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The Honorable George McGovern, Chairman
Subcommittee on Nutrition
Committee on Agriculture, Nutrition, *SEN 06100*
and Forestry
United States Senate

*See 2-115's
May special
attention to
analyses*

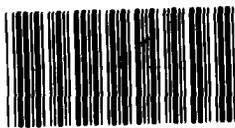
Dear Mr. Chairman:

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Pursuant to your August 7, 1978, letter and later discussions with your office, we reviewed the [use of nutritional supplementation] in the treatment of cancer patients. Specifically, we obtained information on (1) nutritional problems of cancer patients, (2) nutritional supplementation activities at the National Institutes of Health Clinical Center, compared with those of three leading teaching hospitals, (3) the need for research to determine the importance of providing nutritional supplementation to cancer patients, and (4) the need for training physicians and patients to increase their awareness of the importance of patients' nutritional status and to improve the skills of medical personnel in providing nutritional supplementation.

Medical personnel we contacted generally believe that some groups of cancer patients have serious nutritional deficiencies and that nutritional supplementation may be an important adjunct to their treatment. Some preliminary research results indicate that nutritional supplementation may have benefited certain cancer patients. However, great uncertainty exists about the extent of benefits nutritional supplementation has to cancer patients.

1/Nutritional supplementation involves using techniques for either adding nutrients to a patient's daily diet or supplying what is perceived to be a patient's entire nutritional requirement.



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The three general methods for providing nutritional supplementation to patients are (1) by mouth, (2) by a tube, which is usually inserted through the nose and esophagus, and (3) by a catheter, which is usually inserted into the subclavian vein in the neck. The third method of providing nutritional supplementation is often referred to as total parenteral nutrition. It is the sole nutritional supplementation technique available to many cancer patients with nutritional deficiencies and is becoming widely used; however, it is not free of risks to the patient. Medical personnel, including the Director of the National Institutes of Health, expressed serious concern that total parenteral nutrition may become an accepted medical treatment procedure for certain cancer patients without adequate research to determine if it is effective. The results could be additional medical care costs and increased patient risk and discomfort, possibly without compensating benefits.

Nutritional supplementation activities at the Institutes Clinical Center are very similar to those at the three teaching hospitals we reviewed, except that total parenteral nutrition is used less frequently at the Center. From the results of a questionnaire that we sent to selected physicians at the four hospitals, we concluded that one reason for this difference may be that Center physicians are less convinced than physicians at the teaching hospitals that nutritional supplementation helps cancer patients. In commenting on our report, the Institutes pointed out that another possible reason may be that the characteristics of the population of cancer patients in the Clinical Center are probably different from those of the patients in the teaching hospitals we reviewed. The Institutes Director believed it appropriate for Center physicians to reserve judgment about use of nutritional supplementation in cancer patients. He believes that (1) additional research is required to determine its usefulness, (2) the Institutes has a key role in answering questions about the usefulness of medical techniques, (3) the Center offers an ideal environment to perform research to answer the questions while still providing good patient care, and (4) Center physicians should remain skeptical about unproven medical practice techniques, such as use of nutritional supplementation for cancer patients.

The resources presently available at the Clinical Center limit the amount of cancer nutrition research conducted there by a physician who is regarded as one of the Nation's leading nutrition researchers by others in the field. This physician

said that he could more than double the number of nutritional supplementation research projects he conducts with the help of a senior investigator, support staff, and another 500 square feet of laboratory space. The Institutes considers the physician's resource needs to be a relatively high priority and plans to provide him with additional laboratory space when a new Center wing is completed in 1982. The Institutes has no plans, however, to provide the additional staff because of a higher priority need for a new program in treatment of cancer of the pancreas and because of overall staff and space shortages. A group of experts that periodically reviews the National Cancer Institute's Division of Cancer Treatment will consider in its next review the resources needed for nutritional supplementation activities at the Center.

Finally, nutrition research experts believe that physicians need (1) additional nutritional training to make them more aware of their patients' nutritional needs and (2) training in the methods of delivering nutritional supplementation to ensure patient safety. Also, hospitals may need to establish or expand nutritional education programs for patients, especially outpatients, to help them to better understand their nutritional needs. The National Cancer Institute, jointly with other institutes, plans to fund up to 10 nutritional research units at centers with preexisting expertise in nutrition. These units may have an important role in the area of nutritional training and education. We are making a study which concentrates on nutritional training of physicians.

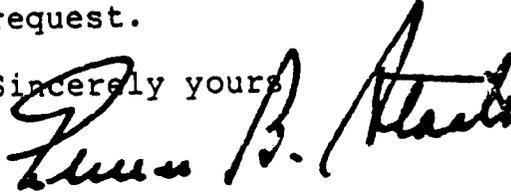
The results of our review, presented to your staff during an October 11, 1978, briefing, are detailed in the enclosure. Page 20 of the enclosure contains a recommendation to the Secretary of Health, Education, and Welfare on the need to insure that the National Cancer Institute consider certain training roles for its proposed nutrition research units.

As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the Senate Committee on Governmental Affairs and the House Committee on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

As instructed by your office, we did not request written comments from the organizations we reviewed, but we did request oral comments. Officials from these organizations, including the Institutes which provided written comments, indicated that matters discussed in our report are fairly and accurately presented. We incorporated their specific comments into the report where appropriate.

Copies of this report have been made available to the Department of Health, Education, and Welfare. As instructed by your office, copies will be furnished on February 1, 1979, to various congressional committees, Members of Congress, and other interested parties upon request.

Sincerely yours

A handwritten signature in black ink, appearing to read "James B. Stewart". The signature is written in a cursive style with a large initial "J" and "S".

Comptroller General
of the United States

Enclosure

USE OF NUTRITIONAL SUPPLEMENTATION DURING
CANCER TREATMENT AT THE NATIONAL INSTITUTES
OF HEALTH CLINICAL CENTER AND
SELECTED TEACHING HOSPITALS

At the request of the Chairman, Subcommittee on Nutrition, Senate Committee on Agriculture, Nutrition, and Forestry, we reviewed the use of nutritional supplementation in connection with the treatment of cancer patients. Specifically, we obtained information on (1) nutritional problems of cancer patients, (2) nutritional supplementation activities at the National Institutes of Health (NIH) Clinical Center, compared with those of three leading teaching hospitals, (3) the need for research to determine the importance of providing nutritional supplementation to cancer patients, and (4) the need for training of physicians and patients to increase their awareness of the importance of patients' nutritional status and to improve the skills of medical personnel in providing nutritional supplementation.

Our review was made at the NIH Clinical Center, a 546-bed Public Health Service research hospital in Bethesda, Maryland, and at 3 leading teaching hospitals: the New England Deaconess Hospital (Deaconess) in Boston, Massachusetts, a 489-bed hospital, affiliated with the Harvard University Medical School; the Hospital of the University of Pennsylvania (Penn), a 694-bed hospital in Philadelphia, Pennsylvania; and the M.D. Anderson Hospital (Anderson) in Houston, Texas, a 520-bed hospital for cancer patients, affiliated with the University of Texas Medical School. Anderson is one of 20 institutions, designated by the National Cancer Institute (NCI) as a comprehensive cancer center, which receive NCI support for multidisciplinary research, clinical services, training, and education.

We spoke with leading nutritional experts, primary care physicians, and other medical personnel. Also, a questionnaire was sent to 128 physicians affiliated with the four hospitals to learn about their views and practices regarding the nutritional supplementation of cancer patients. We received 91 responses, representing a 71-percent response rate.

We visited 23 patients at Anderson and Penn to observe nutritional supplementation techniques and to discuss with the patients their nutritional status. Also, our medical consultant reviewed medical records of 10 patients at the Center and 10 patients at Deaconess to compare how the two hospitals were meeting their patients' nutritional needs.

THREE GENERAL METHODS EXIST FOR
PROVIDING NUTRITIONAL SUPPLEMENTATION

According to nutrition experts, the preferred method of providing nutritional supplementation is by mouth, using either ordinary foods or specially prepared formulas. However, if the patient is unable or unwilling to eat enough to maintain or improve his nutritional status, physicians may introduce nutrients directly into his gastrointestinal tract through a tube. The tube usually is inserted through the nose and esophagus or occasionally is surgically inserted directly into the patient's gastrointestinal tract. If the patient is unable to take adequate nourishment in this manner, physicians may use total parenteral nutrition (TPN). Nutrition experts we interviewed believe that TPN should be used only when enough nutrients cannot be provided by either of the other two methods.

TPN is the only nutritional
supplementation method available
to many cancer patients

Although providing nutrients by mouth or by tube are the preferred methods of nutritional supplementation, neither method is totally adequate for many cancer patients who have gastrointestinal tract impairment or complications caused by their treatment. In visiting patients with gastrointestinal problems, we noted that a few were receiving nutritional supplementation by more than one method; however, for many of them, TPN was the only feasible method.

TPN was first used in the United States in 1966 by a physician who observed that patients often died despite technically successful surgery. Since then TPN has been shown to be valuable in (1) supporting patients recovering from therapy which causes the gastrointestinal tract to be nonfunctional, (2) reducing mortality among children with congenital defects of the gastrointestinal tract, (3) helping patients with kidney failure, and (4) supporting patients with certain other medical problems.

NUTRITIONAL PROBLEMS CAN BE SERIOUS
IN SOME CANCER PATIENTS

Although not all cancer patients are undernourished, nutritional problems can be serious in certain groups of cancer patients. Nutritional problems of cancer patients are caused by the disease process itself and by the radical nature of the available treatment methods. Nutrition experts told us that malnourished cancer patients represent a poor risk for the aggressive treatment they may need.

Many cancer patients may have
less chance of recovery
and longer hospital stays
because of nutritional problems

All but 1 of the 91 physicians responding to our questionnaire believe that, in general, undernourishment or malnourishment is at least somewhat of a problem with cancer patients. In response to our question on the extent to which nutritional problems affect the prognoses and lengths of hospital stay of cancer patients treated in their hospitals, 34 percent of the respondents indicated such problems have a major effect on the patient's prognosis, 53 percent indicated an important but not major effect, 12 percent indicated a minor effect, and only 1 percent indicated no effect. As to the length of hospital stay for cancer patients, 30 percent believed nutritional problems significantly lengthen it, 51 percent believed such problems somewhat lengthen it, 16 percent believed such problems do not lengthen it, and 3 percent had no idea as to whether or not nutritional problems contribute toward a lengthened hospital stay.

Cancer treatment can cause or
increase nutritional problems

Cancer treatment can include surgery, radiotherapy, or chemotherapy, or a combination thereof. The radical nature of cancer surgery may leave the patient with a reduced capacity to ingest or absorb necessary nutrients. For example, surgery of the head and neck may interfere with chewing or swallowing, and tube feeding may be required. Removal of the stomach prevents the formation of vitamin B₁₂ and, therefore, necessitates intravenous administration of the vitamin. Surgery on the small intestine may result in malabsorption of food, while removal of the pancreas may result in loss of digestive enzymes.

Radiotherapy often produces nausea, vomiting, and diarrhea, particularly if the treatment involves the gastrointestinal tract. Radiotherapy to the head and neck may interfere with the sensation of taste and produce inflammation of the esophagus, which will usually reduce oral intake of foods. Radiotherapy may also produce tissue changes, which can result in significant malnutrition. For example, a narrowing of the esophagus as a result of radiotherapy may inhibit passage of food, and radiation damage to the small intestine may interfere with absorption of nutrients, possibly necessitating TPN.

Many cancer chemotherapeutic agents produce nausea and vomiting. If repeated doses become necessary, the patient's nutritional status may be greatly damaged. This problem becomes particularly significant if the patient has already been severely malnourished by the underlying disease. Many chemical agents also interfere with nutrition by producing inflammation and even ulceration in the mouth; in severe cases, the patient may be totally unable to eat. Some chemical agents may also affect the intestines and inhibit the absorption of nutrients.

NUTRITIONAL SUPPLEMENTATION PRACTICES AT
THE NIH CLINICAL CENTER AND THE TEACHING
HOSPITALS ARE SUBSTANTIALLY THE SAME

In general, the staff qualifications and the practices of the NIH Clinical Center in the area of nutritional supplementation of cancer patients were substantially the same as those at the three teaching hospitals we reviewed. Only in the frequency of use of TPN did the Center differ markedly from the other hospitals.

Nutritional supplementation operations at the hospitals we reviewed generally involved their dietetics departments and nutritional supplementation teams.

Variations among the dietetics
services were not very significant

The dietetics departments at the hospitals visited employed registered dietitians. ^{1/} At the Center, all dietitians were registered, while at the three teaching hospitals, all or nearly all were registered. According to dietary staff members at all hospitals, dietitians visit cancer patients to obtain nutritional information, and they closely monitor the nutritional needs of those with nutritional problems. For example, Center officials told us that dietitians (1) evaluate patients' past and current eating patterns, (2) periodically monitor fluid intake and fluid output of some cancer patients, and (3) on occasion, weigh food portions delivered to and returned by some cancer patients with special nutritional problems to monitor food intake.

^{1/}A registered dietitian is one who has met the requirements of the American Dietetics Association, which generally include completing an acceptable 4-year college program, undergoing an internship of 6 to 12 months, and passing an examination.

Dietary staff members at all locations told us that, to the extent allowed by their food systems, they cater to the food preferences and preferred eating times of cancer patients with eating problems. Also, the Center's dietitians said that the Center offers patients a large number of food choices on each daily menu and provides a 4-week rather than the 2-week cycle of menus normal in most hospitals. The four hospitals had similar food service systems, except that the Center and Deaconess had small kitchens on each floor where selected food items could be prepared for patients unable to eat enough at mealtimes. The other two hospitals did not have kitchens on every floor.

Deaconess requires that (1) every patient be seen by a dietary staff member within 48 hours after admission, (2) the results of various lab tests that indicate nutritional status be reviewed by a dietitian, (3) a nutritional plan be developed for each patient, and (4) dietary information be written into the patient's chart, which becomes part of the patient's permanent medical record. However, as discussed later, the requirements were not always followed.

The chief of the nutrition supplemental service at this hospital believed that similar requirements should be adopted by every hospital. In his view, such requirements are simple and only moderately expensive to implement. He added that following these requirements ensures that all patients needing nutritional supplementation are identified and provides a basis to determine if a patient's nutritional needs were met and to study the impact of nutritional supplementation methods.

None of the other hospitals we reviewed had requirements like those of Deaconess. Although 75 percent of the physicians responding to our questionnaire believed that such requirements were desirable, many medical personnel we interviewed were not sure that the benefits were commensurate with the costs involved.

Center dietitians told us that they see all patients within the first day after admission. In addition, they regularly visit patients, and discuss the nutritional status of patients with physicians informally. Center dietitians do not routinely enter dietary notes in patients' medical records, but they stated that they do maintain separate dietary records for individual patients. Center officials said they are developing a computerized medical records system that will enable dietitians to enter information directly into patients' medical records.

Our medical consultant reviewed the medical records of 10 patients at Deaconess to ascertain how their dietary requirements had been met.

--In 2 cases the medical records indicated that nutritional assessments had been made within 48 hours of admission, as required.

--In 5 cases the medical records indicated that nutritional assessments had been made, but not within 48 hours of admission.

--In 3 cases the medical records contained no indications that nutritional assessments had been made.

The chief of the nutrition supplementation service at Deaconess explained that manpower limitations preclude them from making a nutritional assessment in every case. Therefore, medical personnel may delay or waive nutritional assessments in cases where patients do not have apparent nutritional problems.

We also reviewed the medical records of the 10 Deaconess patients to determine the extent to which they had nutritional problems and the type of care provided to them. We similarly reviewed the medical records of 10 Center patients. The medical records of both Deaconess and the Center indicated that certain patients at both hospitals had been diagnosed as malnourished and that in each case action had been taken to combat the problem. Our medical consultant found that the dietary notes in the Deaconess medical records generally facilitated his review of nutritional aspects of patient care.

The Center nutritional supplementation team functions somewhat similarly to the teaching hospital teams and provides high-quality services

The nutritional supplementation team at each of the four hospitals was headed by a surgeon. All teams operated on a consultive basis, making nutritional assessments and providing advice on cases referred to them by primary care physicians. Each team provided TPN supplementation services and was involved in research. Teams at Deaconess and Penn provided tube feeding services. Tube feeding is provided at Anderson and the Center, but by other medical personnel. The team head at the NIH Clinical Center said that he encourages use of tube feedings where appropriate.

To assess the quality of TPN services provided, we obtained information for the four hospitals on the incidences of (1) infections due to catheter contamination and (2) problems encountered during catheter insertion, such as internal injuries. Rates for these complications were generally similar, and the Center's rates were as low as or lower than those at the three teaching hospitals.

TPN is used less frequently at the Center than at the three teaching hospitals

The percentage of patients receiving TPN at the NIH Clinical Center was lower than those of the three teaching hospitals we reviewed and significantly lower than those of Anderson and Penn. Center physicians are apparently less convinced than the teaching hospital physicians that nutritional supplementation helps cancer patients. Center physicians responding to our questionnaire often indicated more doubt about the value of nutritional supplementation for cancer patients than did responding physicians at the other hospitals. All the Center physicians responding to our questionnaire believed that nutrition is at least somewhat of a problem in cancer patients. However, a greater percentage of Center physicians than of teaching hospital physicians believed nutritional problems have only a minor effect or no effect on the cancer patient's prognosis and length of hospital stay.

In commenting on our report, NIH pointed out that another possible reason for the lower use of TPN at the Center than at the teaching hospitals may be that the characteristics of the population of cancer patients in the Center are probably different from those of the patients in the teaching hospitals we reviewed. NIH stated that the Center is not primarily a teaching hospital and has substantially different admission criteria.

At Anderson and Penn, where TPN was used much more than at the Clinical Center, about 90 percent of the respondents believed that nutritional supplementation was useful for the severely undernourished cancer patient who was being prepared for major surgery. In contrast, only about half of the respondents at the Center held that opinion. The other Center respondents believed that nutritional supplementation was possibly useful.

According to the Director of NIH, there is a serious risk of TPN becoming an accepted part of medical practice in

treating certain cancer patients without adequate research to determine its effectiveness. He added that NIH has a key role in answering the questions of effectiveness and that the Center offers an ideal environment for performing research while still providing good patient care. He considered it appropriate that Center physicians reserve judgment about the use of nutritional supplementation for cancer patients since (1) additional research is required to determine its usefulness and (2) Center physicians should remain skeptical about unproven medical practice techniques, such as use of nutritional supplementation for cancer patients.

Because of the differences in how often the Center and teaching hospitals use TPN and the apparent uncertainties about the usefulness of nutritional supplementation of cancer patients, we obtained more information on this subject. In the next two sections, we discuss what we learned about the need for more research and training in this area.

MORE RESEARCH ON USE OF
NUTRITIONAL SUPPLEMENTATION
DURING CANCER TREATMENT IS NEEDED

Some preliminary research indicates that nutritional supplementation may benefit certain cancer patients. Use of TPN, the sole nutritional supplementation method available to many cancer patients with nutritional deficiencies, is spreading rapidly; however, the technique is very expensive and poses some risks to patients.

There is uncertainty about

--which nutritional assessment tests are most useful in identifying patients who can benefit from nutritional supplementation and

--whether nutritional supplementation is beneficial to cancer patients.

Thus, more research on these problems is needed. Although NCI plans to fund more extramural research on nutrition and cancer, NIH has provided only limited resources to nutritional supplementation activities at its Clinical Center.

Physicians need a standardized set of
reliable nutritional assessment tests

Although a physician can detect gross malnutrition during the standard physical examination, determining whether a patient who is not visibly malnourished has nutritional

problems may be difficult. Several nutrition experts and other medical personnel we contacted believed that identifying such patients is important because providing nutritional supplementation early may prevent later gross malnourishment during cancer treatment. However, a standardized set of reliable tests to determine the nutritional status of cancer patients is still in the developmental stage. Consequently, numerous tests are used in an attempt to diagnose the nutritional status of some cancer patients.

Over half of the physicians responding to our questionnaire indicated that they periodically use the results of 13 or more different tests 1/ on at least some cancer patients; many respondents doubted the usefulness of some of the tests. Nutrition experts told us that they lack sufficient data to enable them to conclude with assurance which tests should be used to assess the nutritional status of cancer patients. Concern was also expressed that, without more research, some tests, though possibly of little value, will be generally accepted as a means to make nutritional assessments.

As a result of research to determine which tests are important indicators of the nutritional status of cancer patients, experts at Deaconess and Penn have observed an apparently strong correlation between lowered levels of certain blood serum proteins and mortality. They have observed that a higher percentage of patients with adequate levels of these proteins survived than did those with inadequate levels. Although this observation may be important in identifying which tests are of the greatest value in assessing the nutritional status of cancer patients, the experts do not yet know (1) whether an increase in blood serum protein levels of cancer patients can be effectively achieved through nutritional supplementation or (2) whether such an achievement will improve the patient's survival chances. Until they find out, they encourage postponement of cancer therapy while they attempt to increase the patient's blood serum protein levels through nutritional supplementation.

In commenting on our report, NIH stated that NCI recognizes the need for physicians to have a standardized set of nutritional assessment tests. To this end, NIH stated that NCI funded 10 new research contracts in fiscal year 1978, totaling \$1.6 million, to improve nutritional assessment techniques. NIH further stated that each contractor is required to collect a standardized set of available techniques against

1/Some of these tests may be done for purposes other than nutritional assessments.

which new methods will be compared with the ultimate goal of developing relatively simple, inexpensive, rapid, and standard nutritional assessment techniques for use by physicians in clinical settings. These research activities are to be presented at the upcoming meeting of the American Society of Parenteral and Enteral Nutrition in Boston, beginning January 31, 1979.

Uncertainty exists about the effectiveness of providing nutritional supplementation to cancer patients

In the past several years, nutritional supplementation has been provided to thousands of cancer patients, but its effect on reducing morbidity and mortality of cancer patients remains uncertain. Although some preliminary research indicates that nutritional supplementation may benefit certain cancer patients, several nutrition experts stated that malnutrition of some cancer patients is irreversible and that cancer patients in general may belong to a special group that does not respond well to nutritional supplementation.

Also, nutritional supplementation nourishes cancer cells as well as normal cells, possibly causing the cancer cells to reproduce faster in some instances. Experts we contacted acknowledged this possibility and said it could be detrimental in some instances, but studies headed by one expert indicate that this effect of nutritional supplementation is not detrimental to cancer patients. In fact, physicians told us that rapidly reproducing cancer cells are more likely to be destroyed through chemotherapy than are those that reproduce slowly.

Because of these uncertainties about the effectiveness of providing nutritional supplementation to cancer patients, physicians we contacted had a wide range of philosophies as to when to use it. Some physicians indicated that, when in doubt, they would tend to use nutritional supplementation methods such as TPN. They believe that, despite the risks of complications, none of the available nutritional supplementation methods has been shown to be harmful. They also believe that nutritional problems reduce cancer patients' chances for recovery. Other physicians indicated that, because of uncertainties about their usefulness with regard to cancer patients, these physicians would tend not to use nutritional supplementation methods such as TPN except in specific circumstances. Despite the varying opinions among physicians about specifically when to use nutritional supplementation, many physicians believed that it may be useful for patients who are scheduled to receive treatment

and most questioned the usefulness of nutritional supplementation such as TPN for the terminally ill cancer patient.

Patients scheduled to receive treatment

Physicians we contacted generally agreed that nutritional supplementation is at least possibly useful to the cancer patient who is severely undernourished and must undergo prolonged therapy. Physicians heading nutritional supplementation service teams at the hospitals visited believe that, based on their observations and some incomplete clinical studies, nutritional supplementation is useful under such circumstances. Of the physicians responding to our questionnaire, about 15 percent were of the opinion that nutritional supplementation such as TPN is definitely useful to the cancer patient under such circumstances, another 80 percent believed it possibly useful, and the remainder believed it useless or had no opinion. According to several physicians, the severely undernourished cancer patient may not be able to survive rigorous therapy unless he has undergone aggressive nutritional supplementation.

With regard to well-nourished cancer patients undergoing therapy, physicians had differing opinions as to the usefulness of nutritional supplementation such as TPN. Physicians heading nutritional supplementation service teams at the four hospitals believe that nutritional supplementation may be useful for a patient undergoing therapy that produces prolonged reduction of food intake, even though the patient is currently well nourished. One team leader stated that, because undernourished cancer patients will likely become malnourished by cancer treatment, nutritional supplementation should be considered early. Another team leader had placed a patient on TPN although he appeared to be well nourished and was eating well. The team leader explained that he was preparing the patient for surgery for a complex medical problem and hoped that early use of TPN would improve the patient's survival chances by maintaining the current nutritional status.

Physicians responding to our questionnaire had differing opinions as to the usefulness of nutritional supplementation for a well-nourished cancer patient undergoing therapy. Less than 20 percent of these physicians believed that nutritional supplementation such as TPN for patients under these circumstances was definitely useful, about half believed it possibly useful, and the remainder believed it useless or possibly detrimental or had no opinion.

Terminally ill patients

Most physicians responding to our questionnaire were of the opinion that nutritional supplementation such as TPN is useless or detrimental to the terminal cancer patient whose life cannot be expected to be lengthened by therapy. One nutrition expert we contacted believed that it could even be inhumane to use nutritional supplementation such as TPN in these circumstances because the patient's suffering could increase. However, another expert believed that, although nutritional supplementation for the cancer patient nearing death is not beneficial, such action may be appropriate for the terminal patient with some time to live because it might improve his quality of life.

Use of TPN is increasing patient care costs

TPN is costly. Total costs for TPN were not readily available at the hospitals we visited, but charges for TPN solutions and routine nutritional supplementation services often totaled about \$150 per patient day or more. In addition, the three hospitals charge for each placement of the subclavian catheter, laboratory work, and other services. The NIH Clinical Center does not charge for patient care services, but a Center physician estimated that the average additional cost for each patient on TPN is about \$130 per patient day just for the TPN solution and its administration.

Use of TPN is increasing rapidly. At Penn an expert estimated that, nationwide, its use is increasing 15 to 20 percent annually. In his hospital alone, the daily average number of patients on TPN has increased from an estimated 20 just over 2 years ago to 37 as of September 27, 1978. Of the 37 patients, 14 were cancer patients. Interest in TPN is such that this expert gives talks on the use of TPN to staffs of other hospitals several times a month.

Physicians believe that more research is needed in this field

Nearly all physicians responding to our questionnaire indicated that at least a moderate priority should be placed on supporting additional research on nutritional supplementation of the cancer patient. Nearly 20 percent of the respondents indicated that additional support of such research should be given the highest priority, while about 40 percent indicated it should be given a relatively high priority. Physicians often indicated either by questionnaire response

or during interviews that they believe nutritional supplementation could be found to be a useful supportive technique in cancer treatment but that there is as yet no real basis to believe that nutritional supplementation in itself could control or cure cancer. Although these physicians believe that additional support of research on nutritional supplementation of the cancer patient is worthwhile, they believe that the primary research emphasis should be on techniques with the potential for directly preventing, controlling, or curing cancer.

Some questions that experts believe need to be answered through controlled clinical trials and other types of research are:

- What groups of cancer patients benefit from nutritional supplementation in terms of increased (1) cure rates, (2) survival time, (3) response to therapy, and (4) quality of life?
- What are the special nutritional problems of cancer patients due to metabolic changes caused by the disease or the treatment?
- Can therapeutic benefits be derived by manipulating the cancer patient's nutritional intake?
- For what groups of cancer patients is TPN risky or detrimental?

There is a need for more research
on the importance of using TPN

Uncertainties about the importance of nutritional supplementation take on added significance with regard to TPN since (1) it is much more expensive than the other two methods of nutritional supplementation, (2) as yet unidentified differences may exist between the composition of nutrients provided directly into the veins through TPN, compared with nutrients from food passed on to the body through the gastrointestinal tract along with possible nutritional byproducts produced in the process, and (3) some experts believe that future research may show that nutrients can be manipulated through TPN so that healthy cells, but not cancer cells, are nourished.

All the nutrition experts we contacted indicated that additional clinical research is needed immediately to learn more about the importance of using TPN on cancer patients. They explained that the use of TPN is increasing so rapidly

that there is an imminent danger of its becoming an accepted medical practice in treating certain cancer patients without adequate evidence of its usefulness for this purpose. Several experts indicated that, if the technique becomes an accepted medical practice, properly designed controlled clinical trials may be impossible since ethical considerations may preclude withholding nutritional supplementation from patients used as controls. The result could be increased medical care costs and patient risk and discomfort, possibly without compensating benefits.

NCI plans to fund more nutrition-related research and participate in funding nutritional research units

NCI is funding several clinical trials designed to provide more information on nutritional supplementation. For example, at the NIH Clinical Center, two controlled clinical trials are being conducted to test use of TPN in conjunction with chemotherapy to treat patients with selected types of cancer. The three teaching hospitals we reviewed are among the six institutions participating in a similar clinical study funded by NCI contracts. A nutrition expert we contacted described this multihospital study as a "fair first attempt" but indicated that better designed studies must be performed to get more useful data.

The Biomedical Research and Research Training Amendments of 1978 (Public Law 95-622) direct the Department of Health, Education, and Welfare to conduct research on the role of nutrition in the treatment of disease. In September 1978, NCI announced to the scientific community that grant applications were being sought in the area of nutrition. As of December 1, 1978, NCI had received 76 applications. These applications were in the process of peer review at January 18, 1979. According to the Chief of NCI's Diet, Nutrition and Cancer Program, NCI also plans to participate in funding nutritional research units at up to 10 institutions that already have nutritional expertise as a means of making expert nutritional consultive services available throughout the Nation. NIH stated that it is not envisioned that all 10 nutritional research units can be developed this year, that it takes time for institutions to make such a commitment and prepare suitable applications, and that probably 3 such units may be established during fiscal year 1979 or early fiscal year 1980.

NIH has provided limited resources
to nutritional supplementation
activities at its Clinical Center

The resources presently provided at the Center limit the amount of nutritional research done there. The physician responsible for nutritional supplementation research at the Center believes that with additional resources he could significantly increase his nutritional supplementation activities. This physician currently conducts two major research projects involving nutritional supplementation. He also provides consultations to other Center physicians on the nutritional supplementation needs of their patients, provides TPN to patients that he determines to need such services, and performs surgery.

Several nutrition experts who described the physician as one of the Nation's most qualified researchers in the field of nutritional supplementation of cancer patients believe that nutritional activities in general, and this researcher in particular, are not adequately supported at the Center.

According to this researcher, there may be patients at the Center who could benefit from nutritional supplementation but who are not receiving such services because their attending physicians may not be aware of the possible benefits. He said he has not had enough time to pursue the matter.

The Center physician also stated that he could do little more in the area of nutrition research without additional help in the form of a senior investigator (who would require a small supporting staff) and 500 additional square feet of laboratory space. With this additional help, he believes that that he could more than double the number of research projects he conducts and could better assure himself that patients needing nutritional services get them.

Center officials are responsible for the Center's general operations, such as providing patient care services (dietetics, pharmacology, pathology, etc.), while the Director of NIH is responsible for allocating the Center's space among the institutes. Institutes using the Center provide support for certain specialized services, such as nutritional supplementation consultations and TPN, which are provided by NCI. We contacted NCI and Center officials, as well as the Director of NIH, about nutritional supplementation resources at the Center.

NIH officials agreed that additional resources are needed for nutritional supplementation activities at the Center but added that they probably would not be provided because of higher priority needs. Some additional laboratory space is to be provided for nutritional research in about 4 years, when an addition to the Center is scheduled for completion. At the Center, the Chief of NCI's Surgery Branch, which is responsible for providing TPN and nutritional supplementation consultations, told us that if he were given another senior investigator position, he would assign that position to nutritional supplementation activities. Although the official responsible for NCI's staffing at the Center (the Director of NCI's Division of Cancer Treatment) considered the addition of a senior investigator to nutritional supplementation activities to be a relatively high priority, he doubted that the need would be satisfied due to an even higher priority need coupled with staff and space shortages. He explained that he is currently staffing a newly established program in pancreatic cancer at the Center. The program is to include a study of the use of nutritional supplementation.

The Director of NIH explained that it is NCI's responsibility to decide how its activities will be staffed. He added that a board of experts which periodically reviews the activities of NCI's Division of Cancer Treatment will meet in March 1979. This group, known as the Board of Scientific Counselors, will review operations of the Division's Surgery Branch and will consider the resources needed for the Branch's nutritional supplementation activities.

NUTRITIONAL EDUCATION AND
TRAINING PROGRAMS MAY BE NEEDED

Nutrition experts we contacted believe that physicians may not place enough emphasis on their patients' nutritional needs. Several experts told us that some cancer patients could be placed at unnecessary risk because some of the Nation's hospital staffs are inadequately trained to administer nutritional supplementation and because nutrition awareness programs for outpatients are lacking. The Biomedical Research and Research Training Amendments of 1978 direct the Department of Health, Education, and Welfare to conduct nutritional education programs for both health professionals and the public. NCI has recently announced plans to support activities that include nutrition-related education for health care professionals and dissemination of nutrition information to the public. It also plans to establish nutrition research units throughout the United States. We believe that it may be appropriate for these units to have a training role which would include increasing skills of hospital

staffs to administer nutritional supplementation and increasing physician and patient awareness of cancer patients' nutritional needs.

In commenting on our report, NIH indicated that, while its request for applications for nutritional research unit grants did not address specific training and education needs, applicants have been requested to include in their proposals, plans in the area of nutritional education and training.

Physicians may not place enough emphasis
on the nutritional needs of patients

Several nutrition experts, as well as other medical personnel we contacted, believe that physicians are generally not placing enough emphasis on their patients' nutritional needs. One expert cited a study he had made which indicated that for half of the inpatients he had determined to be malnourished, there was no indication on the physician's order sheet of any effort to correct the problem. Another expert cited a case in which a patient was referred to him for surgery in such a malnourished state that he believed the patient could not have recovered from surgery had he not provided prior nutritional supplementation.

One reason nutrition experts cite for this apparent lack of physician awareness of the nutritional needs of cancer patients is the possibility that few medical schools adequately emphasize nutrition in their education programs. Harvard School of Public Health officials reported in the October 1973 issue of the "Journal of the American Dietetic Association" the results of their survey which showed that half of the Nation's medical schools' catalogs did not mention nutrition in any course description and only 4 percent of the catalogs showed an independent course in nutrition as a requirement for all medical students. On the other hand, many medical school officials believe that the appropriate way to teach nutrition is in conjunction with the teaching of other medical subjects, such as diabetes. Nutrition courses were listed as an elective in 17 percent of the catalogs and were mentioned as part of other courses required in the core curriculum in 16 percent of the catalogs. Although no credit courses in nutrition were shown in catalogs of the other 13 percent of the Nation's medical schools, some emphasis on nutrition was observed in biochemistry course descriptions.

As late as 1978, an American Medical Association survey of medical school curriculums showed that only 30 of 118

medical schools responding to a questionnaire required an independent course in nutrition. Further, a nutrition expert told us that, even where nutrition programs exist, they often do not provide adequate exposure to the area of protein-calorie malnutrition, a common problem with cancer patients. Two other experts we contacted have made studies which indicate that malnutrition is a problem with hospital patients. One study indicates that protein-calorie malnutrition was observed in almost half of the patients studied.

We are making a study of the nutritional training of physicians. The study includes a review of nutrition-related courses offered in medical schools.

Well-trained staffs can minimize risks to patients receiving nutritional supplementation

Several nutrition experts said that, although use of nutritional supplementation is rapidly spreading in the United States, nutritional supplementation procedures are often poorly performed. We were told that complication rates from use of TPN were very low at the hospitals we reviewed because they have well-trained, highly experienced staff administering it. Nutrition experts said that complication rates at other hospitals where TPN is provided, including infections which may be particularly dangerous to cancer patients undergoing chemotherapy or radiotherapy, are often much higher due to inadequately trained, inexperienced staff. Adequately trained personnel can substantially reduce risks associated with tube feedings. Use of tube feeding is less expensive than TPN, and experts we contacted indicated that TPN generally should not be used as a substitute for tube feeding or feeding by mouth. Yet, some physicians prefer to use TPN because of possibly fatal choking that has been associated with tube feeding. If these physicians were assured that adequately trained staffs were available to provide tube feedings, they might be more inclined to use this method, rather than TPN, in some instances.

Nutritional education programs for outpatients are lacking

Nutritional problems occur with outpatients, as well as inpatients. We were told that the hospitals we reviewed were relatively progressive in managing the nutritional needs of their patients, but even at these hospitals, relatively little was being done to manage outpatients' nutritional needs. For

example, Anderson had three dietitians assigned to outpatient duties, but the hospital's chief of clinical nutrition told us that a heavy outpatient load of over 900 patients per day limits the number of outpatients they can see. At the time of our visit, this hospital was developing a nutritional education program for outpatients, using literature and videotapes. Officials at both Penn and Deaconess acknowledged that their efforts to manage the nutritional needs of outpatients were limited, but they hoped to expand their efforts in this area.

At the NIH Clinical Center, one dietitian is assigned to service an outpatient load averaging about 350 patients per day. Duties of this dietitian include counseling patients and their families. We were told that wherever possible, the dietitian plans followup appointments to determine that the diet instructions have been understood and are being followed. The Center's chief of dietetics recognizes the need for better outpatient coverage, but space shortages preclude better coverage until a new outpatient wing is completed in 1982. The new outpatient wing will contain office space for an additional dietitian. At that time, the chief of dietetics hopes to implement a group teaching program for outpatients.

NCI could assist the medical community in coping with the needs of outpatients by having nutrition research units it plans to help fund promote nutrition education programs for cancer patients. For example, these units might (1) assess the need to provide additional outpatient awareness services in their areas, (2) cooperate with other organizations to establish patient education programs, (3) work with area hospitals to improve or expand existing patient education programs, or (4) establish their own outpatient nutrition programs.

CONCLUSIONS

Nutrition services provided to cancer patients at the NIH Clinical Center are generally comparable to those at the three teaching hospitals reviewed, except that TPN is used less often at the Center. Although medical personnel generally recognize that nutritional deficiencies can be a serious problem with some groups of cancer patients, great uncertainty exists about the effect of nutritional supplementation on the prognosis of such patients. One nutrition supplementation method, TPN, is expensive, is spreading rapidly, and poses some risks to the patient. More research is needed to clear up these uncertainties. NCI plans to fund more research which should help in this regard; we believe these plans should be actively pursued.

The resources provided at the Center limit the number of nutritional supplementation research projects to half of those that a physician it employs said he could be conducting. This physician was described to us by other experts as among the Nation's most qualified nutritional supplementation researchers. NIH has no immediate plans to provide him with more staff, but it does plan to assign him more laboratory space when a new Center wing is completed in 1982.

NCI should play a role in helping provide appropriate information to both medical personnel and cancer patients in order to assist them in becoming fully aware of the role of nutrition in cancer treatment. Information we were provided indicates that medical personnel may not always act to correct patients' nutritional problems because they are not aware of the importance of nutrition. Further, hospital staffs improperly trained to administer nutritional supplementation techniques can cause potentially dangerous complications. In addition, hospitals often lack nutrition education programs for outpatients. We believe that NCI should consider developing a role for the nutrition research units it plans to help fund in increasing skills of hospital staffs to administer nutritional supplementation and in increasing physician sensitivity and patient awareness to the importance of nutrition in cancer treatment.

RECOMMENDATION

We recommend that the Secretary of Health, Education, and Welfare instruct the Director of NIH to insure that it consider, for the proposed nutrition research units it plans to fund, a role of helping to increase skills of hospital staff to administer nutritional supplementation and physician and patient awareness of cancer patients' nutritional needs.

COMMENTS BY OFFICIALS OF ORGANIZATIONS WE REVIEWED AND OUR EVALUATION

As instructed, we did not request written comments from the organizations we reviewed, but we did request oral comments from them. Officials from these organizations, including NIH which provided written comments, indicated that matters discussed in our report are fairly and accurately presented. We incorporated their specific comments into the report where appropriate.