/0)
5-year estimated survival	370/0	360/o	30 °/0	45%
Most frequent cancer sites:	Breast Lung Colorectal Prostate Cervix	Lung Breast Cervix Colorectal Lymphoma	Lung Head and neck Prostate Colorectal Bladder	Leukemia CNS Soft tissue Bone Kidney

SOURCE: Smart. 1981.

contributes to the lower survival rates in those institutions.

Overall survival rates from "cancer," which includes about 100 different diseases, are not so informative as rates from particular cancers. Smart (108) has compared 5-year survival rates found in whites by NCI in 1965-69 to those found in the American College of Surgeons' survey over the period 1973-79 (see table 18). Improvements are reported for each cancer. Smart cautions against too detailed comparisons between the two sets of data, because the data were collected using different systems during the two time periods. A more meaningful comparison can be drawn by examining survival data collected in a standard method by NCI during two different time periods. Inspection of those data (table 18) show improvements in survival from cancer at almost every site, in both races and sexes. Survival for Hodgkin's disease and acute lymphocytic leukemia have shown the greatest improvements, and stomach, pancreas, and lung the least. Further improvements can be expected when details of more recent data collected by the SEER program are published.

A decade after the estimate that 50 percent of cancers might be curable, the 5-year survival rate remains below that figure in the American

Table 18.-Comparison of Five-Year Relative Survival Rates From NCI Studies in 1960-63 and 1970-73

	White males		White females		Black males		Black females	
Cancer site	1960-1963	1970-1973	1960-1963	1970-1973	1960-1963	1970-1973	1960-1963	1970-1973
Stomach	10	12	13	14	5	15	14	10
Colon	42	47	44	50	32	36	35	38
Rectum	36	43	41	48	28	20	27	40
Pancreas	1	2	2	2	0	0	3	3
Lung	7	9	11	14	5	6	6	10
Melanoma	51	62	68	75	....			
Breast	—	—	63	68	—	—	46	51
Uterine cervix	—	—	58	64	—	—	47	61
Uterine corpus	—	—	73	81	—	—	31	44
Ovary	—	—	32	36	—	—	32	32
Prostate	50	63	—	—	35	55	—	—
Bladder	53	61	53	60	24	38	24	27
Hodgkin's disease	34	66	48	69	....			
Acute lymphocytic leukemia	4	27	3	29	....			

" Number of patients too small to yield reliable rates

SOURCE: National Cancer Institute, 1981

College of Surgeons' study (108). In fact, the one in three cure rate estimated in **1970** is close to that seen today in that review. NCI'S own estimate of cure rates is higher, 46 to 50 percent, and it approaches the goal of curing one case in two. It is likely that more cancers will be cured as improvements move from NCI to the community. Importantly, of course, within the limits of the improvements that have been made, lives have been spared and the side effects of treatment have been reduced. NCI has contributed to these important advances.

Several experts contacted by OTA suggested that adjuvant chemotherapy (drugs used in association with other treatments) has already contributed to improved cure rates, and more improvements are expected. Not unexpectedly, experts with a background in clinical research and applications expressed enthusiasm for curative changes and urged continued emphasis on clinical research. Other people caution that some of the reported improvements may be artifactual because of changes in reporting methods and that additional incremental improvements may be small.

The proper balance between treatment research and other research efforts is continuously debated. Whatever the proper balance, the impression left by the following sentence in the 1981 Director's Report (68) suggests that it has not yet been struck: "Mortality results not only from failure to treat adequately but also from failure to prevent disease. " Many observers would order the failures differently,

Surveillance, Epidemiology, and End Results Program

Measurements of cancer incidence and survival rates depend on data collected by the SEER program. SEER is the first nationally coordinated, continuous, population-based incidence registration system and was begun in 1973 by NCI. SEER is, in part, an expanded sequel to the successful End Results Program.

In SEER areas, attempts are made to ascertain every primary cancer, excluding nonmelanoma skin cancer. All information pertaining to a case is consolidated into one record to facilitate followup and to correlate survival data with treatment, age, and other variables.

SEER program data are collected from about 10 percent of the total population, but the geographical regions covered by the SEER program do not closely represent the demographic makeup of the entire country. A SEER report for the first 4 years of operation compared the demographic characteristics of the population with the total U.S. population (65):

> . . . the participants . . . are fairly representative with respect to age. Blacks are somewhat underrepresented, while other nonwhite populations (Chinese, Japanese, Hawaiians, and American Indians) are somewhat overrepresented. Rural populations (especially rural blacks) are also underrepresented.

The current SEER program costs about $10 million annually out of the total NCI budget of about $1 billion. Expanding the program to collect more representative data and to validate data more thoroughly would cost more money and would also require cooperation of additional local medical organizations to establish new SEER data collection areas. Balanced against these costs are opportunities to gather incidence and survival data representative of the whole country and to learn more about cancer in the U.S. population.

The two basic SEER program functions—collecting data on incidence and on mortality— are complementary, and baselines have been established for both measures. However, because the system is so young at this time, little can be said about trends in either.

The SEER program plays another important role in providing information on cancer cases to be used in epidemiologic case-control studies. The purpose of such studies is generally the identification of possible causative factors for a particular type of cancer. The largest cancer case-control study undertaken by the Federal Government, a study of about 3,000 of bladder cancer uses, relies on cases identified by SEER. Data

from the bladder cancer study are still being analyzed, but already the analysis has produced information of great value to cancer researchers involved in primary cancer prevention. Assembling the cases would have been more difficult and expensive if any other method had been used for case-finding.

TECHNOLOGY TRANSFER ACTIVITIES

Clinical Trials

Clinical trials in cancer research have been used mainly for testing anticancer drugs at varying dose levels and in various combinations. Multimodality studies, testing combinations of surgery, radiation therapy, and chemotherapy are also evaluated in clinical trials. Additionally, clinical trials have an important role in technology transfer; they demonstrate the usefulness of treatment regimens, and, increasingly, they involve community physicians in clinical research.

In cancer, perhaps more so than in other diseases, the results of chemotherapy are extremely variable. Patients with cancers at each stage—local, regional or advanced—of the approximately 100 types of cancer may react quite differently. This means that large numbers of patients are needed to get meaningful results in a treatment trial. A test of a promising therapy might require several hundred patients, which might require 2 to 4 years of recruitment, even with multi-institution cooperation. At least 4 to 5 years of followup are necessary before a reasonable evaluation can be made. Unfortunately, nothing can be done at this time to change those numbers. The nature of the disease, the state of the art of treatment, and statistical probability dictate the limits.

A trial as described above represents a large investment of money, and it does not promise any fast answers. A number of people expressed to OTA the notion that NCI has felt pressure to produce results in a short time and, perhaps as a result of that, some clinical trials funded either directly or indirectly by NCI are short-term, with few patients and with little chance of producing reliable results. These generally represent trials carried out in single institutions. Multi-institution trials generally have larger numbers of patients and go through the formal review process, and, overall, meet higher standards than single-institution trials.

In 1979, a subcommittee of the Board of Scientific Counselors of the Division of Cancer Treatment conducted a review of the large-scale cancer therapeutic Clinical Trials Program (67). The subcommittee found that, “While the clinical trials process has been good, the subcommittee is of the opinion that it can be further improved in preparation for the clinical cancer research era of the 1980’ s.” The subcommittee’s review resulted in four major recommendations (67):

1. We recommend that a new study section be established to review individual investigator initiated clinical cancer research.
2. In accord with federal guidelines, a cooperative agreement should be negotiated between the Division of Cancer Treatment (DCT), NCI and the Cooperative Oncology Groups.
3. We recommend that funds from the Cancer Control Program be transferred to DCT for cooperative group activities in support of groupwide Phase III protocols. . . . It is essential that the peer review process for award of Cancer Control funds be the same as that applied to the groups as a whole.
4. We recommend that DCT continue and increase its efforts toward information exchange on cancer therapy evaluation, It should be extended so that it includes more input and return to participants in clinical program projects (PO1’S) as well as to the cooperative clinical trials groups. . . . we recommend that additional government positions be created in DCT to permit expansion of the Cancer Therapy Evaluation Program.

Each of these four recommendations was addressed by DCT in their September 1980 document, “Future Direction in Extramural Clinical Trials.” The responses to each are summarized as follows (66):

1. The Division of Research Grants (DRG) set up a series of ad hoc study sections to review clinical research proposals. At the time of the response, NCI'S policy was that, "If the results of this experimental group study section are satisfactory, a permanent study section will be considered by DRG." According to recent information from NCI, * "Data accumulated in the course of four such ad hoc reviews of RO1 applications for support of clinical research projects suggested that these 'clinically oriented' review groups disapproved somewhat more proposals and voted, on the average, somewhat higher (worse) priority scores than had been observed when a similar body of applications were reviewed by the most appropriate chartered DRG study section. "
2. "DCT plans to convert the cooperative group program (RO1 grants), the Lung Cancer Study Group (contract), the Gastrointestinal Tumor Study Group (contract), the Brain Tumor Study Group (contract), the Melanoma Tumor Study Group (contract), the Head and Neck Cancer Study Group (contract), and the Parenteral Nutrition contracts, Phase II GI contracts, Large Bowel contracts, and the Breast contracts to the cooperative agreement mechanism. These conversions will be implemented within the next year . . . . All clinical trials research supported under cooperative agreements will be reviewed by a single type of review body. " According to recent information from NCI, * the plan currently underway involves the formation of review branch, "the specific function of which will be to assess the scientific merit of applications of this type requesting support of clinical cooperative groups."
3. "Plans for redistribution of control moneys are being actively discussed with the DRCCA."
4. "Expansion of the Cancer Therapy Evaluation Program (CTEP) staff is being evaluated at present. Funding and position constraints will require careful consideration in making decisions regarding CTEP staff size. "

*NCI, persona] communication, Mar. 10, 1982.

The move to convert most clinical trial research to the cooperative agreement mechanism appears to be the most significant change to come from this review and DCT response. NCI is in the process of converting the currently grant-supported clinical cooperative groups to the cooperative agreement mechanism, after which the contract-supported research will be converted. NCI sees several advantages to this mechanism, relating basically to increased input into and control of clinical trials research, The cooperative agreement mechanism as defined in the 1977 Federal Grant and Cooperative Agreement Act is appropriate for funding trials, because "the purpose of the relationship is the same as that of a grant, but the Federal Government anticipates substantial involvement with the recipient during the course of the activity" (66).

The main difference for current grantees is that the terms of the cooperative agreements award will specify "substantial Government involvement, " which is absent from grant awards. For current contractors, the application and funding process will change, and "scientific and administrative direction by NCI staff for these groups will be diminished" (66). Some of the specific terms of "substantial Government involvement" include increased participation in protocol design, protocol review, quality control, data management, the right to terminate a study, and an increased role in investigational drug management.

NCI states that "both contractors and grantees should have to make only minimal adjustments in their current operating procedures" as a result of the conversion to cooperative agreements, and that the conversion simply makes formal a relationship that already exists (66). The conversion has not gone as expeditiously as expected, however, and agreements may not have been worked out with all of the cooperative groups. One of the people with whom OTA spoke expressed concern over increased control by NCI over clinical research, particularly the provision that NCI retain the right to terminate a trial.

That decision, he said, should be made by the investigators. A number of other points of concern about clinical trials were expressed by the individuals with whom OTA spoke; these are described in the remainder of this section.

Many cancer clinical trials are carried out in single institutions with fewer than so patients, and many are not randomized trials. An added concern with small single-institution studies is that there may be insufficient review of the study protocol or the data analysis. Unless the institution has a data collection system in place, data management may be poor, leading to a poor analysis. These concerns are particularly directed at trials funded only indirectly by NCI, for example, through clinical centers, in which case the study protocol need not have gone through peer review. Nevertheless, NCI has direct involvement in most trials, at least in supplying the necessary drugs.

The opinion was expressed about clinical trials, as about other aspects of NCI-supported research, that funding reviews occur at too short intervals. The cooperative groups have been reviewed every 3 years or so, barely the recruitment period of a medium to large clinical trial. The quest for results in a short time has not been reconciled with the nature of the disease, in which meaningful results can only be measured over the long term.

It is estimated that between 6,000 and 10,000 clinical trials are currently being carried out worldwide, most including a small number of patients. Statistical analysis shows that several hundred trials that are in truth negative will appear to be positive based on probability alone (120). It is impossible in these cases to distinguish between a true positive and a false positive. Because clinical trials in cancer have a fairly low probability of success to begin with, we may in fact be overwhelmed by false positives, but there is no way of knowing this. One step that could be taken to remedy this is to carry out confirmatory studies for therapies that are positive in one clinical trial, One of the experts with whom OTA spoke criticized NCI for giving low priority to funding such studies because they are considered to be duplicative. In light of the admittedly low payoff of most cancer clinical trials, and the importance of introducing only beneficial therapies into practice, this policy might be reexamined.

NCI has recognized the need for large-scale trials for many years and has made improvements in facilitating them. Funding of the Cooperative Oncology Groups Outreach Program was a step forward in getting the community hospitals involved, and the incipient Community Clinical Oncology Program (CCOP) is another (see below). However, the problem is far from solved. At any time, there will undoubtedly be a number of trials going on of treatment of any given type of cancer “competing” for patients. One NCI official said that NCI has failed to act toward supporting the truly high-priority trials. He felt that NCI could be more intrusive in channeling patients nationwide into such studies. This may not be welcomed by all members of the clinical research community, however, who feel that grant-supported investigators should be more and not less free of NCI control.

A shortcoming of some clinical research in cancer today is the lack of biological basis for carrying out studies. Often, a clinical trial is just another combination of existing therapies, or a new dose level, and the only outcome measured is the effect on the tumor. This is, of course, the ultimate measure, and no trial should be conducted if there is no hope of affecting the state of the cancer. But clinical research can also be used to learn more about disease processes, the interactions between the rest of the patient’s body and cancer, and the effects of therapy aside from anticancer activity. This is an area where several of the people with whom OTA spoke noted a lack of communication and coordination between basic and clinical researchers. If much more were known about the cancer process, and if treatment were at a more sophisticated stage, this might not be as important. As it stands, there is much that can be gained in the more basic research area through collaborative efforts with clinical researchers.

Centers Program

Since the early 1960's, NCI has conducted a Cancer Centers Program to provide grants for support of multidisciplinary programs in cancer research at educational and research institutions in the United States. Enactment of the National Cancer Act of 1971 marked the beginning of a period of rapid growth of the Cancer Centers Program. In addition to an increased number of centers, there has been a concomitant growth in their size and complexity, expansion of their research programs and activities, and augmentation of their professional staffs.

Cancer centers have developed in a number of different organizational settings: Some are independent, freestanding institutional entities; other are under the auspices of universities, often involving several colleges; and still others are consortia or multi-institutional in nature. Although a cancer center needs a certain minimum number of research programs for a "critical mass, " existing centers vary greatly in size and breadth of programs—from rather small, specialized centers to large, complex comprehensive centers. They have developed from existing areas of strength at the parent institutions into coordinated multidisciplinary programs of several types (62):

1. Laboratory Cancer Research Centers (LCRC)–centers engaged only in labatory research;
2. Clinical Cancer Research Centers (CCRC) —centers engaged only in clinical research; and
3. Cancer Research Centers (CRC)—centers engaged in both laboratory and clinical research.

In addition, a CRC with a funded Cancer Center Support Grant (CCSG) may apply to NCI for recognition as a Comprehensive Cancer Center. Such recognition may be granted by the Director of NCI if evaluation of the center demonstrates compliance with the guidelines for recognition of a cancer center as comprehensive. These guidelines were established by NCAB and were revised by the Board in 1979 (see addendum D). In fiscal year 1981, there were 20 Comprehensive Cancer Centers, 23 CCRCs, and 18 LCRCs (see table 19).

Cancer centers depend heavily on NCI for research and operational support funds. NCI contributes an average of 77 percent of total external support funds. Other NIH programs provide an additional 11 percent. The total NIH contribution is therefore 88 percent of all external financial support. The remaining 12 percent derives from other Federal, public, and private sources. Any changes in the NCI budget appropriation and its apportionment can be expected to have a significant impact on the centers' research and operational stability.

A number of areas of concern have been identified in the past regarding the centers program, directed mainly at the comprehensive centers and how well they carry out their role. From the beginning, the centers have been individualistic in organization and in their relation with the community. All were respected institutions in cancer research already, all with strengths and weaknesses in various areas. It is obviously advantageous for such institutions to be recognized by NCI, both financially and in terms of prestige, but the institutions did not rework themselves into a uniform mold, nor was that ever the intent of NCI. It does mean that criteria for naming and evaluating comprehensive cancer centers are fairly general, though specific requirements can be included.

Centers vary greatly in the degree of integration of basic and clinical research, though that link appears to be weak in some centers. The degree to which centers serve as focal points for the community or region also varies, but some are have a great deal of community involvement.

A longstanding criticism of the program is the lack of geographic coverage of the centers. One of the guidelines for comprehensive centers is "geographic impact. " A comprehensive center "should increase the national capabilit, to carry out regional trials, regional training, education and information dissemination activities. " There are, however, two comprehensive centers each in Los Angeles and New York, and it appears that "scientific excellence" overrides concerns of geographic distribution. One NCI official ex-

Table 19.—Cancer Centers

comprehensive cancer centers	Clinical cancer Centers	Nonclinical cancer centers
Comprehensive Cancer Center University of Alabama at Birmingham	University of Arizona Cancer Center Tucson, Ariz.	Stanford University Medical Center Stanford, Calif.
Kenneth Norris, Jr., Cancer Research Institute University of Southern California Los Angeles, Calif.	University of California at San Diego La Jolla, Calif.	University of California Berkeley, Calif.
UCLA Jonsson Comprehensive Cancer Center UCLA School of Medicine Los Angeles, Calif.	Northern California Cancer Program Palo Alto, Calif.	City of Hope National Medical Canter Duarte, Calif.
Colorado Regional Cancer canter, Inc.* Denver. Colo.	Cancer Center of Hawaii University of Hawaii at Manoa Honolulu, Hawaii	Scripps Clinic and Research foundation La Jolla, Calif.
Yale University Comprehensive Cancer Center New Haven, Corm	Ephraim McDowell Community Cancer Network, Inc. Lexington, Ky.	Armand Hammer Center for Cancer Biology The Salk Institute La Jolla, Calif.
Georgetown University/Howard University Comprehensive Cancer Center	Hubert G. Humphrey Cancer Research Center Boston University School of Medicine Boston, Mass.	Purdue Cancer Center Purdue University West Lafayette, Ind.
Vincent T Lombardi Cancer Research Center Georgetown University Medical Center Washington, DC.	Cancer Center, Tufts-New England Medical Canter Boston, Mass.	Worcester Foundation for Experimental Biology, Inc. Shrewsbury, Mass
Howard University Cancer Research Center College of Medicine Washington, D.C.	Norris Cotton Cancer Canter Dartmouth-Hitchcock Medical Center Hanover, NH.	Center for Basic Cancer Research Washington University School of Medicine St. Louis, Mo.
Comprehensive Cancer Center for the State of Florida University of Miami School of Medicine/ Jackson Memorial Medical Center Miami, Fla.	Cancer Research and Treatment Center University of New Mexico Albuquerque, N.M.	St. Louis University St Louis, Mo.
Illinois Cancer Council		
Northwestern University Cancer Center Chicago, Ill.	Cancer Research Center Albert Einstein College of Medicine Bronx. N Y	New York University Medical Center Institute of Environmental Medicine New York, N Y
University of Chicago Cancer Research Center Chicago, Ill.		
Johns Hopkins Oncology Center Baltimore, Md.	Hospital for Joint Diseases and Medical Center New York, N.Y.	American Health Foundation New York, N Y
Sidney Farber Cancer Institute Boston, Mass.	Mount Sinai School of Medicine New York, N.Y.	Grace Cancer Drug Center Buffalo, N.Y.
Comprehensive Cancer Center of Metropolitan Detroit Detroit, Mich.	New York University Medical Center New York, N.Y.	Case Western Reserve University Cleveiand, Ohio
Mayo Comprehensive Cancer Center Rochester, Minn.	University of Rochester Cancer Center Rochester, N Y	The Pennsylvania State University, College of Medicine Hershey, Pa.
Sloan. Kettering Institute for Cancer Research/Memorial Sloan-Kettering Cancer Canter	Cancer Research Center, University of North Carolina Chapel Hill, N C	The Wistar Institute of Anatomy and Biology Philadelphia, Pa
Roswell Park Memorial Institute Buffalo, N.Y	Oncology Research Center Bowman Gray School of Medicine Winston Salem, N C	Fels Research Institute Temple University Medical School Philadelphia, Pa.
Columbia University, Cancer Research Center, College of Physicians and Surgeons New York, N.Y.	Puerto Rico Cancer Center University of Puerto Rico, Medical Sciences Campus San Juan, P R	The University of Wisconsin, McArdle Laboratories Madison, Wis.
Comprehensive Cancer Center Duke University Medical Center Durham, NC	Roger Williams General Hospital Providence, R.I.	
The Ohio State University Comprehensive Cancer Center Columbus, Ohio	Memphis Regional Cancer Center Memphis, Term	
University of Pennsylvania Comprehensive Cancer Center		
Institute for Cancer Research Fox Chase, Pa.	St. Jude Children's Research Hospital Memphis, Term.	
University of Pennsylvania Cancer Center Philadelphia, Pa,	The University of Texas Medical Branch Hospitals Galveston, Tex.	
The University of Texas System Cancer Center M.D. Anderson Hospital and Tumor Institute Houston, Tex.	MCV/VCU Cancer Center, Medical College of Virginia Richmond, Va.	
Fred Hutchinson Cancer Research Center Seattle, Wash	Vermont Regional Cancer Center, University of Vermont Burlington, Vt.	
The University of Wisconsin, Clinical Cancer Center Madison, Wis.	Milwaukee Children's Hospital Milwaukee, Wis.	

*Although this center does not have a current core grant, it is a recognized NCI Comprehensive Cancer Center

SOURCE: National Cancer Institute, 1981.

plained that it was never the intent of the program to achieve geographic distribution of centers. It is understandable that there are no centers in areas where there are few large teaching or research medical institutions, but it appears that there is substantial overlap in populations served. The new CCOP program is intended to reach into the community with importance given to geographic spread, according an NCI official.

A number of experts contacted by OTA mentioned that the appearance of almost 2,800 oncologists and more than *3,000* oncology nurses in the past decade has been instrumental in improving care for cancer patients. Part of the expansion in the pool of well-qualified health professionals in this area is credited to the interest developed in cancer as a result of the National Cancer Program. In particular, the cancer centers are credited with having made major contributions to professional training.

> . . . even under the limited mandate of Cancer Control, providing for research and demonstration but not for health care, the program presents great opportunities for the NCPP [National Cancer Program. Plan]. Thus, improvements in today's methods for the education and training of all the health professionals in the cancer fields, technicians, nurses, and physicians, would inevitably result in an upgrading of the quality of cancer care.
>
> If, as an early outcome of the NCPP, the country were to be provided with significant numbers of health professionals, trained in the use of specialized techniques and facilities, this would surely be recognized as a valuable product, solid and highly visible (44).

Centralized Cancer Patient Data System

The Centralized Cancer Patient Data System (CCPDS) began in 1977. The system is addressed at developing a uniform data system in the Comprehensive Cancer Centers. At this time all 20 Comprehensive Cancer Centers have been awarded grants to participate.

Under this system, 38 items of information are collected on each patient meeting certain criteria and reported to the Statistical Analysis and Quality Control (SAQC) center in Seattle, Wash. SAQC maintains the system, analyzes the data and acts as the coordinator for research activities involving CCPDS. Approximately 50,000 new cases are registered annually at SAQC (62).

Two basic goals of the system were to ensure that the comprehensive cancer centers used uniform language and procedures in naming and staging cancers and to develop a resource for cooperative research projects, drawing from all the centers. The first goal apparently has been achieved. Toward the second, a number of projects are in various stages of planning, using the system as a source of cases for case-control studies and studies of rare cancers.

The analyses produced by SAQC will deal mainly with survival of patients with various forms of cancer, representing those receiving the most sophisticated treatment in the country. The other major system for survival statistics, the SEER program (see above), differs in that it theoretically represents the survival of all cancer patients, including those treated in all types of facilities.

The question that arises is whether enough new information is gained from CCPDS to justify its existence. The improvements in statistical capability in the centers and the uniformity of language are undoubtedly of value. The aspects that might be seriously questioned are the emphasis on survival rates and the usefulness of a centralized system for carrying out research. NCI is conducting a concept review of CCPDS in the spring of 1982, to be carried out by an outside ad hoc committee. The committee will make recommendations for the future of the system at that time.

The Cancer Control Program

At the time of the passage of the National Cancer Act, "the scientific community and the Congress thought . . . that many research advances existed which could affect cancer, but these advances were not being disseminated and used. The cancer control program was intended to bridge this gap. " (28).

The act directed that NCI was to establish programs with State and other health agencies

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that were to demonstrate the best methods to apply the most recent advances in diagnosis, treatment, and prevention. The control program was not to perform research to develop new knowledge in those fields; rather it was to develop means for application.

In 1974 and 1978, the act was amended, and Congress mandated that NCI conduct cancer control programs aimed at diagnosing uterine cancer (by use of the "Pap" test). Other specific diagnostic programs—breast and oral examinations—were also mentioned in the legislative history that accompanied the act. NCI has since then carried out some demonstration projects dealing with these subjects. A massive Pap test demonstration was found to have missed its objectives and to have been poorly managed by NCI (28).

The cancer control program was administered from the NCI Director's Office until September 1974, when it was moved to the newly formed Division of Cancer Control and Rehabilitation. In *1980,* an NCI reorganization formed the Division of Resources, Centers, and Community Activities (DRCCA), and cancer control was placed within it. This recent organization brought to the division all NCI programs connected with control and technology transfer. From *1976* through 1980, $302 million were allocated to the cancer control program as a line item in the NCI budget. More than two-thirds of that amount has been obligated for contracts.

GAO Review of the Program

A GAO audit (28) of three completed cancer control contracts found that many specified tasks were never accomplished. GAO found, to some extent, that a shortage of NCI staff had contributed to poor contract supervision and the subsequent failure of the contracts to reach their goals. Beyond the staff shortage, GAO found that poor cooperation among NCI staff and poor management contributed to the failures of the contracts.

Two contracts reviewed by GAO were to provide assistance to populations of workers who had been expected to develop a large number of tumors because of workplace exposures. In both those cases, so few tumors developed that there was no point to the demonstrations. It might be that more attention to the planning of those studies would have revealed the likelihood of there being too few tumors, and the expense of setting up the demonstrations could have been avoided.

The GAO audit (28) interviewed a number of "NCI officials and current and past advisors to the control program . . . . the individuals said this assumption [that medical advances in cancer were slow to get into practice] proved to be incorrect because few cancer advances existed that the medical community was not using. " Despite that conclusion, four out of five advisors expressed opinions that the program in some form ought to be continued.

An NCI official, interviewed by OTA as part of this study, said that the cancer control programs in the 1970's had not been very good. They were, he said, motivated by a desire to do good things in the community. However, they lacked detailed planning, reachable objectives, and evaluation. The official is confident that recent initiatives (such as the Community Clinical Oncology Program (CCOP), see below) will improve the performance of the cancer control activities.

A Critical View of the Cancer Control Program in Contrast to the Success of Cancer Control

The value of NCI programs in cancer control projects is dismissed in an article by Yarbro that points to major improvements in the treatment of cancer in the community (119).

> Let's go back to square one for a moment . . . to what everyone already knows. Research is finding out which treatment is best: Control is making that treatment available. Now, I submit that we and the NCI know a great deal about cancer research, but precious little about cancer control. . . . Why?
>
> To explore the answer to that question, let me present you with a paradox: The Cancer Control Program of the NCI has been a dismal failure, and yet, the quality of cancer care at the community level has improved in quantum leaps every year. How can a program so gener-

> ally agreed to be such a disaster have succeeded so magnificently? The answer, of course, is that what we defined and funded as cancer control had nothing at all to do with the remarkable progress in cancer care at the community level.

Yarbro goes on to say that great improvements in the community have occurred in facilities, personnel, and treatment protocols (119). He says that better facilities have come from "hospitals and doctors . . . competing with each other to provide the best. " This was "competitive cancer control, " he says, neither planned nor NCI-funded.

According to Yarbro, "We now have more than enough oncologists in practice and in the pipeline to serve cancer patients for years to come. " NCI training programs have contributed to this supply, but they are fading because of funding cutbacks. However, the university need for trainees ("the ones to do all the work") ensures the continued production of trained personnel. Finally, Yarbro concludes (119):

> So much for facilities and personnel. What about new treatment protocols? Surely we need special people (at Federal expense) to carry these from the university centers to community hospitals! Here I am forced to admit that the Federal government has been heavily involved. It does pay such people. They are called postmen and they deliver medical journals. With few exceptions, new treatment protocols enter community use when oncologists read journals or attend meetings. This is *self-education* cancer control!

Yarbro is positive about enlisting community physicians in clinical trial programs. It will, he says, facilitate movement of new therapies to the community which will benefit patients. At the same time, it will "unleash the awesome power of the private practice sector in clinical research. "

In addition to the involvement of community physicians in clinical trials, Yarbro sees a need for some demonstration projects. The widespread distribution of "hospital cancer programs with (tumor) registries, tumor boards, and guidelines" should be a goal for the 1980's. He sees demonstrations of workable methods to reach that goal as worthwhile projects for cancer control.

Yarbro's opinions represent an extreme, but they illustrate questioning of the basic tenet of the cancer control program. Is there a lag in transfer of research information to the community setting? Any answer to that question is likely to be qualified. GAO interviews with NCI officials and advisors were almost consistent in saying that cancer control programs may have accelerated the transfer, but that transfer would have occurred, perhaps more slowly, in their absence (28).

Opposing Views About Technology Transfer

Sharply differing opinions about cancer control were voiced during hearings of the Investigations and General Oversight Subcommittee of the Senate Committee on Labor and Human Resources on May 21, 1981 (9). Some witnesses said that publication of research findings does not constitute effective communication of information and that NCI needed to develop better means for technology transfer.

Also discussed at those hearings was the role of clinical trials in technology transfer (9). Methodist Hospital, Indianapolis, Ind., therapist William Dugan said that it would be "inappropriate to substitute clinical trials for cancer control. "

An opposing view was expressed by Harold Amos, a member of the President's Cancer Panel and NCAB (9). Amos said, "Clinical trials are technology transfer. " The establishment of research advances "as clinical practice throughout the land, admittedly of utmost importance, must be the task of some other network already in place." Amos viewed suggestions for increased emphasis on technology transfer "as a threat to divert NCI from the one thing it was created to do and can do admirably, i.e., conduct and develop programs in research into the etiology, diagnosis, prevention, and treatment of cancer. In that role its resources are already overtaxed. "

These differences illustrate the varied positions taken on the subject of technology transfer. There is no doubt that research advances

need to be applied, but there is disagreement about whether or not special methods are necessary to transfer those advances. Beyond that, if methods are needed, there is another question about whether NCI or some other organization is appropriate to manage the transfer.

Goals of the NCI Cancer Control Program

In 1979, NCI described he cancer control program as focused on (28):

- identifying, evaluating, and planning the application of innovative, practical methods of cancer control;
- developing demonstration programs to promote the use of effective cancer control methods by the Nation's health professionals;
- developing training resources for educating health professionals in the use of cancer control interventions;
- developing methods of encouraging beneficial attitudes and lifestyles as they relate to the control of cancer with emphasis on hard-to-reach populations, such as minority groups and blue collar workers;
- providing mechanisms for organizing the Nation's resources for an effective, coordinated attack on specific cancer control problems.

Early in 1982, major attention had been focused on CCOP that will involve community physicians in trials of new treatment protocols. This program, described below, is an example of attention to the second goal in the list above.

NCI is also planning to emphasize education about workplace exposures that have been associated with cancer. In the past few years, NCI has had an interagency agreement with the Occupational Safety and Health Administration (OSHA) for its New Directions Program. That program funded cancer-related educational efforts by employers, employees, unions, and academic institutions to improve workplace health and safety. During 1981, OSHA eliminated its peer review of New Directions grants, and NCI has decided to fund a limited, similar program. It is now considering different methods to reach the groups described in the fourth goal above.

Community Outreach and Rehabilitation Branch Activities

The Community Outreach and Rehabilitation Branch supports programs designed to (62):

- increase the transfer of cancer management technology from research centers to the community;
- develop effective cancer management capabilities within the community;
- continue the development of rehabilitation devices and strategies;
- develop new approaches to the management of pain associated with cancer; and
- study the problem of optimal care for the terminally ill cancer patient.

The Community Outreach and Rehabilitation Branch supports the following programs, which are described in the sections below (62):

1. Clinical Cooperative Group Programs.
2. Clinical Oncology Programs.
3. Community Hospital Oncology Programs.
4. Community Clinical Oncology Programs.
5. Rehabilitation Program.
6. Pain Programs,
7. Hospice Program,

Clinical Cooperative Group Programs

According to NCI (62):

> The reduction of cancer morbidity and mortality in the community setting is the goal of the Cooperative Group Outreach Programs. The objectives of these programs are to upgrade the skills of community physicians and other health professionals in the management of cancer patients and to increase the number of these patients receiving the best available care.
>
> The objectives are being fulfilled by the mechanisms of increasing the number of community hospitals affiliated with the cooperative groups, expanding the groups' referral networks, providing support services to the community hospitals, and developing a broad range of profes-

sional educational programs at both national and regional meetings and workshops.

The involvement of community hospitals with these groups, originally comprised of university hospitals and other major cancer centers, is a recent phenomenon (see Eastern Cooperative Oncology Group Community Hospital Program, below). In 1980, six cooperative groups had outreach activities supported by either a grant or contract.

ECOG Community Hospital Program.—The Eastern Cooperative Oncology Group (ECOG) Community Hospital Program is discussed as a specific example of technology transfer activities. In the early 1970's, in large part as a result of the success of NCI-funded training programs, a growing number of cancer patients were being treated by trained oncologists in community hospitals, as opposed to being treated in major teaching or research hospitals. Recognizing this trend and the importance of involving community hospitals in the cancer control effort, one of the NCI-funded Cooperative Groups, ECOG, applied for funds to be used for supporting the participation of community hospitals in clinical trials. The application was rejected on grounds that community hospitals should not be participating in clinical trial research. However, the next year NCI initiated a program to allow for just such involvement of community hospitals, and in October 1976, NCI awarded funds to ECOG to begin the ECOG Community Hospital Programs.

The first 5 years of the ECOG Community Hospital Program have been a great success in the participation of community hospitals and in the quality of data they have submitted (s). At present, 112 community hospitals are participating, having enrolled in protocol studies over 5,000 patients in 5 years, now averaging well over 1,200 patients per year. Perhaps more important, the quality of participation in ECOG clinical trials and the patient outcomes in community hospitals were no different than those for member institutions. The success of the ECOG program has been one factor in encouraging NCI to embark on CCOP.

An individual associated with ECOG expressed great dissatisfaction with NCI involvement in the Community Hospital Program. There was resistance to the program at a time when it was obvious to the ECOG people that the community should have been involved. There seems to be little doubt that ECOG has taken a successful approach to involving community hospitals in clinical trials (6), and the approach has also worked for some other cooperative groups. NCI is planning to make a very large investment in CCOP, a program that many see as competing with the ECOG type programs, and which will be organized in a manner quite opposite to them. In CCOP, the community hospitals (or consortia) will apply directly to NCI, and it will be each hospital's (or consortia's) responsibility to find a research base with which to affiliate. Financial incentives and autonomy for the community hospitals may be greater in CCOP than through the cooperative groups, and the possibility exists that the cooperative groups may be irreparably damaged. The request for applications (RFA) for CCOP has not yet been released, and the criteria for awards are not yet fully known, so these potential problems may be ironed out before the program gets underway.

Clinical Oncology Programs

Community hospitals or consortia of hospitals were funded under the Clinical Oncology Program (COP) to demonstrate that effective multidisciplinary diagnosis, treatment and rehabilitation services can be provided to patients in community setting, through small cost-sharing contracts. Criteria against which community participation are measured are (62):

- involvement of physicians, nurses, and other allied health professionals in initial planning of a community treatment and referral system for the patient;
- participation of physicians and allied health professions in designing multidisciplinary guidelines for patient treatment, nursing care, rehabilitation and terminal care;
- funding and direction of the cancer programs by a locally accepted hospital or fiscal agent of the regional consortia;

- practical relationships concerning patient treatment that can be developed with regionally appropriate universities or comprehensive cancer centers; and
- leadership, in the form of an individual or group that can motivate a community to cooperate for the benefit of the cancer patient and family.

Five COPS have completed 3 years of implementation. The final contract year has been devoted to evaluation with support for operational aspects of the program assumed by the community. Analysts of the experiences of the pilot COPS resulted in a model approach to the development of Community Hospital Oncology Programs (CHOPS).

Community Hospital Oncology Programs

According to NCI (62):

Twenty-three contracts have been awarded to field test (in single institutions, community consortia of institutions, and rural institutions) a model approach to development of a community cancer program.

The purpose of these CHOPS is to provide evidence that implementation of the COP model in a community will improve the scope and quality of cancer care for cancer patients over that received prior to development of the program.

In the development and implementation of each program, the cooperating hospitals and health care professionals will:

- define criteria for cancer patient care through the development of management guidelines;
- plan and implement a program to encourage community cancer care practices in accordance with these criteria for care;
- use a data management system (e. g., through upgraded tumor registries) to assess the extent to which community cancer care practices correspond to the recommended criteria; and
- use the information obtained to correct, modify, and improve the clinical oncology program and to document effective changes in community cancer care.

The **23** CHOP contractors are in an 18-month planning phase. Contractors submitting satisfactory implementation plans will be eligible for a further two-year implementation contract.

Implementation and evaluation plans resulting from the first 12 months planning activities have been submitted as proposals for peer review.

Community Clinical Oncology Program

The NCI Director has put a high priority on funding CCOP, a new program designed to involve small community hospitals and community oncologists in NCI-sponsored clinical trials. NCI will provide resources for the hospitals to join forces with large institutions already involved in NCI-supported research. Through this arrangement, a technology flow from NCI to the community will be established.

The impetus to initiate CCOP came, in part, from a directive of Senator Hawkins asking NCI to upgrade the quality of cancer treatment in community hospitals. The program was "concept-approved" in the fall 1981 and an RFA was prepared. The RFA was scheduled for release in April 1982, but NCAB at its February 1982 meeting expressed interest in knowing the contents of the RFA before release. An NCAB subcommittee reviewed a letter from NCI that describes the contents of the RFA in early March 1982. The subcommittee has decided to review the CCOP concept and plan and report to the full NCAB in May.

Up to 200 CCOP units are expected to be funded initially. Estimates of the number of applications expected range from 100 to 1,000. Geographical distribution will be considered among other factors in making decisions about where to fund units.

Rehabilitation Program

According to NCI (62):

This program seeks to reduce the morbidity from cancer and its treatment through stimulating study, demonstration, and research in new techniques of rehabilitation that have specific applicability to the physical, cosmetic, and functional problems associated with cancer.

The comprehensive nature of cancer rehabilitation determines support for a variety of projects that seeks to achieve the cancer patients' early adjustment and re-entry into the everyday

world of work, social activity, and physical functioning.

The rehabilitation program supports 21 grants which presently investigate six major areas of cancer rehabilitation, and four contracts to support training for dental personnel interested in pursuing postsurgical restorations for cancer patients.

Pain Programs

NCI states (62):

Pain is one of the most feared consequences of cancer. Severe pain generally occurs in advancing and terminal disease, and pain may also be an early manifestation of cancer or its presenting symptoms. Cancer pain has been the focus of considerable attention and concern for clinicians, patients, their friends and families, the general public, and the Government. However, it is now the consensus that no adequate data base exists from which to determine the true magnitude of the cancer pain problem. DRCCA has initiated pilot studies of cancer pain with the goal of gathering valid data defining the incidence and natural history of pain in cancer. Under the contract program *Pain Control in Cancer,* seven institutions are participating in a collaborative study to demonstrate that pain control for cancer patients is best instituted early in its onset after careful planning and evaluation by a multidisciplinary team of experts. This program addresses the management of pain associated with advanced and metastatic diseases and chronic pain associated with localized disease.

Hospice Program

According to NCI (62):

Three projects in Implementation of the *Hospice Concept* for *the Care* of *Terminal Cancer Patients* were implemented with a home care program and a backup in-house facility. These projects provided a demonstration of comprehensive terminal care given in three different settings, i.e., a nursing home, a community hospital, and a health maintenance organization. A collaborative, descriptive study developed by the hospice contractors and NCI program staff was implemented in October 1979 with data collection ending September **30, 1980.** The study focused on a thorough description of care in the three settings which included a longitudinal assessment of the patient and the bereaved family members (significant others). In describing the hospice patient population, age, sex, socioeconomic status, medical condition, and other pertinent characteristics were recorded. Data analysis is proceeding and a report is to be available by the end of this year,

PREVENTION PROGRAMS

The goals of the NCI cancer control program include "developing methods of encouraging beneficial attitudes and life styles . . . " A number of experts with whom OTA talked mentioned two areas that may deserve special attention because of their importance to prevention programs. Those two areas, epidemiology and nutrition research, are discussed below.

Epidemiology

In 1975, the Environmental Epidemiology Branch was created in the Division of Cancer Cause and Prevention, and has expanded in size and budget. The objective of the branch has been to attain a comprehensive and balanced program to enhance our capacity at the national level to generate fresh ideas and help settle key questions in cancer epidemiology and etiology. Along with expansion of the intramural and collaborative programs, parallel efforts were made to stimulate and encourage extramural grant-supported programs in epidemiology, including some support for training in epidemiology and biostatistics.

The epidemiology and biometry program of NCI plays a pivotal role in the National Cancer program. It has responded to requests at all levels to increase the scope of its work and to help develop Federal programs and policies in several areas. NCI efforts have contributed not only to research in cancer etiology, but also to our understanding of natural history, end results, clinical trials, preventive measures, and strategies involved in administrative planning

and decisionmaking. Increasingly, epidemiologic and biometric approaches permeate various aspects of the National Center Program, and are fundamental to the design and evaluation of methods to control cancer. *

In spite of the laudable achievements of the last few years, a number of people that spoke with OTA expressed strong feelings that NCI has failed to emphasize epidemiology sufficiently.

Much of the information available today about how to prevent cancer has come from epidemiology. The convincing evidence that cigarettes, asbestos, radiation, and some chemicals definitely cause cancer is based on epidemiologic studies. There is a lack of consensus about whether or not there are many good epidemiologic hypotheses that are going untested because of lack of support for training in epidemiology and biostatistics. Support for such training is seen as always having been minimal, and as being further reduced in recent budget tightening. The lack of trained people in this area has been recognized for many years and has been publicized by the National Research Council.

Primary prevention—preventing cancers from developing at all—is the ultimate goal, and it depends to a large extent on epidemiology. That is not, however, a practical short-term goal or even a foreseeable goal. Epidemiology, however, is a necessary component of other aspects of cancer control. For example, screening programs, leading to early diagnosis of existing cancers, have been a major thrust of secondary prevention efforts at NCI. Yet, some screening programs have been misapplied. One of the experts who spoke with OTA claimed that as much was known about the Pap smear as a successful technique for detecting cervical cancer in 1941 as is known today. In the 1960's, as part of the cancer control program, a demonstration screening program was initiated, but it was directed at a segment of the population that would benefit little from it. Some experts contend that the same thing is happening today in breast cancer screening. Increased epidemiologic input would reduce the chances of such misapplications. Epidemiologic guidance could be the integrating factor between the clinic and the community, identifying the population groups who would derive the greatest benefit from screening.

Epidemiology might be a unifying force between different phases of research, but in the past, resources for epidemiology have been relatively small compared to other parts of NCI. There are hopeful signs at present of expansion in epidemiologic efforts.

Nutrition Research

Components of diet are associated with cancer occurrence. During Senate hearings in 1978, a large number of witnesses referred to estimates that 60 percent of cancer in females and 40 percent in males were related to diet (115). Relationships are not always clear, but some associations between dietary components and cancer risks are widely accepted, For instance, high-fat diets are associated with elevated colon and breast-cancer rates. Such findings produce immediate suggestions for reducing cancer incidence. The Division of Cancer Cause and Prevention has been active in looking at dietary risk factors for cancer in a number of epidemiologic studies.

Within the last year, a number of studies have contributed to the hypothesis that eating beta-carotene, a precursor of vitamin A found in green, leafy plants and carrots reduces cancer incidence (20,86,96,106). Identification of protective components in the diet may be as important for prevention as is describing risk factors.

Nutrition has also been studied in relation to cancer treatment. Many cancer patients have no appetite and have difficulty in "keeping food down;" they waste away during treatment. The term used for providing nutritional support to the patient is "hyperalimentation." Although the Senate heard some presentations about nutritional support of the patient, it is clear from the hearing record that Congress was most interested in cause and prevention.

Another example of interest in nutrition and cancer is a major National Academy of Sciences' study of that subject that is now underway. Its report is expected in late 1982.

* J. F. Fraumeni, Jr., NCI, personal communication, Mar. 10 1982.

At least partly as a result of congressional interest in the nutrition-cancer link, NCI established a program in this area. Many early efforts of the program were directed at treatment, not at cause and prevention. Presentations from that program that are described in the NCAB annual reports in the late 1970's discussed hyperalimentation.

A change in direction is now apparent. NCAB'S Subcommittee on Nutrition and Cancer has recently examined NCI'S efforts in this field, and it has recommended a time-limited allocation of funds to stimulate cancer-nutrition research and the establishment of a task force to coordinate NCI efforts (71).

"Chemoprevention" has become a popular word in the cancer lexicon. It refers to identification of agents that can be ingested with the expectation of reducing cancer. The NCAB subcommittee published a list of the 10 chemoprevention trials that are ongoing at NCI. Eight of the 10 trials are being conducted in cancer patients, and, therefore are aimed at prevention of recurrent or worsening disease. Only one study of the 10 is directed at primary prevention in general populations. It is a study to be conducted in a population of 21,900 healthy males, ages 50 to 75. The study is designed to test the effectiveness of beta-carotene in reducing cancer occurrence and to test the effectiveness of aspirin in reducing heart attacks. This large-scale study is being jointly supported by NCI and NHLBI. The contrast between this chemoprevention study, involving a large number of healthy people and prevention strategies directed at the number one and two killers, and the other chemoprevention trials needs no elaboration.

A number of experts who were contacted by OTA make a point of the difficulties of executing these studies. Such studies involve a large number of people in making changes, albeit small ones, in their lifestyles, and the studies will be difficult. Though it is a first step, merely carrying out such a study is no guarantee that meaningful results will be obtained.

The NCAB subcommittee, which was critical of the current efforts in nutrition research, draws attention to the possible lack of good, testable ideas in nutrition and cancer, and proposes a number of changes at NCI to promote better research in this area. Such changes may lead to better understanding of the connections between diet and cancer.

SUMMARY

Improvements have been made in the control of cancer. The reasons for some of the improvements are well understood. The reasons for some others remain obscure.

Some encouraging changes in incidence and mortality are apparent. Lung cancer mortality has decreased as a consequence of changes in smoking patterns in young males. Decreased stomach and uterine cancer incidence have resulted in declines in mortality. Improved treatment regimens have dramatically reduced mortality from some cancers.

NCI research has played a major role in these improvements. The role of formal cancer control programs and technology transfer activities in moving improvements to the community is less clear. Management of technology transfer is a difficult task, and NCI is trying a number of activities to decide upon effective strategies. A related, also difficult task, is the development of measures for the success or lack of success of technology transfer programs. A new focus of cancer control at NCI will be the Community Clinical Oncology Program (CCOP), which, like the successful Clinical Cooperative Oncology Group (CCOG) Program, will involve community physicians in NCI-sponsored clinical trials. These programs directly transfer the most recent treatment and management methods to the community through physician participation. Experts contacted by OTA were complimentary about NCI'S role in the progress being made against cancer and in understanding the disease; at the same time, some expressed concerns about some features of its many programs. Those concerns are not definitive opinions, but they identify difficult issues that merit attention.

ADDENDUM A: GROWTH OF THE NATIONAL CANCER INSTITUTE AFTER PASSAGE OF THE NATIONAL CANCER ACT

The NCI Budget

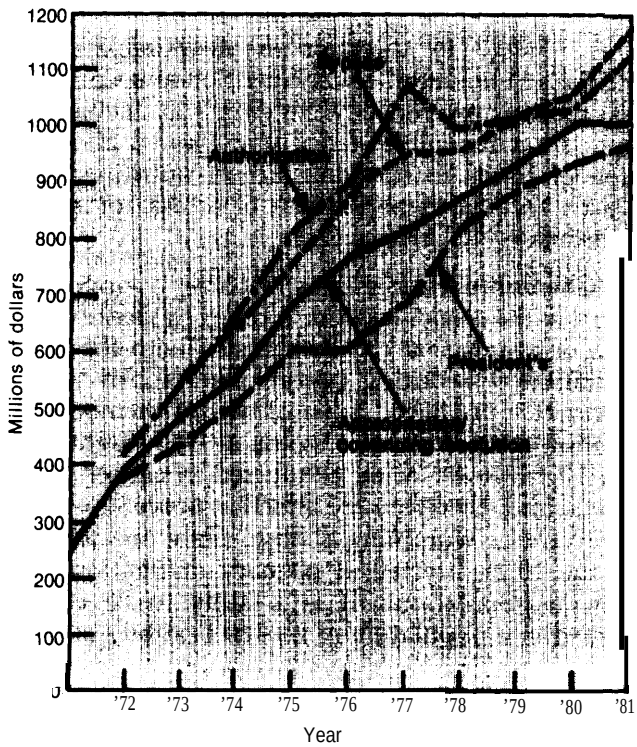
Financial support for NCI more than doubled between 1972 and 1981 (see table 20 and fig. 4), The budget includes funds for both cancer research and cancer control; the dollar amounts in this section are the sums for both activities.

The NCI budget exists in four forms. The annual authorization figure is the amount specified in the enabling legislation. It and the "bypass request, " which is a budget prepared by NCI staff and advisors, have been for approximately the same amounts each year and have increased almost in parallel since **1972.** By legislative authority, the bypass request is submitted directly to the President and bypasses the budget process imposed on other components of the Public Health Service (PHS) and the Department of Health and Human Services (DHHS) by the executive branch. The Department may comment on the bypass budget but cannot change it.

The "President budget request" is the final amount proposed by the administration after the President and the Office of Management and Budget have reviewed and evaluated the bypass request. That mark has been consistently below the bypass request, and during 1973 through 1977, it ran between 64 and 82 percent of the authorization (see table 21 and fig. 5). However, because the percentage increase in the President's request in recent years has been greater than the increase in the authorization, the President's budget has been **85** percent or more of the authorized figure for the last 3 years.

The final budget figure, the continuing resolution or appropriation figure, is the amount of money

Figure 4.-Authorized, Requested, and Appropriated Budgets of NCI, Fiscal Years 1972-81



SOURCE: Office of Technology Assessment from NCI data

Table 20.—Authorized, Requested, and Appropriated Budgets of NCI, Fiscal Years 1972.81

	Authorization[a]	Bypass request	President's budget request	Continuing resolution appropriate ion
1972	$ 420,000,000	—	$374,338,000	$ 378,794,000
1973	530,000,000	$ 550,790,000	432,205,000	492,205,000
1974	640,000,000	640,000,000	500,000,000	551,191,000
1975 ...., ...	803,500,000	750,000,000	600,000,000	691,666,000
1976	898,500,000	898,500,000	605,000,000	761,727,000
1977 ....., . .	1,073,500,000	946,000,000	687,670,000	815,000,000
1978	1,008,150,000	955,000,000	818,936,000	872,388,000
1979	1,015,000,000	1,036,000,000	878,802,000	937,129,000
1980	1,030,000,000	1,055,000,000	936,958,000	1,000,000,000
1981	1,128,600,000	1,170,000,000	965,105,000	1,001,330,000

[a]Includes both cancer control authorization and research authorization.

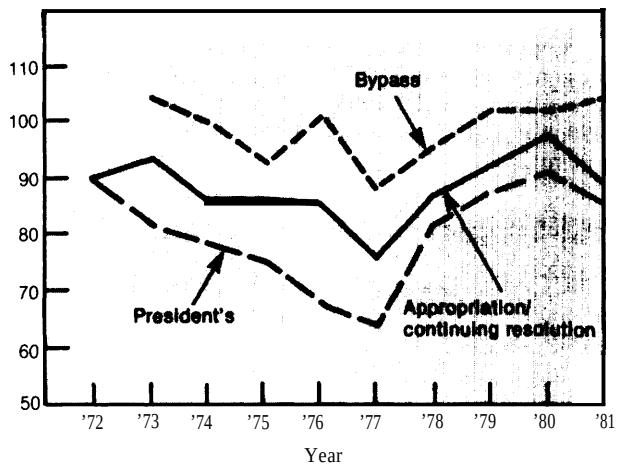
SOURCE: National Cancer Institute, Jan. 4, 1982.

Table 21.– Requested and Appropriated Budgets of NCI, as Percentages of the Authorized Budget, Fiscal Years 1972.81

	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981
Bypass	—	104%	100%	93%	100%	88%	9570	102%	102%	10470
President's budget	89%	82	78	75	67	64	81	87	91	85
Appropriation. . . .	90	93	86	86	85	76	86	92	97	89

SOURCE: Office of Technology Assessment from data in table 20.

Figure 5.—Requested and Appropriated Budgets of NCI, as Percentages of the Authorized Budget, Fiscal Years 1972-81



SOURCE" Office of Technology Assessment from NCI data.

Table 22.–Annual Percentage Increase in the NCI Appropriation Compared to Increase in the Consumer Price Index, 1972.81

	(I) Percent change in NCI appropriation over previous year[a]	(2) Percent change in Consumer Price Index[b]	(3) Net change in **NCI** budget (1) -(2)
1973	13.9	6.2	7.7
1974	34.8	11.0	23.8
1975	20.3	**9.1**	11.2
1976	8.8	**5.8**	3.0
1977	7.1	**6.5**	0.6
1978	7.2	**7.6**	(0.4)
1979	7.4	**11.5**	**(4.1)**
1980	6.5	**13.5**	**(7.0)**
1981	O.1[c]	**13.5**[d]	**(13.5)**

Increase in purchasing power of NCI between 1972 and 1981 after adjusting for inflation:

1972 dollar = 0.798 purchasing power of 1967 dollar[e]

1981 dollar = 0.397 purchasing power of 1967 dollar

1981 dollar = $\frac{0.397}{0.798}$ 1972 dollar = 0.498

1981 appropriation = $1,001 million x 0.498 = $498 million in 1972 dollars.

Therefore, actual increase = $498 million (1981 appropriation in 1972 dollars) -$379 million (1972 appropriation) = $119 million in crease over period 1972-1981 = $1 19/379 million = 31 percent.

[a] 1980 NCI Fact Book.
[b] Consumer Price Index for urban wage earners and clerical workers, table 22, *Statistical Abstracts of the United States*, 1981
[c] Calculated from data in table 20.
[d] R,t, for 1981 is based on the annual rate calculated from changes between Jan. and May in table 23, *Statistical Abstracts of the United* States, 1981.
[e] Calculated is r,ciprocal Of "all items" Consumer price Index in *Statistical Abstracts of the United States*, 1981

SOURCE: Office of Technology Assessment.

received by NCI each year. Despite the fact that in some years either the President's request or the appropriation figure showed little or no increase, the sum of money received by NCI has increased each year except in 1981. The overall impression is that, until 1981, an increase in either the bypass request or the President's request signaled an increased appropriation. In 1981, there was hardly any appropriation increase, even though the authorization, the bypass request, and the President's request increased.

Appropriations increased most rapidly during the period 1972 through 1976, the first years of the National Cancer Program. In fact, had the NCI budget continued to increase at that rate, appropriations would have doubled every 3 1/2 years. The rate of increase dropped significantly between 1976 and 1980 however, so that the period of very rapid growth in NCI appropriations occurred over only a few years.

Increases in NCI'S appropriations exceeded the inflation rate for the period 1972 through 1977 but not since then (see table 22). The impact of inflation has reduced the purchasing power of the 1981 NCI appropriation to **$498** million in 1972 dollars. In other words, after allowing for inflation, the NCI appropriation increased only about 31 percent between 1972 and 1981.

Research costs are a small part of the national expenditure on cancer. The National Center for Health Statistics estimates that cancer accounts for 10 percent of the cost of illness in 1977. Assuming that percentage remained constant, $24.7 billion was spent on cancer in 1980. During that year, the NCI

budget was $1 billion or less than 5 percent of the total cost of the disease.

Research Support From NCI Since Passage of the National Cancer Act

The NCI research budget can be divided between intramural projects and extramural projects (see addendum B). In 1980, about 17 percent of NCI'S expenditures were for intramural research. The amount spent was $197 million as compared to $802 million spent extramurally in grants and contracts (see addendum B).

The number of extramural grant applications submitted to NCI, the number of applications approved for funding, and the number funded are shown in table 23 and figure 6. "Competing" applications (see table 23) are those for which no NCI money has been awarded for the period for which funds are being requested. They can be either of two types. "New" competing applications describe a project that is not currently being supported by NCI. In general, grant applications usually request funds for 3 to 5 years, and, if an award is made, the award is usually for 3 years. "Renewal" competing applications describe continuations of currently supported research, but the current grant period will expire at the time for which continuing support is sought. For instance, suppose that Investigator A had submitted a new competing application in 1977 that was successful and that a 3-year award was made to begin on January 1, 1978. If the scientist wished to continue that line of research, sometime late in 1979 or early 1980, he or she would submit another application. That application, coming from a supported investigator, would be a "renewal. "

During the period of Investigator A's first grant, he or she would receive two "noncompeting" (see table 23) awards, in 1979 and 1980. This bookkeeping results from grants being made for more than l-year periods but dollar allocations having to be made on a yearly basis.

Competing applications must cross the peer review hurdle to obtain funding. In this process, they are either "approved" or "disapproved. " Approval means that the research outlined in the application is worthy of support. Each approved application is then awarded a numerical score. In general, applications with the best scores are funded.

Renewal applications fare significantly better than do new ones. The approval rate is higher and the percentage of approval applications funded is also higher (table 23 and fig. 6). The better performance of renewals is to be expected.

The number of awarded grants (both competing and noncompeting) increased from 1,834 to 2,555 between 1974 and 1980 (table 23 and fig. 6). The bulk of that increase, from 2,113 to 2,555, came during the years 1978, 1979, and 1980. Therefore, that increase occurred after the days of halcyon budget increases between 1974 and 1977 (see above). The increased number of regular research grant awards represents a reprogramming of funds at NCI and increased emphasis on investigator-initiated grants. The percentage of NCI'S extramural support going to investigator-initiated research grants increased from 52 percent (1974) to 66 percent (1980). The average value of grant awards has almost doubled during the 7 years 1974 to 1980 (table 23).

In 1974, 18.5 percent of NCI'S extramural expenditures was for research support contracts and interagency agreements. During the next 4 years, the percentage varied between 17 and 19 percent, and in 1979 and 1980 it increased to 21.9 and then 23.6 percent (62).

NCI Support of Basic Research

NCI expends a smaller proportion of its resources on basic research than does the rest of NIH as a whole (see table 24). Its expenditure of 33 percent of its funds is also the smallest percentage spent on basic research by any institute. The National Institute of Dental Research (NIDR) spends the next lowest proportion for basic research, 44 percent. The National Institute of General Medical Sciences (NIGMS) spends the greatest proportion, 74 percent.

NCI spends 28 percent of all research and development funds spent by NIH. It spends 18 percent of the basic research dollars; and 35 and 57 percent, respectively, of applied research and development funds (table 24).

Because of NCI'S spending distribution, it spends a larger percentage for "applied research" and "development" than the rest of NIH as a whole (table 24). Despite NCI'S spending a low proportion of its funds on basic research, it spends more than any other institute because of its large budget ($382 million from a budget of $958 million); NHLBI spends the next largest amount ($302 million from a budget of $530 million) on basic research.

Among the many forces that play on NCI are ones that urge greater support of basic research, Other opposing forces want greater support for applied research and development. In OTA'S conversations with experts about NCI, one end of a spectrum was represented by those who strongly favored investigator-initiated research programs, grant support, and limited centralized planning. At the other end were

Table 23.—NCI Regular Grant Awards— 1974-80 (including clinical cooperative groups)
(dollars in thousands)

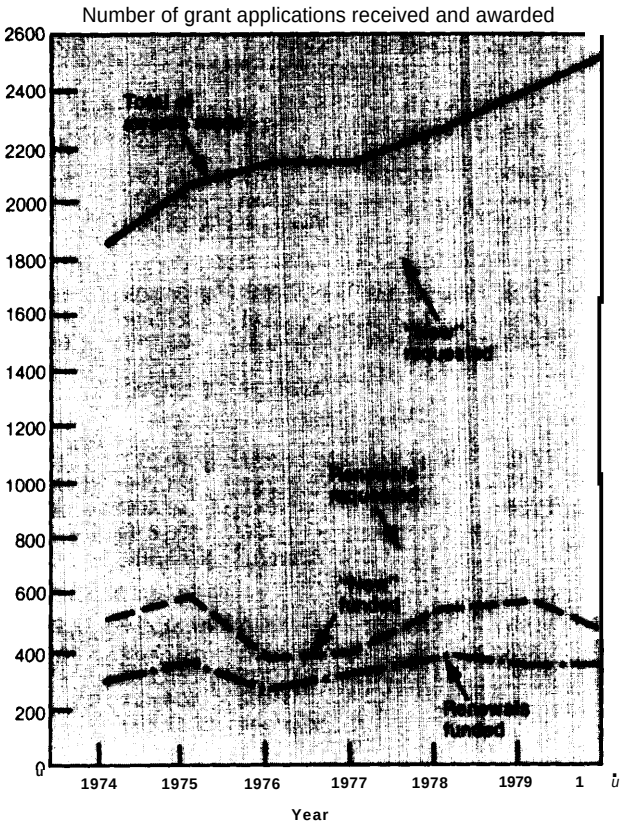
Type award	Requested		Approved		Awarded		Percent funded
	Number	Amount	Number	Amount	Number	Amount	
1974							
Competing							
New	1,382	$100,717	909	$ 45,713	500	$27,824	55.0%
Renewals	379	33,651	336	22,815	285	20,413	84.8
Total	1,761	134,368	1,245	68,528	785	48,237	63.1
Noncompeting	—	—	—	—	1,049	62,803	—
					Average	$ 34,200	
1975							
Competing							
New	1,509	$108,621	979	$48,023	581	$ 30,605	59.3
Renewals	555	55,314	429	31,876	349	27,949	81.4
Total	2,064	163,935	1,408	79,899	930	58,554	66.1
Noncompeting	—	—	—	—	1,112	72,917	—
					Average	$35,700	
7976							
Competing							
New	1,499	$113,135	910	$ 47,342	388	$ 22,230	42.6
Renewals	517	53,992	376	28,070	257	21,236	68.4
Total	2,016	167,127	1,286	75,412	645	43,466	50.2
Noncompeting	—	—	—	—	1,486	106,818	—
					Average	$ 51,100	
7977							
Competing							
New	1,756	$147,591	1,071	$60,155	398	$ 23,781	37.2
Renewals	728	87,162	578	50,221	303	32,436	52.4
Total .....,	2,484	234,753	1,649	110,376	701	56,217	42.5
Noncompeting	—	—	—	—	1,412	104,431	—
					Average	$ 49,400	
1978							
Competing							
New	1,854	$153,528	1,264	$ 75,014	513	$32,591	40.6
Renewals	752	97,937	617	57,131	381	38,905	61.8
Totals	2,606	251,465	1,881	132,145	894	71,496	47.5
Noncompeting	—	—	—	—	1,341	111,916	—
					Average	$ 50,100	
1979							
Competing							
New	1,950	$177,989	1,414	$97,596	576	$ 45,287	40.7
Renewals	653	80,521	570	52,012	334	35,025	58.6
Total	2,603	258,510	1,984	149,608	910	80,312	45.9
Noncompeting	—	—	—	—	1,485	141,198	—
					Average	$ 60,000	
7980							
Competing							
New	1,891	$188,988	1,401	$103,389	470	$ 37,605	33.5
Renewals	632	89,866	610	62,289	346	39,167	56.7
Total	2,523	278,854	2,011	165,678	816	76,772	40.6
Noncompeting	—	—	—	—	1,739	171,312	—
					Average	$ 67,000	

NOTE: Average dollars presented in this column represent the total amount of money expended on grants dlvded by the number of grants That dollar value is expressed in dollars, not in "dollars in thousands

SOURCE: National Cancer institute, 1981

those who, while acknowledging the importance of basic research, favored more emphasis on centralized planning and grant and contract support of opportunities for making improvements in treatment. To a major extent, people in the first group view most of cancer problems as being in the "prefeasib]e" stage. They see an absence of understanding of cancer that can be overcome only by basic research. The second group see many more cancer problems as being in the "feasible" stage. They see improvements coming

Figure 6.—NCI Regular Grant Awards, Fiscal Years 1974-80



SOURCE: Office of Technology Assessment from NCI data.

from empirical studies that can be applied now or in the near future to treating cancer patients.

There was also a clear division between experts along the lines in which they view cancer treatment. Some who are involved in basic research see the reported improvements in survival rates as limited, at best. In their eyes, research at the most fundamental level is necessary to provide insight and understanding to break away from methods that have changed little over the years. Some experts who argued in support of basic research at the same time voiced support for epidemiology. In their eyes, studying cancer in humans identifies "black boxes" of higher and lower cancer occurrence. Investigating those black boxes is seen as providing opportunities to learn about human cancer.

The other group views the reported improvements as real and clear indications that continual incremental advances will lead to continued betterment of cancer care.

NCI accommodates both points of view, and it funds both types of research. The division between basic and other kinds of research is argued continually.

NCI Staffing

The National Cancer Advisory Board (NCAB) **(70)** has drawn attention to the fact that NCI staff has not increased in step with its increased budget (see table **25).** In particular, the number of personnel declined

Table 24.—Basic and Applied Research and Development Spending at NCI

A. Proportion of budget spent on basic and applied research and development, 1982a

	1. Basic (o/o)	2. Applied (o/o)	3. Development (%)	Total 1 + 2 + 3 (%)
NCI	$328 (33)	$414 (43)	$215 (22)	$958 (100)
Others[b]	$1,491 (61)	$776 (32)	$161 (07)	$2,427 (100)

B. NCI expenditures as a percentage of all NIH[b] expenditures

(18)	(35)	(57)	(28)

aDollar amounts are given in millions.
[b]other Institutes not Including Fogarty International Center, National Library of Medicine, Office of the Director, Buildings and Facilities,

SOURCE: Office of Technology Assessment from NIH data.

Table 25.—Comparison of the Increases in NCI Funding and Changes in the Number of NCI Personnel, Fiscal Years 1971-80

Fiscal year	Dollars			Positions		
	Obligations ($000's)	Percent of increase over base year	Percent of increase over prior year	Actual full-time permanent employees	Percent of increase over base year	Percent of increase over prior year
1971	232,855	(Base year)	—	1,426	(Base year)	–
1972	378,636	62.6%	62.6°/0	1,665	16.80/0	16.80/0
1973	431,245	85.2	13.9	1,736	21.7	4.3
1974	581,149	149.6	34.8	1,805	26.6	4.0
1975	699,320	200,3	20.3	1,849	29.7	2.4
1976	760,751	226.7	8.8	1,955	37.1	5.7
1977	814,957	250,0	7.1	1,986	39.3	1.6
1978	872,369	275.0	7.2	1,969	38.1	– 0.9
1979	936,696	302.3	7.4	1,973	38.4	0.2
1980	998,047	328.6	6.5	1,837	28.8	– 6.7

SOURCE: National Cancer Institute, 1981

in 1978 and 1980. When a comparison is made between the increase in annual appropriations and the increases in staff, there is a great discrepancy.

The changes in staff positions can also be compared to the 31-percent increase in the NCI budget expressed in constant dollars. When that is done, the 10-percent increase from 1,665 positions in 1972 to l,837 in 1980 does not seem so out of line.

Making comparisons of positions to inflated dollars or to constant dollars is superficial. Conversations that OTA had with non-NCI experts revealed difference opinions about the number of NCI employees needed. Some NCI grantees (it must be remembered that scientists contacted by OTA were almost all successful grantees) saw little need for more NCI staff. The peer review system (see below) evidently has sufficient staff support, and grantees see little need for NCI consultation or guidance in managing their research projects. The number of competing grant applications received by NCI increased from 1,761 in 1974 to a peak of **2,606** in 1978; it then declined to 2,523 in 1980 (see table 23). Since that number has become relatively stable, no increases appear to be needed in that area. NCI notes, however, that its recent separation of program management activities from review activities will require additional staff for review activities.

Researchers who depend on individual research grants or program project grants (see app. B) appear to favor an NCI largely limited to review, more so than researchers supported mainly by contracts. They believe that standard measures of scientific success—publication in professional journals, invitations to speak to scientific meetings, promotion, etc. —are sufficient to make judgments about a scientist's progress. Objections to increased demands for accountability, which involve reports being submitted to NCI, are frequently expressed. The protests about too many demands for accountability do not extend to financial affairs. Reporting expenditures and surpluses is seen as necessary, but accounting for research results through reports to NCI is seen as unnecessary.

Other experts, particularly those associated with NCI centers, expressed a desire for more NCI senior staff. The additional senior-level personnel were seen as being useful in making decisions about the management of the centers' programs and the relationship between NCI and the centers. Some experts also think that the NCI senior-level officials can take a more active role in suggesting or targeting research areas through issuing program announcements or requests for applications in specified areas.

Researchers who run larger enterprises requiring coordination of several investigators, and, especially, clinical research and community outreach programs which have many special rules, favor more expertise at NCI. They believe that decisionmaking and advice from NCI would be improved by more staff.

Furthermore, some experts favored more accountability. Currently each grantee submits a progress report to NCI at the end of each grant year and at the end of the grant period. By general consensus, hardly any of the yearly reports are read by anyone. The response to this observation by some experts is that the annual reports serve no function and should not be required. Others believe that the annual reports should be read and evaluated. The latter procedure would require more NCI staff.

The differing opinions about the value of annual reports illustrate that the number of people needed at NCI depends on what NCI is expected to do. If it is primarily to provide review services to assure that the best research gets funded, it would require a minimum of people in the extramural programs. As NCI gets more involved in aiding in the management

of extramural moneys and in contracts, more people would be required.

Contracts require more NCI supervision, and the General Accounting Office (GAO) (25,26,27,28) has placed part of the blame for poor contract monitoring by NCI on a shortage of personnel. In addition, however, GAO has faulted some aspects of the NCI management system.

In contrast to increased numbers of grants and grant applications, which might require few new staff positions, increased numbers of contract proposals and contracts might require much more staff. Whether or not more staff positions are necessary, then, depends on perceptions of the role of NCI.

Staffing needs of intramural programs appear to be straightforward. The budget allows a certain number of projects; staffing needs are probably directly related to the number of the projects.

No attempt was made in this study to determine the staffing needs of NCI. It seems to be a thorny problem, with experts disagreeing. To some extent the disagreement reflects the relationships that exist between different extramural scientists and the Institute.

ADDENDUM B: QUESTIONS POSED TO EXPERTS BY OTA STAFF

1. What have been the most significant advances in cancer research and applications of research since 1971? What role has NCI played in bringing them about?
2. What have been NCI'S most significant advances?
3. In what areas will we likely see breakthroughs in the next decade?
4. What are appropriate yardsticks by which NCI success can be measured? Should we expect to see direct effects of NCI progress in incidence and mortality statistics?
5. What are realistic short- and long-term goals for NCI?
6. Based on today's knowledge, which areas of effort should NCI be emphasizing in the next decade? What areas should be cut back or eliminated?
7. Are there identifiable roadblocks to major breakthroughs in cancer research?
8. Has an appropriate balance been struck between NCI intrarnural and extramural programs? Between grants to individual researchers and to institutions? Between program project and center grants?
9. Have large NCI center grants to major biomedical research institutions been productive? Is the mechanism for monitoring the performance of such institutions adequate?
10. Can you suggest changes that could be made in NCI management policies that would accelerate progress?
11. Has NCI been successful in technology transfer, as NCI defines it? Have NCI'S programs had a positive impact on the community? Are there problems with the mechanism of technology transfer? Are there technologies to be transferred at this time? Are there negative consequences of attempts at technology transfer? What yardsticks can be used to measure success in technology transfer?

ADDENDUM C: EXPERTS CONTACTED BY OTA

Dr. Harold Amos
Harvard Medical School

Dr. David Baltimore
Massachusetts Institute of Technology

Dr. Lester Breslow
UCLA School of Public Health

Dr. Irwin D. J. Bross
Roswell Park Memorial Institute

Dr. Vincent T. DeVita, Jr.
National Cancer Institute

Sir Richard Doll
Oxford University

Dr. Bernard Fisher
University of Pittsburgh School of Medicine

Dr. James F. Fries
Stanford University Medical Center

Dr. Armand Hammer
Occidental International Corporation

Dr. Maureen M. Henderson
University of Washington

Dr. Thomas J. King
Kennedy Institute for Ethics

Mrs. Rose Kushner
Kensington, Maryland

Dr. Joshua Lederberg
The Rockefeller University

Dr. Brian MacMahon
Harvard University School of Public Health

Dr. Elizabeth C. Miller
McArdle Laboratory for Cancer Research

Dr. Marvin Schneiderman
Clement Associates, Inc.

Dr. Guy Newell
M.D. Anderson Hospital & Tumor Institute

Dr. Norton Nelson
New York University

Dr. Henry C. Pitot
McArdle Laboratory for Cancer Research

Dr. David P. Rail
National Institute of Environmental Health Sciences

Dr. Frank Rauscher
American Cancer Society

Dr. Frederick Robbins
Institute of Medicine, National Academy of Sciences

Mr. Benno C. Schmidt
J. H. Whitney & Co.

Dr. Irving J. Selikoff
Mt. Sinai School of Medicine

Dr. Charles Smart
American College of Surgeons

Dr. Howard Temin
McArdle Laboratory for Cancer Research

Dr. Lewis Thomas
Memorial Sloan-Kettering Cancer Center

Dr. Arthur Upton
New York University

Dr. Sidney Wolfe
Public Citizen Health Research Group

Dr. Ernst Wynder
American Health Foundation

Dr. John S. Zapp
American Medical Association

ADDENDUM D: GUIDELINES FOR RECOGNITION OF A CANCER CENTER AS COMPREHENSIVE

These guidelines describe the qualities and characteristics that the National Cancer Advisory Board (NCAB) considers essential for recognition of a cancer center as comprehensive. They will be used by reviewers to evaluate centers that are seeking recognition as new comprehensive centers and also to evaluate established centers to determine the advisability of continued recognition.

In establishing these guidelines, NCAB does not intend that every institution participate in all possible activities relevant to cancer. For example, although one of the requirements for recognition as comprehensive center is the existence of high quality research activities, there is no requirement that all research areas be pursued at a given center. Rather, there is the requirement that there be high quality activity in some aspects of cancer control and some aspects of training, education, and information dissemination. The term comprehensive is intended to convey that the cancer center has high quality activities in each of these major areas, but that within any given area, the center may choose to pursue particular topics and not others.

National and Local Support

The cancer center must have a funded Cancer Center Support (Core) Grant, indicating that center activities are of sufficient quality to achieve funding from the National Cancer Program. *In* addition, there must be evidence of material support for center activities from the parent institution(s) and the local community.

Research Activities

The cancer center should support laboratory, clinical, epidemiologic, and evaluative research efforts of

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the highest quality and should create an environment which fosters cancer-related information exchange, cooperation, and collaboration between laboratory scientists of multiple disciplines and between laboratory scientists, clinical scientists, and epidemiologists. Centers should maintain their own clinical investigative activities, Those activities should include participation in regional and/or national clinical trials related to the cancers being studied by the center in question. The center should have available the personnel and facilities to carry out high quality diagnostic, therapeutic, and rehabilitative procedures in the interdisciplinary setting most suited to the cancers being investigated. The center should make a commitment to participate in uniform clinical data acquisition and reporting through the Centralized Cancer Patient Data System (CCPDS).

Cancer Control Activities

The cancer center should serve as an important focal point for local and regional programs designed to control cancer through research and demonstration activities in areas such as prevention, detection, diagnosis, treatment, and rehabilitation. The center should seek the active participation of all sectors of the professional and lay community in control activities.

Training, Education, and Information Dissemination

The cancer center should serve as an important focal point for local and regional information dissemination, as well as for professional and lay education programs. Programs to assess which methods of information dissemination and education effectively modify professional and lay behavior patterns are desirable. Centers should also be actively involved in training of professional and support personnel.

Administration

The cancer center (or in the case of consortia, the constituent institutions) should have a formal commitment of support from the parent institution(s), manifested by the center director having the following: 1) primary control of space and equipment; 2) necessary control over professional and staff appointments to enable the center director to effectively direct the center and assure accomplishment of its mission; 3) control of grouped beds and ambulatory facilities for clinical cancer research; and 4) responsibility for program planning, evaluation, and implementation, preparation of budgets and control of expenditures. In addition, the center must have an administrative structure that will assure long-term viability, efficiency of operation, and sound financial practice.

Geographic Impact

Scientific excellence of any center is a primary consideration. The geographic location of the cancer center, however, should increase the national capability to carry out regional training, education and information dissemination activities. The location of other comprehensive centers and the size of the regional population with access to the center are additional factors bearing on recognition.