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AGREEMENT REACHED ON MOST CCOP ISSUES; FIRST RFA TO BE OUT IN MARCH, AWARDS TO BE MADE IN FISCAL 1983

NCI executives and their advisors have worked out the final controversial aspects of the Community Clinical Oncology Program, with only

(Continued to page 2)

In Brief

MOST NCI GRANTS, INCLUDING NONCOMPETING AND R01s, WILL TAKE CUTS OF AT LEAST 4 PERCENT; PAYLINES SET

HERE'S HOW NCI intends to fund grants with the overall four percent budget reduction in effect: R01s—noncompeting grants will be reduced four percent; competing grants will receive either recommended levels minus four percent or current levels plus eight percent, whichever is lower. The payline for competing grants is 180 priority score. P01s (program projects)—noncompeting, four percent reduction; competing, either recommended levels minus four percent or current levels plus seven percent, whichever is lower. The payline for P01s is 167. Organ site program grants—noncompeting, four percent cut; competing, recommended levels minus four percent or current levels plus eight percent, whichever is lower. The payline for organ site grants is 170. Cancer center core grants—noncompeting, four percent reduction; competing renewals, recommended levels minus four percent or current levels, whichever is lower. The payline is 209. Cooperative groups—noncompeting, four percent reduction; competing, no percentage formula, cuts to be established in negotiations, some will be substantial. New investigator awards—no reductions in noncompeting or competing awards. Competing R01s with priority scores from 180 to 197, and P01s with scores from 167 to 207, which would not be funded under the present plan, will receive three month phase out money amounting to 25 percent of last year's level. That will keep them going until the final budget picture clears up; NCI would pick them up and continue their funding if more money becomes available. . . . **HENRY KAPLAN** will speak on human hybridoma research on the first day of the National Cancer Advisory Board meeting, Feb. 1, 10:30 a.m. Other talks will be on foreign awards and opportunities for U.S. scientists to receive foreign support, by Claude Lenfant, director of the Fogarty International Center; cancer and minorities, by NCAB member LaSalle Leffall; and minority training and the M.D. Anderson experience, by NCAB member Robert Hickey. . . . **ONE FOURTH** of American cancer deaths in 1982 will be from lung cancer, the American Cancer Society reports in the 1982 edition of its annual publication, *Cancer Facts & Figures.* In 1950, lung cancer accounted for only 8.7 percent of cancer deaths. Lawrence Garfinkel, ACS vice president for epidemiology and director of cancer prevention, said, "If it weren't for lung cancer, the overall cancer death rate would actually be going down."

DEVITA, MOERTEL, ACCC REPS AGREE ON CCOP ISSUES; FLEXIBILITY ASSURED

(Continued from page 1)

one hurdle—the National Cancer Advisory Board—to clear before the program is initiated with publication of a request for applications.

The Board of Scientific Counselors of the Div. of Resources, Centers & Community Activities last week agreed to details which satisfied NCI Director Vincent DeVita, the foremost proponent of the program; Charles Moertel, chairman of the Board's Community Oncology & Technology Transfer Subcommittee which played a primary role in drafting CCOP guidelines; and Charles Cobau, member of the Board and subcommittee and former president of the Assn. of Community Cancer Centers which developed its own recommendations for CCOP, most of which have now been written into the guidelines.

Gale Katterhagen, an NCAB member and also a former ACCC president, agreed that the final draft of the guidelines was acceptable.

The major items left apparently unresolved following the DRCCA Board's previous meeting was that of the relationship of the CCOP community institutions and the "research bases," the cooperative groups or cancer centers with which each program must be affiliated.

Moertel had argued that research bases should receive their funds directly from NCI, while ACCC and NCI staff felt they should go through the community organizations. Previous relationships between community hospitals and university centers or cooperative groups sometimes have resulted in communities having little to say about management of the consortia, protocol development, etc. Communities needed the leverage of control of the money, ACCC argued.

Moertel also was concerned about disrupting prematurely and unnecessarily existing community-cooperative group relationships which have been developed through NCI's Cancer Control Cooperative Group Program. Six cooperative groups were funded to extend their clinical trials into community hospitals, and some have been so successful that up to 40 percent of their patients on group protocols are coming from the communities.

Two of those contracts expire April 1 and three end on May 1 of this year. The other is a grant, to the Northern California Oncology Group. The Board last fall approved a recompetition for two more years, with the understanding that they would be phased out as CCOP is implemented.

DeVita, the DRCCA Board including Moertel and Cobau, and Katterhagen attending the meeting as an NCAB observer, agreed that these general principles would be applied relating to those controversies:

- CCOP community institutions will be the principal agencies in the cooperative agreements, making their own arrangements for CCOP research base support. When it is appropriate, research bases may receive funds directly from NCI for support of their community related activities; in most cases, that would be from the existing Cancer Control Cooperative Group Program, or other mechanisms such as supplements to their cooperative agreements funds administered by the Div. of Cancer Treatment. An "appropriate" instance of direct payment to a research base from CCOP funds could be when it is affiliated with several CCOPs, making it more efficient to handle with one payment mechanism. NCI intends to develop guidelines which permit flexibility in those arrangements.
- Research bases with existing community programs will have to affiliate with a CCOP (probably with several) or have their funds reduced accordingly. Some of their present affiliates may compete successfully for CCOP awards. If not, they will be expected to seek affiliation with those that do.

As CCOP matures, the expected result will be a steady and sufficient flow of patients into cooperative group trials which should permit phasing out of the cancer control contracts without harm to the groups.

Donald Buell, DRCCA program director for community activities, said that with NCAB concurrence, the CCOP RFA would be published before the end of March. Applications would be due by late July, with review to be completed in time to send recommendations to the NCAB at its first meeting (January or February) in 1983. A total of $3 million will be set aside in the 1983 fiscal year budget to support the program in its first year.

DeVita said he did not expect more than 25 to 50 CCOP awards being made in the first year. "Most people think that right now no more than that will be able to do it. We could handle 200 at $100,000 (not in 1983, however)." He insisted he did not want to get pinned down on numbers of CCOPs NCI eventually will support. "I have vivid memories of the CHOP controversy over 23 versus 30. It was under the stimulus of that that the idea of CCOPs popped into my head."

The Community Hospital Oncology Program, which includes clinical and cancer control elements but not the requirement to enter patients into national protocols that CCOP will have, funds contracts with 23 hospitals or consortia. NCI at one time had suggested it might support 30 CHOPs; considerable bitterness ensued when only 23 awards were made.

The figure 200 as the ultimate number of CCOPs was rather loosely developed as that needed to provide reasonable access to them to the greatest number of patients around the country. DeVita has said that when that many good programs can be developed and pass peer review, "we'll find the money to sup-

Supplement
THE CANCER LETTER
Jan. 22, 1982

A Collaborative Evaluation Design For The Community Hospital Oncology Program (CHOP)

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SYNOPSIS

In this initial paper, fourteen (14) of the recently funded Community Hospital Oncology Programs describe how they have joined together to develop a sophisticated evaluation of their local CHOP programs as well as key national questions regarding the CHOP concept and community cancer care. The authors describe their understanding of the concept, the evaluation design process, the evaluability of the CHOP model, accepted and rejected hypotheses, the methods chosen, key clinical variables and future directions for the project.

INTRODUCTION

This plan is the product of an extraordinary collaborative process. The Principal Investigators, Administrative Directors, Oncology Nursing Coordinators, Tumor Registrars and Committees of the fourteen participating CHOP's contributed over 3,500 hours of time in its development to date. An effort of this magnitude reflects the genuine interest of the authors and other participants in the testing of key questions about community cancer care which we discuss in this article.

The fourteen programs which participated in the evaluation design (which we describe as the National CHOP Evaluation Study Group) constitute 60% of the 23 funded CHOP's, and 75% (40) of the 57 CHOP hospitals. We realize this is a substantial group of institutions with which to test hypotheses. Moreover, the participants represent:

- 7 of the 13 funded single hospital CHOP's
- 6 of the 9 funded urban consortia CHOP's
- the sole funded small community CHOP.

The National Study Group concept arose out of a desire of some CHOP contractors to ensure development of an evaluation that:

- used scientifically meaningful methods;
- allowed comparable data to be collected and analyzed;
- permitted the larger questions of CHOP effectiveness to be studied;
- included a sufficiently large sample to test causal relationships;
- was timely, allowing individual CHOP's to develop data systems that are compatible with evaluation needs;
- contributed significantly to advancing our knowledge of how community cancer programs can have a significant impact on care of cancer patients.

Thus, several issues were constantly at the forefront of discussions in the evaluation design process. First, throughout the process, Study Group members indicated a desire for a scientifically valid study. At several crucial decision points, members opted for rigor, although it meant a greater data burden.

Second, the Study Group members participated fully in discussions of alternative evaluation designs. While some program members exhibited a high degree of prior knowledge of evaluation, each methodologic issue was described and discussed openly, and decisions were made by open vote or consensus. Group members were in full control of the process.

Third, the Study Group chose to consider all parts of the program on a collective basis. Thus, for example, while there is a Nursing Component subcommittee, the Group chose to review together the possible research hypotheses and data collection that would relate to the Nursing Component. This ensured that the total data collection burden imposed by all segments of the study was collectively considered by all CHOP leaders in the context of individual program resources.

Fourth, the Study Group members discussed the function of the evaluation design as being useful for the individual program as a single program's local evaluation; and, useful nationally as a collective evaluation of the CHOP concept.

Study Group members recognized and discussed the problems inherent in an isolated single program evaluation, including:

- A tendency to collect data which cannot answer meaningful questions;
- Inability to control for ongoing environmental changes (i.e., all communities change their patterns of care in some fashion over time);
- Inability to develop significant analysis of causation, due to small sample sizes, lack of adequate controls, etc.;
- Inability to make meaningful comparisons with other single program evaluations due to differences in definition (e.g., different staging systems used for the same organ site).

It was our concern over the viability of isolated single program evaluation that, in large part, sparked the formation of the Group. As a group and individually, the participating CHOP's are clearly committed to the development of a high quality meaningful evaluation that will illustrate the utility of the concept (or its lack of utility), to members of Congress, scientific peers, NCI staff and most importantly, to the physicians and other health professionals in our communities who have invested their own time and interest in the development of our individual Community Hospital Oncology Programs, and who want to know if it makes a difference.

THE CONTEXT FOR EVALUATION: The Rationale for The National Cancer Institute's Community Hospital Oncology Program

In late 1980 and early 1981, the National Cancer Institute funded twenty-three demonstration programs to test some of the prevailing concepts on ways community cancer programs can organize to stay current with rapid changes in state-of-the-art cancer management. The basic concept is to provide administrative resources to community physicians and other health professionals to develop voluntary, cancer site-specific guidelines for management of cancer patients. In the process of formulating (and later revising) these guidelines, physicians and other health professionals become acquainted with prevailing concepts of cancer management, primarily through reviews of the literature and discussion.

Alternative methods of conveying new technology to community health care providers have been attempted in the past with mixed results. The CHOP concept departs from other approaches in several ways. It funds the community directly to seek out new technology. It provides sufficient funding for communities to develop and maintain data systems that record and report both the outcomes of care and the process of care. It consciously attempts to impact a broad range of physicians in the community, rather than just the oncologic specialists. It is based upon seven pilot demonstrations (the Clinical Oncology Programs, primarily the Grand Rapids COP) which have been able to demonstrate the potential for improved end-results with increased utilization of locally-developed voluntary guidelines.

The program is primarily aimed at affecting physician behaviors. Studies conducted in several community hospitals indicate that over fifty percent (50%) of cancer patient admissions are by physicians who see ten or less cancer patients each year. These physicians tend to be primary care physicians. Thus, the CHOP strives to involve as many non-specialists as possible, investing them in the process of guideline development, and involving medical staff who account for at least 75% of cancer patient admissions.

Since the first management decisions are critical to the patient's eventual outcome, the CHOP guidelines tend to concentrate on pre-treatment evaluation, staging, appropriate consultations, and multidisciplinary cancer treatment. Given the rapid changes in technology, most guidelines do not tend to specify a treatment regimen (e.g., x amount of Adriamycin or y number of rads).

The program reinforces the decisions of the physician committees by placing copies of the guidelines on the charts of patients and by regularly reporting to medical staffs the number of patients treated according to the guidelines. Reporting of data on the process of care is a departure from traditional cancer reporting systems, which focus on end results.

Thus, utilizing both participatory process and rapid feedback techniques, the CHOP concept combines methods to effect the rapid transfer and adoption of new technology and a system to measure the effects of the program.

THE PROCESS OF EVALUATION DESIGN DEVELOPMENT

ELM Services, Inc., under the direction of Mr. Lee E. Mortenson and Dr. David J. English, facilitated the development of the fourteen linked evaluations utilizing evaluability assessment techniques and group process techniques to: 1) Define the causal logic underlying the CHOP project; 2) define key purposes and objectives of the CHOP experiment as seen by NCI; 3) determine key research questions which relate to each objective; 4) define possible research hypotheses which could be investigated for each question; 5) determine the priority of researchable hypotheses on the basis of data availability, data collection burden, national priority, relationship to key CHOP purposes, and availability of credible and validated instruments; and 6) define data collection instruments, procedures, and suggested data analysis plans.

As a preliminary to the evaluation design requested by the 14 programs, ELM (at its own expense) chose to utilize the process of evaluability assessment (at first suggested by Wholey, later by Schmidt, et. al.) to assist in definition of the evaluation questions.

Evaluability assessment is designed for use primarily with operating programs, not demonstrations. This means that some of the techniques usually employed may be of less use in this case. For example, in a case where program demonstrations are involved (rather than ongoing programs), it is difficult to conceive of demonstration objectives being changed midway through the demonstration. This would obviously affect the evaluability of the rest of the program and would likely encounter serious objections from contractors who applied for and received demonstration funding under set objectives.

One of the other potential drawbacks of evaluability assessment is its reliance on a sample of program operators. This limits input and does not provide adequate opportunity for independent contractors to develop a consensus on the kinds of evaluation they can successfully support. We have reviewed this concept and specific use of evaluability assessment with Dr. Joseph Wholey, the originator of the technique. He concurs with our judgments and with the specifics of this formulation.

Assessment of CHOP Evaluability

Assessment techniques were utilized as the prelude to evaluation design to determine the perceptions of Congressional, National Cancer Institute and cancer community leaders on the purposes of the demonstration and the questions they expect it to answer; to determine the perceptions of program operators about the questions the program is expected to address; to determine the degree to which perceptions agree with program objectives; and to determine the degree to which program objectives can be measured. Specifically, ELM staff conducted a brief literature search on the Congressional basis for the program, and on some of the theoretical framework which includes the program concept. Based upon the review of the literature, the RFP, and bidders conference materials, nine program objectives were identified and logic models developed. Logic models were reviewed with Congressional staffs, two members of the NCAB, two members of the DRCCA Board, key members of the national cancer community and NCI staff.

The Study Group then met in Kansas City, where logic models were reviewed and modified to reflect individual CHOP review and dissemination processes. Specific questions based upon program objectives were formulated. Potential data sets and variables were also discussed. A uniform set of critical cancer management events (which we call the National Clinical Data Set) was formulated by physician directors, allowing the development of a uniform national comparison of patterns of care.

Next, site visits to all fourteen programs were conducted to determine the availability of potential data sets and variables for measurement.

Exhibit 1 illustrates the program's basic logic and best illustrates the understanding expressed by national leadership, program management, and Principal Investigators of the demonstration's intent and likely causal logic chain. Essentially, Federal resources, combined with local participation and resources (inputs) are utilized to support the development of guidelines, targeted educational measures and feedback to providers on the processes of care. This should result in changed patterns of care and impact on the mortality and morbidity of patients.

Exhibit 2 is an expansion of the basic concept and includes both the program planning and program implementation phases. It should be noted that the familiar input-process-outcome cycle is expanded and repeated in this model. Indeed, it is clear that one phase's outputs are the next phase's inputs. Specifically, this expanded logic model suggested a more complete process which opens our view of the causal chain underlying the CHOP program.

The first two columns of boxes note the Federal and local inputs. The next four columns describe the planning process, with the following four columns detailing the implementation process, its eventual impact on local outcomes (mortality, quality of life) and Federal objectives for the demonstration.

Exhibit 3 extends the logic model concept, incorporating potential questions about events at each step. This exhibit allows us to look at the generic flow of events (the top row of boxes) and at the individual measurable changes in the causal logic chain.

Among the questions this model poses are: Were Federal resources expended? Were local resources allocated? Did local CHOP processes happen? Was approval of local groups received? Were final products developed? Were products disseminated? Were products used? Did changes occur? Did patient outcomes improve? Did program results have a larger impact?

Exhibits 1, 2, and 3 were utilized by ELM staff in interviews with key leaders, NCI staff and program participants. Exhibit 3 was utilized as a method of focusing attention on specific questions and to define linkages of prior events to later consequences. For example, one could ask the question, "Did the physician patterns of care change?" In and of itself, this is an interesting question. But, of course, we are more interested in knowing if it can be linked to some prior event, such as physician participation on site committees.

Based on the interviews, logic models, group process sessions, and site visits, staff concluded that the CHOP model is evaluable.

The techniques of evaluability assessment were easy to apply to this demonstration model. However, it should be noted that in this case there were clear objectives stated in the RFP, which were utilized by the programs in their applications and by the review committees in selecting applicants. Further, pilot programs had been developed and received a high level of media support in advance of the development of this new demonstration. Thus, it is not surprising that a high degree of concurrence on program purpose, objectives, critical questions and even processes of program development and management were well known. Nonetheless, the techniques of evaluability assessment (literature review, logic models, interviews, group process sessions, and site visits) were instrumental in expediting the evaluation development process.

Through use of evaluability assessment techniques we are able to conclude the following: There is consensus of CHOP program purpose. There is consensus of the major elements of the program (i.e., objectives). There is consensus on how the programs will function. There is consensus on the key questions the demonstration must answer. There is consensus among Study Group members on the key elements to be gathered in order to evaluate the key questions. Given this high degree of consensus, local program evaluations of CHOP can be linked together to answer both local and national questions.

EVALUATION DESIGN

Following the development of 30 specific questions, contractor staff prepared an Interim Report for Study Group member review. This report suggested 70 possible null hypotheses, based on the 30 questions. For each of these hypotheses, the contractor developed and presented to Study Group members: 1) the cancer *sites* for which data would be collected; 2) *variable categories* which would be tested, with specific examples of possible variables; 3) *research comparisons* and *experimental designs* (including time periods of data collection; 4) *unit of analysis* (i.e., the patient, the physician, the hospital, the nurse, etc.); 5) *sample size;* 6) *sampling plan;* 7) *methodology* including source(s) of the data, method of collection, and data collector; 8) *data burden,* an arbitrary designation based on ELM approximation of level of CHOP staff effort to collect data, scaled on a 1 to 10 basis with 10 being most burdensome; 9) potential *effects on data quality* (i.e., absence of data, lack of physician cooperation, etc.); 10) potential *data collection problems* that might raise questions of accuracy or reliability of data.

Study Group members reviewed each hypothesis and accepted or rejected it on one or more of the following criteria: 1) centrality to evaluating the CHOP concept in a nationally credible manner; 2) the national priority of the question; 3) the likelihood that the hypothesis can be tested given available data; 4) the cost of data collection given the most valid method; and 5) the staff burden of data collection. A final group of hypotheses was thus defined by the Study Group.

A. Summary of Hypotheses To Be Tested

The following 17 hypotheses were selected for study. In this section we note the objectives to which specific hypotheses relate, the likely levels of interest in the results of the study, and major rationale for selection. It should be noted that several hypotheses were consolidated during the Group's discussion.

Objective 1 — To define and implement appropriate and complete pretreatment evaluation and staging of newly diagnosed cancer patients.

Objective 2 — To incorporate multidisciplinary recommendations into patient management decisions.

The following hypotheses were selected for testing:

- Hypotheses 1 — There is no difference in the critical elements of management (as defined by the National Clinical Data Set) provided the cancer patient due to the CHOP.
- Hypothesis 2 — There is no difference in the percentage of cancer patients being managed according to the local guidelines due to the CHOP.
- Hypothesis 3 — There is no difference in the work-up for extent of disease provided the cancer patient due to the CHOP.
- Hypothesis 4 — There is no difference in request for multidisciplinary consultations due to the CHOP.
- Hypothesis 5 — There is no difference in cancer patient mortality due to the CHOP.

Rationale for inclusion: Hypotheses 1 through 5 were all considered to be of the highest priority by CHOP Principal Investigators, NCI program staff and members of the national cancer community. Specifically, the concept of showing significant differences in the process of care (Hypotheses 1-4) and in length

of survival and mortality (Hypothesis 5) were mentioned as important by all those interviewed. While data burden was considered to be extremely high in all cases, the centrality of these concepts to testing the CHOP concept outweighed other considerations.

These hypotheses (with the exception of Hypothesis 2) are to be tested using comparison communities and all will be analyzed in relation to other variables, such as physician participation in site committees, CHOP educational conferences attended, etc.

Objective 3 — To create a mechanism to assure that appropriate specialized treatment protocols are available in the community and that referral to specialized centers will be facilitated for cancer patients needing such care.

The following hypothesis was selected for testing:

• Hypothesis 6 — There is no difference in the number of cancer patients formally registered on research protocols before and after CHOP development.

Rationale for inclusion: This hypothesis has a moderate rating by CHOP Principal Investigators, but was considered relatively easy to test and of some importance to NCI leadership and staff.

Objective 4 — To provide cancer nursing procedures of the highest standards and under the advice and guidance of trained oncology nurses.

The following hypotheses were selected for testing:

• Hypothesis 7 — There is no difference in the attitude of nurses toward cancer patients before and after participation in CHOP core curriculum training.

• Hypothesis 8 — There is no difference in knowledge of nurses before and after participation in CHOP core curriculum training.

• Hypothesis 9 — There is no difference in the administration of cancer patient pain medication by nurses before and after CHOP program implementation.

• Hypothesis 10 — There is no difference in cancer patient anxiety before and after CHOP implementation.

Rationale for inclusion: These four hypotheses represent the most difficult decisions on the part of the Study Group. While each addresses a key objective of the CHOP concept, the data burden is substantial, instruments are scarce and in some cases archival records must be used where documentation is questionable. Nonetheless, Study Group members expressed interest in determining the effects of nursing core curriculum training (Hypotheses 7 and 8) and while most nursing care activities are not regularly documented in the chart, pain management appears to be one measure considered to be more reliably reported than others. Thus, Study Group members and Subcommittee members suggested this as one area where possible changes in the patterns of nursing care could be most readily observed (Hypothesis 9). CHOP program oncology nurse coordinators uniformly reported their expectation that patient anxiety would be reduced as a direct by-product of the CHOP oncology nursing program (Hypothesis 10), and thus, this outcome measure was also selected for study.

Objective 5 — To develop a coordinated hospital-community resource to assure that necessary cancer rehabilitative and appropriate supportive care resources are available and utilized.

The following hypotheses were selected for study:

• Hypothesis 11 — There is no difference in referrals to cancer rehabilitation and supportive services before and after CHOP program development.

• Hypothesis 12 — There is no difference in the assessment of cancer patients' rehabilitation and supportive care needs as documented in the discharge plan before and after CHOP program development.

• Hypothesis 13 — There is no difference in the cancer patient's quality of life before and after CHOP program implementation.

Rationale for inclusion: Measures for all three of these hypotheses present problems of reliability and validity. Hypotheses 11 and 12 were chosen to begin the development of some base line measurements, which, it must be noted, are considered to be separate from classic evaluation. Study Group members recognized the inherent weakness of archival data in both cases but felt primary data gathering and likely changes in documentation were important to stimulate, record and observe. Hypothesis 13 has a wide body of literature and some validated instruments; however, Study Group members recognized that quality of life remains an elusive concept. While this measure (Hypothesis 13) is associated with Objective 5, it clearly relates to the total CHOP program. Data burden is moderate to high.

Objective 6 — To provide a continuing care program that the terminally ill might receive the benefits of modern pain and symptom management in an atmosphere that emphasizes the quality of survival and death with dignity.

The following hypotheses were selected for study:

• Hypothesis 10 (described above)

• Hypothesis 13 (described above)

• Hypothesis 14 — There is no difference in referral to terminal care resources before and after CHOP development.

• Hypothesis 15 — There is no difference in resources available to the terminally ill cancer patient before and after CHOP development.

Rationale for inclusion: Study Group members determined that terminal care resources were sufficiently limited to permit relatively open access to appropriate referral records (Hypothesis 14). While the outcome of Hypothesis 15 is likely to be a simple number, and causality difficult to associate, Study Group members expressed the opinion that it would illustrate levels of activity under this objective. Data burden was considered modest for both hypotheses. Hypothesis 13 (on quality of life) and Hypothesis 10

(on patient anxiety) may also be important in measuring this objective.

Objective 7 — To assure that up-to-date cancer management information is continually made available to physicians, nurses, and other health care personnel.

The following previously stated hypotheses relate to this objective:

- Hypothesis 1
- Hypothesis 2
- Hypothesis 3
- Hypothesis 4
- Hypothesis 5
- Hypothesis 7
- Hypothesis 8

Rationale for inclusion: Previously stated and also useful in the context of this objective, each of these hypotheses measures the educational process of site committees, guidelines on the chart, and nursing educational sessions, all of which are likely to be unique to the CHOP.

Objective 8 — To develop and implement a cancer data management system that permits monitoring of program effectiveness, documentation of program accomplishments, assessment of community cancer care practices and patient outcome status.

The following hypothesis was selected for study:

- Hypothesis 16 — There is no difference in physician utilization of patient care data systems before and after CHOP development.

Rationale for inclusion: Study Group members expressed the opinion that the basic index for the development of an effective and useful cancer data system will be the frequency of its utilization by physicians. Data burden was considered to be light.

Objective 9 — To develop a community endorsed plan to continue the cancer care program after Federal funding ceases.

The following hypothesis was selected for study:

- Hypothesis 17 — There is no difference in the presence of identifiable elements of the CHOP before and after termination of CHOP funding by NCI.

Rationale for inclusion: Study Group members noted that data burden for this important concept was modest and the centrality to the CHOP concept high.

B. Hypotheses Rejected for Testing

Hypotheses were rejected for testing based on the criteria stated earlier (i.e., centrality to the CHOP concept, national priority of the question, likelihood of testing the hypotheses, cost of data collection, and staff burden). It should be noted that several originally suggested hypotheses were consolidated into the 17 hypotheses to be tested.

In this section we note the objectives to which specific hypotheses relate, and a brief rationale behind their rejection. The Group indicated that some very high priority questions could not be addressed given the limitations on funding.

Objective 1 — To define and implement appropriate and complete pretreatment evaluation and staging of newly diagnosed cancer patients.

Objective 2 — To incorporate multidisciplinary recommendations into patient management decisions.

The following hypotheses were rejected for testing:

- Hypothesis 18 — There is no difference between date of diagnosis and date of treatment by consulting physicians due to the CHOP.
- Hypothesis 19 — There is no difference between date of completion of work-up for extent of disease and definitive treatment due to the CHOP.
- Hypothesis 20 — There is no difference in the length of time between detection and diagnosis due to the CHOP.
- Hypothesis 21 — There is no difference in the length of time between date of diagnosis and date of referral(s) to consulting physicians due to the CHOP.

Rationale for rejection: These four (4) hypotheses were originally developed to consider the effect the CHOP might have on speeding referrals to subspecialists. They were rejected for several reasons. First, centrality to the CHOP concept was low to moderate. Second, documentation of specific dates, especially of detection, would be difficult. Third, Group members did not believe that speed, in and of itself, was important. The major emphasis was considered to be appropriate action.

Objective 3 — To create a mechanism to assure that appropriate specialized treatment protocols are available in the community and that referral to specialized centers will be facilitated for cancer patients needing such care.

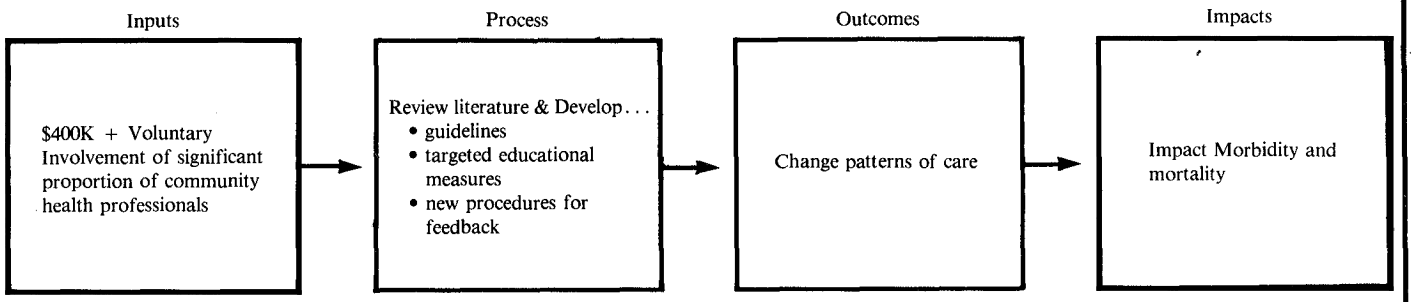
The following hypotheses were rejected for testing:

- Hypothesis 22 — There is no difference in the number and type of referrals to university-based cancer centers before and after CHOP development.
- Hypothesis 23 — There is no difference in the number of contacts with educational programs of university-based cancer centers before and after CHOP development.

Rationale for rejection: Interface with university-based cancer centers is an important aspect of the CHOP. In an attempt to consider this relationship, Hypotheses 22 and 23 were considered. Both were rejected for several reasons. First, records on referrals (Hypothesis 22) are not kept as part of the chart in all cases. Many times the patients are referred before they even enter the hospital (i.e., before they would be recorded as a CHOP patient) or well after discharge, when this referral is likely not to be documented. Since CHOP records are inadequate to test this question, Study Group members considered contacting centers to ask them to sort their data. However, this was rejected as a methodology since it is likely that centers would have records that only indicated a referring physician who, in turn, might have

EXHIBIT 1

BASIC LOGIC MODEL
COMMUNITY HOSPITAL ONCOLOGY PROGRAM



multiple hospital privileges. Further, some patients might come to the center having been referred by a physician from a CHOP hospital, but not be recorded as a CHOP patient.

Hypothesis 23 was rejected for similar reasons. Much of the contact with centers on educational programs, or joint programs of any type, is likely to be informal. Quantity is not likely to be meaningful. Joint programs with the centers are likely to be meaningful but will vary significantly from CHOP to CHOP and center to center.

Objective 4 — To provide cancer nursing procedures of the highest standards and under the advice and guidance of trained oncology nurses.

The following hypotheses were rejected for testing:

- Hypothesis 24 — There is no difference in patterns of teaching by nurses of the patient/family/significant other due to the CHOP.
- Hypothesis 25 — There is no difference in knowledge of patient/family/significant other about self-care due to the CHOP.
- Hypothesis 26 — There is no difference in the attitude of the patient/family/significant other due to the CHOP.
- Hypothesis 27 — There is no difference in the self-care behavior by the patient/family/significant other due to the CHOP.
- Hypothesis 28 — There is no difference in patient satisfaction resulting from the "functional oncology nurse component" before and after CHOP development.
- Hypothesis 29 — There is no difference in the patient's perception of accessibility of care resulting from the "functional oncology nurse component" before and after CHOP development.
- Hypothesis 30 — There is no difference in referrals made by nurses before and after CHOP development.

Rationale for rejection: These seven hypotheses on the oncology nursing portion of the CHOP were very difficult for the Study Group to reject. Indeed, several were considered of very high priority, but the additional data collection burden (above those nursing-related hypotheses which the Group accepted) was considered to be beyond the capabilities of the programs to perform without significant additional funding.

Specifically, Hypothesis 24 and Hypothesis 27 are testable hypotheses but require on-site observation by trained observers to be meaningfully tested. The cost for centrally trained observers is obviously beyond the means of the programs and local observers were likely to vary widely in training, objectivity, observation experience, etc.

Knowledge and attitudes about self-care (Hypothesis 25 and Hypothesis 26) were possible surrogates for actual observation of behavior, but were considered to be less reliable measures and more intrusive on patients. The observation was considered less intrusive since the nurse will ask the patient and/or surrogate to repeat the self-care technique. The other forms require the patient or surrogate to do something additional (i.e., respond to a survey) which does not directly benefit the patient and thus, adds to their burden.

Hypothesis 28 and Hypothesis 29 were rejected because of similar patient burden and because of concerns over definition and documentation. The "functional oncology nursing component" varies significantly from CHOP to CHOP. Prior documentation of patient perceptions of accessibility and patient satisfaction are nonexistent except in one or two programs. The Group considered changing these hypotheses to "before and after CHOP implementation" but determined this was insufficient to correct all of the other data collection difficulties (i.e., definition of the component and of the patients affected; patient burden; staff data collection burden; lack of validated instruments).

Hypothesis 30, on nursing referrals, was rejected based upon the lack of available documentation. A survey of all fourteen programs indicated that several phenomena were likely to interrupt the successful study of this activity. Specifically, many nurses do not chart their referrals; many nurses catalyze physician referrals, but are restricted in their own referral authority; referral authority is likely to be an institution-wide policy, with informal deviations on some units; and while it is expected that charting of referrals will increase, the actual amount of increased re-

EXHIBIT 2

PROGRAM LOGIC MODEL

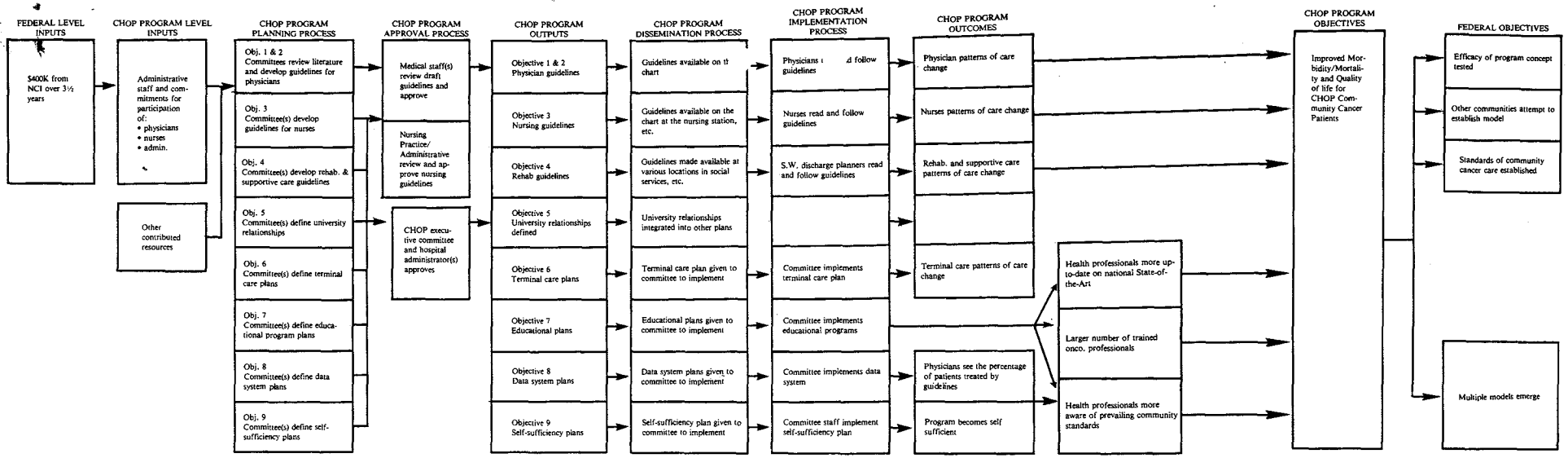
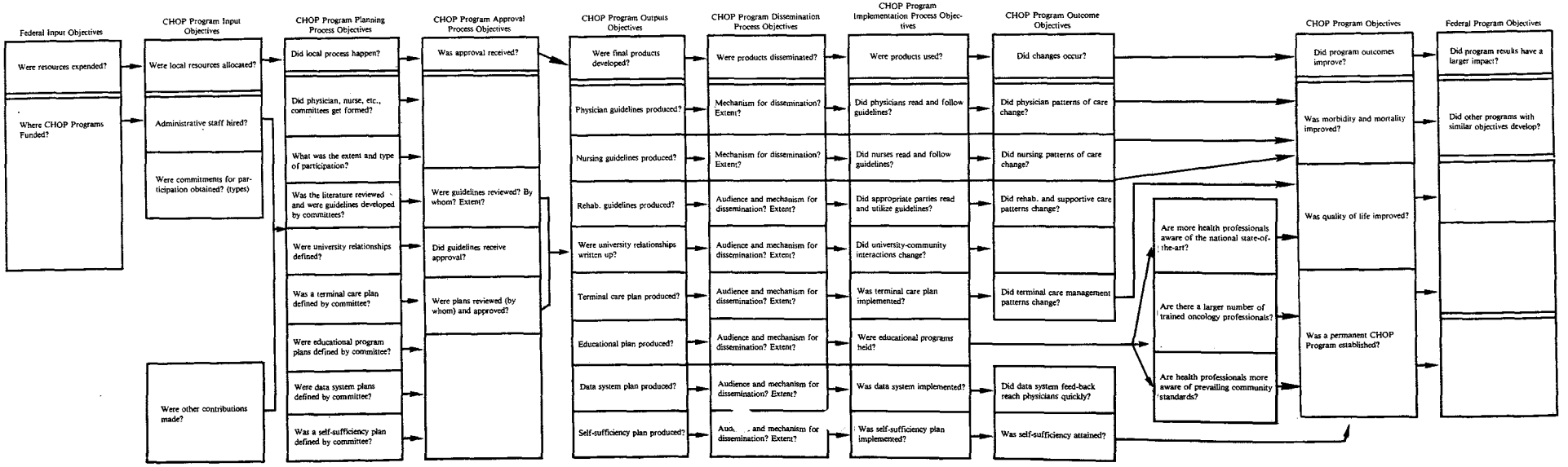


EXHIBIT 3

CHOP PROGRAM MEASURABLE OBJECTIVES



ferrals or those attributable to CHOP would be impossible to determine.

Objective 5 — To develop a coordinated hospital-community resource to assure that necessary cancer rehabilitative and appropriate supportive care resources are available and utilized.

The following hypotheses were rejected for study:

- Hypothesis 31 — There is no difference in the cancer patient's activities of daily living before and after CHOP program implementation.
- Hypothesis 32 — There is no difference in the perception of patients in regard to their rehabilitation needs being met before and after CHOP development.
- Hypothesis 33 — There is no difference in the attitude of physicians toward use of supportive services before and after CHOP development.
- Hypothesis 34 — There is no difference in the timing of identification of rehabilitation needs before and after CHOP development.
- Hypothesis 35 — There is no difference in the identification of "teaching needs" as documented in the discharge plan before and after CHOP development.
- Hypothesis 36 — There is no difference in the degree to which identified rehabilitative needs are met before and after CHOP development.
- Hypothesis 37 — There is no difference in the perceptions of health professionals with regard to patient rehabilitative needs before and after CHOP development.
- Hypothesis 38 — There is no difference in the perceptions of patients and health professionals with regard to patient rehabilitative needs before and after CHOP development.
- Hypothesis 39 — There is no difference in the number and type of ancillary personnel used by physicians before and after CHOP development.

Rationale for rejection: These nine hypotheses were rejected primarily because of the difficulty in collection of valid data, their lesser national priority, and lack of centrality to the CHOP concept.

Hypothesis 31 on activities of daily living was rejected due to the difficulties of administration and data collection.

Patient attitude (Hypothesis 32), physician attitude (Hypothesis 33), health professionals' perceptions of rehabilitative needs (Hypothesis 37), and differences between patient and health professional perceptions (Hypothesis 38) are all important concepts. Increased exposure to the interdisciplinary team through committee meetings might change physician attitudes and health professional perceptions, but these are not explicit objective of CHOP interventions. Patient attitude may or may not be a measure of actual linkage to services, which *is* a CHOP objective.

The timing of identification of needs (Hypothesis 34), the actual identification of "teaching needs" (Hypothesis 35) and the degree to which needs are met (Hypothesis 37) are central to the CHOP concept. There are, however, significant problems in data collection. First, a survey of hospital charts shows that actions by social service, social workers, discharge planners and nurses are *sometimes* charted. Without exception, none of the institutions in this group could exhibit charting of needs in any consistent fashion. This is not uncommon in any institution. Thus, useful pre-test data is not available. If we alter the hypotheses to consider pre- and post-CHOP implementation, allowing documentation to be upgraded in the next six months, we still encounter major secondary effects of the change in documentation.

Recognizing the importance of this area, the Group determined to focus on documentation and referrals to certain documented services (Hypothesis 11 and Hypothesis 12), and to collect data about service delivery, rather than attempt to measure change.

Hypothesis 39 (on ancillary personnel use) was judged to be too low in priority to pursue.

Objective 6 — To provide a continuing care program that the terminally ill might receive the benefits of modern pain and symptom management in an atmosphere that emphasizes the quality of survival and death with dignity.

The following hypotheses were rejected for study:

- Hypothesis 40 — There is no difference in the attitudes of physicians and health care professionals toward caring for the terminally ill before and after CHOP development.
- Hypothesis 41 — There is no difference in the perceptions of physicians and other health care professionals toward death and dying before and after CHOP development.

Rationale for rejection: While some instruments have been devised and tested on a preliminary basis for both questions suggested by Hypothesis 40 and Hypothesis 41, these two questions were considered less central than actual service delivery and resource development and had substantial data collection burden.

Objective 7 — To assure that up-to-date cancer management information is continually made available to physicians, nurses, and other health care professionals.

The following hypotheses were rejected for study:

- Hypothesis 42 — There is no difference in the number and type of physicians exposed to oncology education programs before and after CHOP development.
- Hypothesis 43 — There is no difference in the number and type of nurses exposed to oncology education programs before and after CHOP development.
- Hypothesis 44 — There is no difference in the number and type of health professionals (other than physicians and nurses) exposed to oncology educa-

tion programs before and after CHOP development.

• Hypothesis 45 — There is no difference in the number and type of patients exposed to oncology educational programs before and after CHOP development.

Rationale for rejection: All four of these hypotheses were rejected based upon several factors. First, it is difficult to determine the multiple sources of educational exposure to oncology programs. In all of the areas where CHOP's are located, other organizations, societies, hospitals and independent forums present oncology education. Second, didactic oncology education programs may not increase under CHOP. It is the participatory educational experience (in site committees or review sessions) that is the focus of CHOP interventions. Additionally, most CHOP hospitals had a substantial number of didactic sessions prior to CHOP funding.

The patient education question (Hypothesis 45) is measurable but is not a critical focus of the CHOP concept.

Objective 8 — To develop and implement a cancer data management system that permits monitoring of program effectiveness, documentation of program accomplishments, assessment of community cancer care practices and patient outcome status.

The following hypothesis was rejected for study:

• Hypothesis 46 — There is no difference in physician satisfaction with the cancer data system before and after CHOP development.

Rationale for rejection: Study Group members suggested that this hypothesis added significantly to the burden, while measuring an intervening variable. Physician utilization, which they chose to test (Hypothesis 16), is more easily measured and should reflect physician attitude and satisfaction with the system.

METHODS

In the next few pages we will summarize the major features of the design and the clinical variables we have selected as the initial National Clinical Data Set. Given the constraints of space, we will focus this presentation on the initial two CHOP objectives and the initial five hypotheses.

Hypotheses 1 through 5 — The Clinical Management Hypotheses

Design Considerations

A pre-post quasi-experimental design with two prior observations will be utilized for six cancer sites. It will be an interrupted time series, where there is nonrandom assignment. A non-equivalent comparison (control) group will be used to collect data for similar time periods.

Since assignment of patients to groups is not random, the design is quasi-experimental rather than experimental. Where possible, adjustments for group differences will be made by using statistical techniques such as analysis of covariance. A final determination can only be made at the time of analysis. It is recognized that threats to internal and external validity exist when random assignment to groups is impossible and these factors must be considered in interpretation of the results of the analysis.

A pre-post quasi-experimental design with one prior observation will be utilized for three additional sites. This design has less power for these sites, but will benefit from a comparison group.

For six sites, the design sequence will be:

CHOP institutions $O_1\ O_2\ X\ O_3\ O_4\ O_5\ O_6$
Non-equivalent comparison group $O_1\ O_2\quad O_3\ O_4\ O_5\ O_6$

For three sites, the design sequence will be:

CHOP institutions $O_2\ X\ O_3\ O_4\ O_5\ O_6$
Non-equivalent comparison group $O_2\quad O_3\ O_4\ O_5\ O_6$

where O stands for observation and X for the initiation of program interventions. Specifically, O_1 is the period prior to submission, O_2 is the last six months of planning, X is the initiation of implementation (i.e., guidelines on the chart) and O_3 through O_6 are the four years following implementation. It should be noted that the last two time periods following the intervention are beyond the completion of the CHOP implementation phase. The first 12 months of the planning period may have some effect, which should be detectable when we analyze the data from the six sites.

Hypothesis 2, which deals with local guidelines, will not utilize controls since each local set of guidelines will vary in its full extent. Thus, a single interrupted time series design, without controls, will be used to test this hypothesis:

Individual CHOP Institutions $O_1\ O_2\ X\ O_3\ O_4\ O_5\ O_6$

Optimally, all nine sites could utilize the controlled interrupted time series design with two prior observations. However, in discussions with Study Group members, it became apparent that there would be a substantial data collection burden on several of the multiple institution consortia if data for all nine sites had to be abstracted retrospectively. For example, if all nine sites were retrospectively abstracted in Cincinnati's 10 hospital consortium, approximately 3420 records would need to be reviewed. Without additional funding, this is clearly too substantial a data collection burden. To limit the burden, six "bellweather" sites were chosen for the longer controlled interrupted time series. These are: breast, Hodgkin's disease, ovarian, small cell carcinoma of lung, non-small cell carcinoma of lung, and testicular.

The three additional sites for which prospective data will be gathered and compared are: cervix, colorectal, and prostate. Obviously, this leaves open the

possibility that later supplemental funding may allow for additional retrospective case review.

The nine sites were chosen by the Principal Investigators of the participating CHOP's on the basis of the following: 1) recent technologic breakthrough(s); 2) rapid, high frequency, changes in technology; 3) number of cancer patients affected and 4) those sites where multidisciplinary therapy appears to be effective in reducing mortality and/or increasing survivals.

Comparisons:

Since random assignment was not utilized in the selection of programs and non-program controls, a comparison group selected by several general criteria is the next most powerful tool.

In the selection of the CHOP program comparison group, it is important that the characteristics of the two groups be as similar as possible. Thus, for example, if 85% of the CHOP hospitals are ACoS approved, the comparison group should have similar composition.

Among the characteristics which will be utilized to select a comparison group of institutions are: size and type of institutions; geography; urban/rural mix; use or planned use of CHOP-type interventions; size and type of cancer program; ACoS approval; ACCC membership; quality of data collection facilities and staff; willingness to participate; and ability to collect process data.

Of these, it may be important to consider a special control group of institutions which are already attempting CHOP-type programs with key interventions. Specifically, the Study Group noted that interventions currently unique to CHOP's include: site committee formulation of guidelines involving large scale physician participation; attaching guidelines to charts; and, rapid feedback of process of care information to medical staffs. The first two interventions were considered to be the most crucial in distinguishing the CHOP's from other programs.

Initially, the Group has solicited institutions to participate. This group will be matched with a profile of Group institutions. If this is insufficient, other techniques will be utilized. Dr. James Diamond of RTOG has suggested that a broad scale solicitation of neighboring radiation therapy centers (with appropriate characteristics) to serve as controls for an RTOG study proved highly successful. This technique will be considered after analysis of the voluntary applicants is completed. It should be noted that, to date, response to a solicitation for controls has been extremely high, even with the clearly stated inability to monetarily compensate controls for their involvement.

There are several sources of control groups: American College of Surgeons-accredited hospitals; SEER hospitals; CCPDS participants (e.g., Comprehensive Cancer Centers); hospitals selected to fit some comparison criteria; and voluntary hospitals selected to fit some comparison criteria. We have chosen to seek some combination of the latter two groups for our controls. Our rationale is that only some of the CHOP's fall into the first three categories. Responses to a request for voluntary comparison institutions appear to be more than sufficient to form an adequate comparison population.

Timing of Collection:

Considerable discussion preceded the selection of six time periods for collection of data. Initially, ELM staff suggested six time periods, twelve month intervals from August 1 to July 31st of the years 1978-79 through 1983-84.

Study Group member comments and site visits led to the amendment of the time periods to six suggested periods, including the twelve months prior to award, the months between submission and award, the planning period (the 6 month planning period — O2):

- O1 — 12 months prior to planning proposal submission (9/1/78 to 8/31/79)
- O2 — The last six months of planning
- O3 — First 12 months of implementation
- O4 — Second 12 months of implementation
- O5 — Third 12 months of implementation
- O6 — Fourth 12 months of implementation

Only data from the O2, O3, O4, O5 and O6 periods will be utilized for the second group of three sites.

The periods of time were changed and these specific time frames were chosen for the following reasons. The full planning period varies widely among the group from 16 months in one case to 21 months in others. This variation was caused by Federal contracting procedures. Similarly, the time period between submission and award varies, with some programs being funded in thirteen months and others being funded in twenty months. Some programs initiated planning activities immediately after submission, convening site committees, hiring staff, developing guidelines and developing data systems. The O2 observation takes place after the bulk of planning occurs but before implementation, while the CHOP's await approval of implementation plans. Thus, we have data that may show two sets of interventions having effects, the planning period itself and the beginning of implementation.

An additional retrospective time period for data collection (9/1/77—8/31/78) was considered but dropped due to the substantial additional data collection burden.

Time frames beyond the end of Federally-funded implementation were chosen in support of the premise that, to be widely accepted by the scientific community, end results *and* process of care must both be documented. This is virtually impossible,

given the short implementation time currently planned by NCI.

Variables:

Among the categories of variables to be studied are: NCDS (site-specific); patients treated or not treated "according to the guidelines"; physician admissions; multidisciplinary consultations; mortality; length of survival; physician participation in site committees and/or educational conferences; charts (for absence/presence of guidelines); and CCPDS.

The unit of analysis of these five hypotheses is the patient. Attempts to measure the care of patients across CHOP programs are likely to fail if some uniformity is not introduced. On the other hand, attempts to force uniformity on the CHOP guidelines would defeat the very principles upon which the program is founded.

Thus, the fourteen Study Group organizations and ELM technical staff devised the concept of the National Clinical Data Set.

The National Clinical Data Set (NCDS):

The concept of the NCDS was developed so that a CHOP could measure a minimum number of critical elements of the processes of care, and yet, not surrender its autonomy.

Essentially, the NCDS was devised through a series of iterations by CHOP Principal Investigators and by members of CHOP staffs.

Among those individuals involved in its creation were medical oncologists, hematologists, surgeons, radiation therapists and pathologists.

A modified Delphi technique was used. Of major importance was the agreement by all CHOP's to collect, report, and analyze the NCDS, regardless of whether or not a specific variable was selected as part of a local guideline. This ensured both autonomy and inter-CHOP comparability.

Criteria for NCDS Variable Selection:

The NCDS is not intended to be a complete set of actions to be taken prior to treatment of a patient. Not every variable is indicated in every case. However, CHOP P.I.'s selected variables for the NCDS on the basis that the absence of these variables (activities, patient care elements, etc.) may indicate insufficient data upon which to base a management decision. It is important to note that the presence of all of these elements does not by any means indicate "good" care, nor does the absence of any single item indicate "bad" care. A substantial subset of the variables is only indicated with some patients at certain stages of the disease (See Exhibit 4)

To ensure that all cases within a site are comparable, CHOP P.I.'s agreed to utilize the same staging classification for each site. Thus, when retrospectively reviewing charts, patients will be restaged. Prospectively, patients will be staged utilizing the selected classification.

OTHER METHODS

Exhibit 5 illustrates all the hypotheses to be studied and several key facets of the methods intended for use: quasi-experimental design, time periods of collection, type of collection (primarily archival and survey) and categories of variables.

FUTURE DIRECTIONS

The Study Group is in the process of identifying comparison sites. In the coming months, we expect to finalize our selection and discuss specifics with potential comparison institutions. A preliminary analysis of information is planned in the 01 year of implementation. Funding is scarce and not sufficient for the optimal evaluation program one might desire. However, the Group believes it is this type of evaluation, developed by a collaborative process, which has the highest likelihood of achieving significant results, and of culminating in truly evaluable cancer control programs.

Finally, we recognize the immense potential of this type of collaboration and intend to consider ways this Group, including the comparison groups as full members, can test other important questions on community cancer care, technology transfer, and the role of the community in cancer prevention and management.

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We are deeply appreciative of the additional evaluation design and biostatistical expertise provided by two Study Group members: Mr. Thomas C. Tucker and James Murphy, Ph.D.

Several other key Study Group members played an important role in the development of the evaluation design and the program. These CHOP Administrative Directors share equal responsibility and deserve equal credit for this product: Marianne Chapman, R.N., M.N.; Barbara V. Estep, R.R.A.; Moira Feingold; Joanne Hayes, M.A., R.N.; Randi Moskowitz, R.N., M.S.; Patrick Moylan; Diana D. Parker, M.H.A.; J. Raymond Rhodes; Bud Rogers; Carolyn Russell, M.S.W.; Carole Rust; Thomas C. Tucker; and Ann T. Welch, M.H.A.

Exhibit 4

National Clinical Data Set

BREAST:

Pathology

- Initial Tumor Size
- Number of Axillary Nodes
- Menopausal Status
- Estrogen Receptors
- Progesterone Receptors

Diagnostic Studies

- Chest X-ray
- Chemistries
- Mammogram for Opposite Breast

Treatment

- Surgery
- Chemotherapy
- Radiation Therapy
- Combination of Above

HODGKIN'S DISEASE:

Pathology

Diagnostic Studies

- Clinical Staging–(Yes)
- Pathological Staging–(Yes/No)
  - Laparotomy
- Chest X-ray and/or Whole Lung Tomograms
- Abdominal CAT Scan and/or Lymphangiogram and/or Gallium Scan
- Bone Marrow
- Chemistries

Treatment

- Surgery
- Chemotherapy
- Radiation Therapy
- Combination of Above

OVARIAN:

Pathology

Diagnostic Studies

- Adequate Surgical Evaluation Including:
  - Omentectomy
  - Evaluating Diaphragm
  - Washings
  - Pre-operative IVP
  - Chemistries
  - One or more of the following:
    - Pelvic CAT Scan
    - Barium Enema
    - Ultrasound of Pelvis

Treatment:

- Debulking (tumor reduction surgery)
- Radiation Therapy
- Chemotherapy

SMALL CELL CARCINOMA OF THE LUNG:

Pathology

- One or more of the following:
  - Biopsy (bronchoscopy)
  - Biopsy (closed chest needle)
  - Bronchial Washings (bronchoscopy)
  - Sputum Cytology
- Report to specify one of the following:
  - Small cell
  - Oat Cell
  - Undifferentiated small cell

Diagnostic Studies

- One or more of the following:
  - Bone Scan
  - Brain Scan – CAT or nuclear
  - Liver/Spleen Scan
  - Bone Marrow

Treatment

- Multidrug Chemotherapy (Yes/No)
- Radiation Therapy:
  - Prophylactic Whole Brain
  - Other Site

NON-SMALL CELL CARCINOMA OF THE LUNG:

Pathology

Diagnostic Studies

- Chest X-ray
- Mediastinal Evaluation (such as Mediastinoscopy, gallium scan, bronchoscopy, mediastinal tomograms, lung CAT Scan)
- Chemistries
- Bone Scan
- Brain CAT Scan
- Liver/Spleen Scan

Treatment

- Surgery
- Chemotherapy
- Radiation Therapy
- Combination of Above

Exhibit 4

National Clinical Data Set

TESTICULAR:

Pathology	Diagnostic Studies	Treatment
	● Surgical Staging ● Whole Lung Tomograms or Lung CAT Scan ● Lymphangiogram and/or Abdominal CAT Scan ● Biomarkers: ●● Alfa-Feto Protein ●● Beta Subunit HCG (RIA) ●● Chemistries (LDH)	● Radical Orchiectomy ● Other Surgery ● Chemotherapy ● Radiation Therapy

The following three sites and variables were selected for inclusion in the second, shorter, interrupted time series:

CERVIX:

Pathology	Diagnostic Studies	Treatment
	● IVP ● Barium Enema and/or Endoscopic Exam ● Date of Last Pap Smear Prior to Diagnosis ● Chest X-ray ● Chemistries ● Fractional Curretage	● Surgery ● Chemotherapy ● Radiation Therapy ● Combination of Above

COLO-RECTAL:

Pathology	Diagnostic Studies	Treatment
	● Barium Enema and/or Endoscopy ● Liver/Spleen Scan ● Chest X-ray ● Chemistries ● CEA ● IVP	● Surgery ● Chemotherapy ● Radiation Therapy ● Combination of Above

PROSTATE:

Pathology	Diagnostic Studies	Treatment
	● Bone Scan ● Acid Phosphatase ● Chemistries ● IVP ● Node Biopsies ● Pelvic CAT Scan	● Surgery ● Chemotherapy ● Radiation Therapy ● Combination of Above

STAGING CLASSIFICATIONS

Breast	TNM
Hodgkin's Disease	Ann Arbor Classification (I, II, III, IV; A or B)
Ovarian	FIGO
Small Cell Carcinoma of the Lung	Limited or Extensive
Non Small Cell Lung Carcinoma	TNM
Cervix	FIGO and Surgical Staging
Colorectal	Dukes' System
Prostate	A, B, C, D

Exhibit 5

Summary of Evaluation Methods

HYPOTHESIS SUMMARY	QUASI-EXPERIMENTAL DESIGN	TYPE OF DATA COLLECTION/TIMING	TYPES OF VARIABLES
H1: National Clinical Data Set H2: Work-up H3: Consultations H5: Mortality H6: Use of protocols	For CHOP's... $O_1\ O_2\ X O_3\ O_4\ O_5\ O_6$ For comparison group $O_1\ O_2\ \ O_3\ O_4\ O_5\ O_6$	Archival... 01: Pre-Submission 02: Last 6 months of planning 03-06: Implementation Years	• NCDS • Guideline Use • Physician Admissions • Participation etc. • Guidelines on charts
H4: Local Guideline Use	For CHOP's only... $O_1\ X_1\ O_2\ X_2\ O_3\ O_4\ O_5\ O_6$	SAME AS ABOVE	SAME AS ABOVE
H7: Nursing Attitudes H8: Nursing knowledge	$O_1\ X\ O_2$	Survey... Pre- and post-CHOP training sessions	• Length & type of course(s) • Teachers • Nurse characteristics • Current environment of caregiving
H9: Pain medication administration H11: Rehab & support referrals H12: Rehab & support documentation H14: Terminal care referrals H15: Terminal care resources	For CHOP's... $O_1\ X\ O_2\ O_3$ For comparisons... $O_1\ \ O_2\ O_3$	Archival and survey... 01: Pre-submission 02-03: First two years of implementation	• Types of orders • Length of pain medication admin. interval • Patient Characteristics • Environment of treatment • #of referrals • #of resources • Documentation
H10: Patient anxiety H13: Quality of life	For CHOP's... $O_1\ X\ O_2\ O_3$ For comparisons... $O_1\ \ O_2\ O_3$	Survey... 01: Last 6 months of 02-03: First two years of implementation	• Patient anxiety variables • Quality of life variables
H16: Data system use	$O_1\ X\ O_2$	Archival... 01: 2 years prior to submission 02: 2 years of implementation	• #of studies • #of requests
H17: CHOP continuation	$O_1\ X\ O_2$	01: First 2 years of implementation 02: First 2 years post-funding	• FTE of administrator

Copies, reprints, quotation permission and details of study process may be obtained by contacting: Lee E. Mortenson, CHOP Evaluation Study Group Project Director, ELM Services Inc., 11600 Nebel Street, Suite 201, Rockville, Maryland 20852. Telephone: 301-984-1242.

port them." He qualified that a bit last week.

With as many as 700 hospitals showing interest in CCOPs and 300-400 expected to submit proposals, DeVita said, "If 700 come in and are good, we would be in terrible trouble."

Buell presented the Board with a draft of the RFA. It is not in its final form, but most of the major provisions probably will remain more or less intact. Certain details are spelled out for the first time, including research base affiliation options. The draft follows:

Background Information

In this country, over 80 percent of patients with cancer are treated in primary care community hospitals and clinics close to their homes. The remainder are treated in university and government hospitals and cancer centers. Currently, the NCI Div. of Cancer Treatment supports a national clinical trials program largely through academic centers. These have included (1) multimodal national and regional cooperative groups, (2) groups in which the investigators have a particular expertise (such as pediatricians), (3) groups that are designed to deal primarily with high technology single modality studies and (4) groups that are specifically disease oriented. Additional large cancer centers are involved in implementation of local clinical research protocols. The past decade has seen increasing numbers of highly trained clinical cancer specialists, experienced in clinical research and protocol care, enter private practice in the community. Thus there are highly qualified professionals in the community capable of participating in clinical research. Experience with several cooperative groups has indicated that cancer physicians in community practice produce clinical research data of similar high quality to that of the academic centers. Coupled with this growing community expertise in the ability to perform clinical trials, is a need for increased accrual of patients seen primarily in the community setting into high priority national clinical trials.

National end results statistics show that 50 percent of all cancer patients are curable by treatment approaches currently available. Continued improvement in these statistics will come from the conduct of clinical trials. Additional hope for patients is offered through entry on clinical research programs. Participation in clinical research activities will facilitate the delivery of high quality cancer care to those patients who remain in their communities.

Under this procurement, NCI will seek to meet the needs of community cancer patients nationwide, utilize the trained specialist now practicing in community hospitals and clinics and facilitate its own clinical research goals by establishing a system of 100-200 community clinical oncology programs with national distribution. Participating programs will be required to enter a minimum of 50 evaluable patients annually into NCI approved clinical trials and must be prepared to enter 12 percent or more of eligible patients to clinical trials designated as high priority by the research base with which the CCOP is affiliated. These research bases may be national or regional cooperative groups, specialized cooperative groups or cancer centers currently participating in NCI approved clinical research protocols. Patient entry onto clinical trials will be done through collaboration with a primary multimodality research base having a spectrum of clinical trial protocols available and if desired through one or more secondary specialty research bases. In this instance, patients under a CCOP program may not be allocated to competing protocols. One protocol must be utilized.

This program will be developed and supported by the Centers & Community Oncology Program, Div. of Resources, Centers and Community Activities. Community Clinical Oncology Programs must be prepared and indicate a commitment to participate in NCI sponsored cancer control programs.

Qualification for Award

Community Clinical Oncology Program

A. A Community Clinical Oncology Program (CCOP) is defined as a single clinic, a group of practicing physicians, a single hospital, or a consortium of physicians and/or clinics and/or hospitals. In the latter instance administrative cohesion must be demonstrated. The consortium approach is particularly encouraged when several community cancer centers are serving the same population area. The CCOP may not be situated in an NCI designated cancer center. Qualified community hospitals or clinics currently funded by NCI as members of cooperative groups may choose to apply for CCOP funding but it is understood that receipt of a CCOP award would be coupled with cancelation of current funding. Similarly, funds received as a satellite under NCI's Cooperative Group Cancer Control Program would terminate upon receipt of a CCOP award.

B. Each funded CCOP should have a designated and committed multidisciplinary professional team including surgical oncologists, radiation oncologists, medical oncologists, pathologists, and oncology nurses. Appropriate other disciplines may be added, e.g., gynecologic oncologists, pediatric oncologists. One of this group will serve as principal investigator. An associate principal investigator will also be named to assure continuity in the event of departure of the principal investigator.

C. Each CCOP must have a well defined area for administrative activities which will serve as a focus for data management, quality control, and communication.

D. Each CCOP must have evidence that an affiliation has been established with a nationally recognized clinical cancer research base, e.g. major cancer center, national or regional cooperative group. Multiple affiliations are permitted provided they are not conflicting. These affiliations must exist in the form of a written agreement between the CCOP applicant and corresponding research base(s) at the time of proposal submission. This agreement must specifically state how the problem of competing protocols is to be resolved. Initial affiliations must be maintained during the first three year funding cycle. Changes in research base affiliations may be presented in the application for funding renewal. CCOP affiliations with centers and regional cooperating groups must be geographically appropriate. A CCOP may not bypass regional research base programs to establish ties with distant centers.

E. Each CCOP must identify the population it serves. Emphasis will be placed on demogrpahic and geographic distribution of community centers. Multiple CCOPs competing for the same patient population will not be approved. Consortia of hospitals, physicians, or clinics serving the same population are encouraged.

F. Each CCOP must have a demonstrated potential and stated commitment to contribute at least 50 patients per year to approved clinical research protocols active in the center or group with which the community center is affiliated, to nonconflicting protocols of other groups, or to overall national protocols, e.g., for rare tumors. There must be a clear commitment by the CCOP to enter patients on all protocols designated in the CCOP-research base agreement and recognized as high priority by NCI. Obligations cannot be met by entering 50 patients onto only a small number of protocols, i.e., only the most common tumors. Programs will be monitored annually with the expectation that at least 12 percent of eligible patients will be entered for each cancer for which a protocol exists.

G. Each CCOP must have established well planned procedures for regular communication with the practicing

physicians of its region, e.g., education programs, workshops, grand rounds, tumor boards, etc. Each CCOP must demonstrate effective community cooperation so that entry onto protocols will not be impeded by competing, nonparticipating physicians.

H. Funding for a CCOP will be based on ability to contribute patients to national clinical research protocols and the ability to conduct required cancer control and evaluation activities. Anticipated total yearly treatment research budget for a center contributing the minimum of 50 patients and without supplemental cancer control activities would be $50,000. The allocation of CCOP funds to support the cost of receipt, handling and analysis of patient data by the affiliated research bases must be specified in the CCOP proposal and in the written agreement between the CCOP applicant and its research base. The budget could be increased for community centers capable of greater case contributions. Allowable items in the budget would be for personnel engaged in data handling and study assistants, supplies and services directly related to study activities (e.g. processing and sending material for pathology review, processing and sending port films for radiation therapy quality control), limited travel to meetings directly related to study activities, and support for cancer control activities. Physician compensation would be allowable only for time spent on the project other than clinical care. Total funding as well as allowable physician compensation may be increased proportionately for participating in NCI initiated cancer control activities. Initial funding is to be for three years.

I. A list of research base options from which each CCOP may select appears below. CCOP affiliation with a cancer center will receive accrual credits only for those protocols which have been reviewed and approved by the NCI-CTEP protocol review process.

J. The following provisions will apply to all CCOP programs.

1. Each CCOP must have a human subjects review committee which conforms with NIH guidelines.

2. Each CCOP must maintain a log of all research drugs. This log should identify, for each unit of drug, the patient, physician, and protocol and should permit ready tracking of drug use.

3. Each participating investigator must file a form 1573 with the Investigational Drug Branch, Cancer Therapy Evaluation Program, Div. of Cancer Treatment, NCI.

4. Each CCOP agrees to accept on site monitoring by representatives of its research base(s) or NCI or an NCI designee. The purpose of such on site monitoring will include monitoring of use of investigational drugs, accuracy of data recording and completeness of reporting adverse drug reactions.

5. Each CCOP agrees to an annual review of its progress by the executive committee of its research base(s) and NCI staff. This review will include, but not be limited to, overall case accrual, accrual to high priority protocols, patient eligibility, patient evaluability, and timeliness and quality of data reporting. This annual review may be the basis for probationary status or adjustment in funding.

6. Radiotherapy equipment must have its calibration verified by the Radiological Physics Center or one of the regional Centers for Radiological Physics in order for institutions to participate in this program.

Research Base Participation

Each research base will need to develop a plan to receive funds from CCOP awardees to support the administrative and data management functions of its associated CCOPs. Since it will not be known how many CCOPs will be funded, these plans should express budget requirements on a prorated basis, prorated as to patients accrued and/or number of CCOPs affiliated. CCOP affiliation agreements should specify which procedures are to be used in quality control, annual review and on site monitoring of the affiliated CCOPs.

The general function of a research base is to stimulate, facilitate, coordinate and help evaluate research activities of its associated community clinical oncology programs. The CCOP-Research Base agreement should define mechanisms for community participants to have input as active research base members with appropriate representation on governmental and operational committees.

D. Specific functions to be negotiated by the CCOP and research base should include the following:

1. Assessing the capabilities of community members and affiliates for participation in clinical research and cancer control activities.

2. Assisting the community members and affiliates in any necessary upgrading of personnel and facilities and to provide training when indicated for supporting personnel, e.g. data managers, study assistants, oncology nurses, etc.

3. Joint activities in developing and/or making available appropriate clinical research protocols.

4. Provision of appropriate quality control procedures for data recording, protocol compliance, and reporting of adverse reactions.

5. As necessary assisting with treatment planning and providing quality control both with regard to standardization of equipment and to dose and field.

6. Cooperative development of standardized operative reporting and, when feasible, operative procedures.

7. Joint efforts of pathologists of the research base, community members and affiliates to standardize pathology reporting, to standardize pathology procedure, and in providing mechanisms for pathology review for appropriate protocols.

8. Provision of a statistical center for data management and statistical assistance in protocol design, protocol monitoring, data analysis, and manuscript preparation.

9. To monitor new drug procurement, to transmit new drug orders, and to monitor new drug use by affiliated community clinic members.

10. Provision for regular meetings of the research base with its community members and affiliates for review of ongoing research activities, planning of future activities, and related professional education.

Mechanism of Support

CCOP awards will be made as cooperative agreements. These are assistance relationships which feature substantial collaboration and involvement with NCI staff. NCI anticipates making multiple awards under this request and to issue a program announcement over several subsequent fiscal years. The total number of awards in this and subsequent fiscal years will be determined by available budgetary funds. While peer review determined technical merit will be the primary factor, NCI will also consider factors of cost and geographic distribution in selection for award. Awards will be for periods of three years. Renewal of the initial award beyond three years will be contingent upon satisfactory review of a competing renewal application by a scientific peer committee as well as the National Cancer Advisory Board.

Review Procedures and Criteria

1. Plan for review: Application will first be reviewed for responsiveness to this program announcement. Those judged to be nonresponsive will be returned with explanation to the offeror. Responsive application will be evaluated by an NCI peer review group composed of non-federal scientific consultants.

Research Base Options

A. A Multi-Disease Research Base (may choose one)

1. An NCI designated comprehensive cancer center.

2. An NCI-funded clinical cancer center.

3. Cooperative Groups—Cancer & Leukemia Group B (CALGB), Eastern Cooperative Oncology Group (ECOG), North Central Cancer Treatment Group (NCCTG), Northern California Oncology Group (NCOG), Southeastern Cancer Study Group (SEG), Southwest Oncology Group (SWOG), and the new regional cooperative groups, as they are funded.

B. Pediatric Oncology Research Base (may choose one)
Children's Cancer Study Group (CCSG), or
Pediatric Oncology Group (POG).

C. Special Category Research Bases (may choose more than one)
Gynecologic Oncology Group (GOG)
Radiation Therapy Oncology Group (RTOG)—must clarify allocation if protocols overlap with category A choices
National Surgical Adjuvant Breast and Bowel Project (NSABP)—participation in surgical protocols falls in this category. Participation in the adjuvant protocols of this group may be a potential conflict with the protocols of a category A research base and allocation of patients must be clarified and both NSABP and the category A research base must concur in this allocation plan.
Lung Cancer Study Group (LCSG)—the academic interests of a cancer oriented thoracic surgeon must be documented if this research base is chosen.
Gastro-Intestinal Tumor Study Group (GITSG)—participation in the protocols of this group may conflict with protocols of a category A research base and allocation of patients must be clarified and both GITSG and the category A research base must concur in this allocation plan.

Not all of the issues were resolved at the Board meeting. Moertel objected to the prospect that university hospitals at cancer centers which have lost their NCI grants may compete for CCOP awards (DeVita and Buell said that was not the intent and that it could be taken care of in review, but that some university hospitals would qualify as community hospitals).

Moertel also objected to a rigid 12 percent requirement on patient entries into protocols and questioned how the total number (12 percent of what?) would be determined.

Board member Lester Breslow cast doubts about limiting the cost to $50,000 per CCOP. "Never underestimate the ability of hospital administrators to build up indirect costs," Breslow said.

The Cooperative Group Cancer Control Program contracts which expire this year have been administratively extended until Aug. 31. NCI last week announced its intention to offer the RFP for recompetition of the five contracts to all 13 groups, as decided upon by the DRCCA Board last October. The RFP will go out Jan. 25, if NIH goes along with maintaining the program with contracts. Some NIH officials insist this should be switched to cooperative agreements. If that view prevails, it would be extremely difficult to renew the program before it expires at the end of August.

NCI CONTRACT AWARDS

Title: Particle beam radiotherapy
Contractors: Massachusetts General Hospital, $419,167; and Univ. of Pennsylvania, $255,715.

NCI CHANGES EMPHASIS, DROPS OUTREACH CORE SUPPORT IN FAVOR OF CC RESEARCH

Among the criteria established by the National Cancer Advisory Board for recognition as a comprehensive cancer center were those requiring outreach activities to serve the center's region—professional and public education, prevention, cancer "hotlines," development of psychosocial and other support programs and other activities falling under the general area of cancer control.

Developing and operating outreach programs required a certain amount of core activities at the centers for which little or no support was available through established mechanisms. Center directors chaffed over the fact that the government required them to carry on those activities without providing any money for them. To provide that core support, NCI developed a new mechanism, Cancer Centers Outreach Grants, administered through the Div. of Cancer Control & Rehabilitation (now Resources, Centers & Community Activities). Sixteen comprehensive and seven other centers presently receive a total of $10.7 million a year through that mechanism.

The DRCCA Board of Scientific Counselors last week, following through on a major policy change that has been brewing for the past year, ended that program.

In its place will be a mechanism which will provide core support for cancer control research, marking NCI's change in emphasis in cancer control, dropping outreach support in favor of research.

The existing program was limited to centers, which were defined as institutions with NCI cancer center support (core) grants. The new program has no such limitation.

At its meeting last October, the DRCCA Board failed to agree on details of the new program, other than that it would emphasize research and exclude most outreach activities. At that time, the Board did agree to establish another core support program for "Cancer Control Research Units" in which research would be limited to that carried out in "defined populations."

The defined populations requirement would preclude participation in that program by many of the centers with the existing core support grants. With epidemiologists on the Board insisting that valid results to many studies could not be expected without that requirement, Board members agreed that some other mechanism should be worked out to permit those centers without access to defined populations to remain in the game.

Last week, the Board decided that the type of research and personnel involved with cancer control research in other than defined populations would not be that much different from that required for CCRUs in defined populations. Members agreed that the

guidelines previously approved for CCRUs should be applied to the other program, but without the defined population requirement.

To differentiate between the two programs and for lack of better names, they were dubbed CCRU-I and CCRU-II.

CCRU-I will solicit grant applications through an RFA which will be published by NIH Jan. 31. It appears below, with some editing to conserve space.

CCRU-II will use the program announcement to solicit applications. No date has been established for its publication. The major difference between the program announcements and RFAs is that the latter specifies a dollar total which has been set aside for the program.

NCI had intended to earmark $5 million for the first round of CCRUs, expecting to award as many as five at $1 million each. However, the RFA puts the limit at $3 million, which brought an objection from Board member Lester Breslow.

DRCCA Director Peter Greenwald said the lower limit was adopted because of the budget reduction imposed upon NCI. Breslow suggested that a policy be adopted earmarking equal amounts for CCRU-I, CCRU-II and the CCOPs (see preceding article). There were no objections from other Board members, but Greenwald was noncommittal.

Most of the Cancer Center Outreach Grants expire by June, 1983. Carlos Caban, program director, said that an Oct. 1 deadline for applications for CCRU-II will be required to provide continuity. A major problem for some centers with outreach grants is that core staff was recruited for expertise in outreach activities and may not be qualified to manage a research operation. Those centers will have only six to eight months to revamp their staffs and develop competitive grant proposals.

The CCRU-I RFA:

NIH-NCI-DRCCA-CCB-82
CANCER CONTROL RESEARCH UNITS FOR DEFINED POPULATION STUDIES
Application Receipt Date: July 15, 1982

The Div. of Resources, Centers & Community Activities of NCI invites grant applications from interested investigators for the establishment of Cancer Control Research Units for Defined Population Studies.

The present RFA announcement is for a limited competition with a specified deadline of July 15, 1982. A letter of intent will be required and will be due on March 30, 1982.

Cancer control research includes both prevention (primary and secondary) and management (diagnosis, pretreatment evaluation, treatment, rehabilitation, and continuing care). It builds on the research and knowledge bases of epidemiology, biomedical, clinical, behavioral and other sciences. It requires carefully designed investigations, often including both study and control groups and/or defined denominator populations.

The "Statement on Cancer Control," [*The Cancer Letter,* Feb. 6, 1981] which sets forth the general scope and definition of cancer control research, has been focused for this announcement as follows to emphasize research in defined populations:

The goal of a cancer control program is to reduce cancer incidence,, morbidity and/or mortality by:

1. Identifying approaches that might accomplish this and performing research in defined populations to determine which are effective.
2. Selective promotion and evaluation of these approaches.
3. Selective education and information dissemination for health professionals and/or the public.

The scope of cancer control includes prevention, screening, diagnosis, pretreatment evaluation, treatment, rehabilitation, and continuing care activities.

The national cancer effort includes both research into and application of control methods. These are complementary and not antagonistic activities and are part of an ordered sequence, as indicated in the following statement adapted by the Board of Scientific Counselors from the report of the President's Biomedical Research Panel:

The continuum from the discovery of new knowledge to the application of such knowledge in health care includes a number of steps:

1. Discovery, through research, of new knowledge and the relating of new knowledge to the existing base.
2. Translation of new knowledge, through applied research, into new technology and strategy for movement of discovery into health care.
3. Validation of new technology through clinical trials in defined populations, and in other ways.
4. Determination of the safety and efficacy of new technology for widespread dissemination through demonstration projects.
5. Education of the professional community in proper use of the new technology and of the lay community on the nature of these developments.
6. Skillful and balanced application of the new developments to the populations.

Cancer control includes 2 through 5, although different relative emphasis may be placed on each of those points depending on the specific cancer and whether prevention or treatment efforts are involved.

Control and research must be mutually reinforcing and only the coordinated planning and implementation of research and control strategies will assure maximum yield from the dollars invested, maximum quality of the activities supported, and maximum probability that the research effort will continue to provide advance suitable for future application in the control of cancer.

Cancer control should support three types of activities in defined populations:

1. Research to determine how, whether and to what extent, actions proposed for a particular cancer are effective for defined populations.
2. Research to determine the optimal strategies for reducing incidence, mortality or morbidity for a particular cancer(s) in a measurable way, and research on methods for efficiently implementing these strategies.
3. Selective implementation of strategies proven efficacious for particular cancer(s) and assessment of the efficacy and practicality of such strategies for large populations.

Cancer control efforts should give highest priority to cancers meeting more than one of the following criteria:

1) Cancers causing the greatest mortality/morbidity in the United States.

2) Common exposures associated with substantial cancer risk.

3) Cancers for which apparently effective actions are available.

The development of an effective national program for cancer control requires qualified personnel, particularly with training and experience in the disciplines of epidemiology,

biostatistics, and disease control administration, and the placement of these individuals in responsible positions.

Concept of the Cancer Control Research Unit

The DRCCA Board concluded that there is a critical need for a special research effort on certain cancer control research questions and that this could most effectively be answered through establishment of several specialized research units. These research units would focus on cancer control research studies in cancer prevention and/or management, require long term support, involve multidisciplinary participation, and need to have access to defined populations so that the population impact of any cancer control activities could be measured. It is believed that, at this time, a number of institutions or organizations in the United States have the "critical mass" of resources and qualified personnel to become research units of this type, but lack a clear mandate and method of support. The concept of the Cancer Control Research Unit for Defined Population Studies is being put forth to address this critical need.

The CCRU will be organized around a core group of highly competent investigators, each capable of obtaining peer reviewed project support. The theme will be cancer control research in the areas of prevention and/or management on a specific defined population(s) to which the CCRU investigators will have access. The director of the CCRU will be an experienced investigator and adminstrator of control research programs or a field of clear relevance to cancer control. There will be a cancer control research team of qualified investigators. Several of the investigators will receive project support within the CCRU grant for research using the defined populations. The rest of the investigators will be capable of undertaking other research projects using developmental funds or will seek other peer-reviewed funding support. A minimum of three such projects must successfully pass peer review and be approved as part of the application before the CCRU application will be considered for funding based on its priority score. The CCRU may request support for five years, with the opportunity for renewal.

Grants under this RFA will support a limited number of geographically dispersed CCRUs which will be designed to plan and implement cancer control research studies in the areas of prevention and/or management, on defined populations, and to serve as a resource for the cancer control research program of the National Cancer Program. It is hoped that these studies will include innovative approaches to the problems and be generalizable to larger populations.

It is not the intent of this RFA to create a CCRU in a location where a critical mass of resources and qualified investigators does not exist, but rather to redirect, focus, and recruit institutions already having highly competent investigators into cancer control research. At present, there are no comparable research units which are devoted to cancer control research of this kind.

Definition of a Defined Population

A defined population is a population which is characterized in terms of: numbers and methods of identifying individuals in the population; demographic characteristics such as age, sex, color, ethnic group; social and economic factors such as occupation, education, socioeconomic status; vital statistics such as incidence, morbidity, and/or mortality; personal or life style factors such as diet or smoking; genetic and/or biological characteristics or other factors associated with disease. For this RFA, there must be methods for identifying the population denominators and the occurrence of cancer within the population.

The population may be defined either geographically, or by exposure, or by characteristics proven to have a statistical association with cancer.

Examples of cancer control research for defined populations in the general area of prevention (primary and secondary) could include evaluating the effectiveness of actions proposed for a particular cancer, such as methods for lessening smoking for a large population group, dietary assessment in relation to cancer risk, chemoprevention trials, assessment of population effectiveness of approaches to cancer screening, reduction of hazards in occupational settings, and evaluation of methods of cancer control monitoring and surveillance.

Examples of cancer control research for defined populations in the general area of management (diagnosis, pretreatment evaluation, treatment, rehabilitation, and continuing care) could include assessing the population effectiveness of approaches to patient management, and evaluating the effectiveness of methods of introducing new technology into the population and of measuring its effectiveness.

It is the responsibility of the applicant to specify the area of program interest (prevention and/or management), the types of cancer control research studies which will be conducted, the defined populations which will be available to the CCRU, and the generalizability of the studies to population groups. If multiple CCRU applications are competitive for the same defined population, and more than one application receives a fundable priority, NCI will make an award to only one of the competitors.

The core group of investigators will consist of the director of the CCRU and the multidisciplinary group of investigators needed to achieve the research goals of the CCRU. At least three research projects designed by these investigators must be approved as part of the CCRU.

The CCRU director should be an established investigator with prior research and administrative experience in cancer control or other disease control research programs. The director must make a significant commitment of time to the CCRU, and may receive salary support as director of the CCRU, as principal investigator of an approved project within the CCRU, and as a shared resource director. The director may also receive salary support from other peer reviewed projects, or other sources. The CCRU director should describe his general duties, responsibilities and authority in the CCRU.

The necessity and detailed scientific justification for a multidisciplinary core group of investigators, and the criteria for designation as a core investigator, must be presented by the applicant. This should include the investigator's qualifications, potential scientific contributions to the CCRU, the level of effort which they will contribute to the CCRU, and the level of support requested from the CCRU grant.

Examples of the types of expertise which may be needed for cancer control research include epidemiology, biostatistics, clinical oncology, oncology nursing, data management, behavioral science, occupational health, nutritional science, health economics, health planning, community health, health services research, professional education, public education, and communication.

It is not the intent of NCI to provide salary support under this grant as a substitute for salary support awarded in peer reviewed grants or contracts. Instead, core investigators should be capable of obtaining the majority of their support through these other mechanisms. Qualified senior investigators who are entering the field of cancer control research may require core investigator support for a short time until they obtain this type of support. Accordingly, support requested for proposed core investigators who are not principal investigators on the projects included in the CCRU application, or who do not have other peer review support, must be carefully justified.

The CCRU application may request developmental funds. These funds may be used for support of either pilot projects or for new investigators.

A detailed description of plans for use of developmental funds must be provided, including internal review processes to

be used, criteria for award, length of awards, and names and CVs of internal review group members. Developmental funds shall be limited to a maximum of three years per project or investigator. Proposed pilot projects should not be presented in the grant proposal.

Funds for new investigators may be requested and should be justified in terms of documented need to fill recognized voids in meeting program goals. A separate budget page should be included in the CCRU budget section for developmental funds.

A listing of all funded cancer control research projects or related research at the institutions should be provided. For each project, indicate the name of the principal investigator, the title of the project, the funding source, identification numbers, current annual direct costs, direct costs for the entire project period, and project period dates. This listing will be considered the research base supporting the CCRU.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. Write to the Contracting Officer or Contract Specialist for copies of the RFP, citing the RFP number. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs to the individual named, the Blair Building room number shown, National Cancer Institute, 8300 Colesville Rd., Silver Spring, Md. 20910. RFP announcements from other agencies reported here will include the complete mailing address at the end of each.

SOURCES SOUGHT

Title: *Correction and addition to Sources Sought for Current Cancer Research Analysis Center (CCRESPAC). (See* ***The Cancer Letter****, Jan. 1)*

Deadline for capability statements: *Feb. 5*

Small business size standard is average annual receipts for preceding three fiscal years do not exceed two million dollars.

Qualifications of the organization will be rated using the following criteria: Extent of experience with similar and directly related projects, with the analysis/organization of highly technical biomedical data; with the maintenance of computer files containing bibliographic and descriptive data; and with the preparation of computer tapes acceptable for driving photocomposition devices currently used by the Government Printing Office; In-house availability of or guaranteed access to equipment needed for computer processing; and availability of space, facilities, and equipment other than computers for carrying out the required workscope.

Contract Specialist: Barbara Mercer
RCB, Blair Bldg. Rm. 327
301-427-8877

RFP NCI-CP-FS-21009-63

Title: *Support services for occupational studies*
Deadline: *March 25*

The Environmental Epidemiology Branch, Div. of Cancer Cause & Prevention, NCI, is seeking an organization highly experienced in conducting all phases of occupational health studies including:

(1) Study initiation and liaison; (2) preparation of study matierials and procedures; (3) data collection; (4) data preparation; (5) computer programming and processing; and (6) monitoring and quality control. Epidemiologic methods commonly employed include cohort mortality, proportionate mortality, and case-control.

This procurement will not involve independent research by the contractor, although advice from the contractor will be sought for various phases of studies including data collection procedures, computer file management, data editing, and tracing techniques. The duration of the contract is expected to be three years and is expected to begin approximately July 1.

Personnel required include: (1) Project director (fulltime) experienced in occupational studies to supervise all aspects of the contract; (2) two data collection managers (fulltime) to prepare data collection materials, hire and train abstractors and interviewers, and monitor data collection; (3) five computer programmers (fulltime) to create and manipulate computer files and to develop and use computer edit programs; (4) one clerk typist (fulltime); (5) one industrial hygienist (50 percent time); (6) one person to oversee procurement of death certificates (50 percent time); and (7) additional field or office persons (a total of 10 person years) to be hired or assigned to the contract as needed.

Respondents must have or be willing to establish a commercial office within 50 miles of the off-campus Landow Bldg., 7910 Woodmont Ave., Bethesda, Md., housing the project director and support staff (i.e., clerks, typists) necessary to monitor and direct all aspects of the contract.

Epidemiologic studies undertaken by the Environmental Epidemiology Branch may involve collaboration with other groups or organizations resulting in complex logistical and organization efforts. At the present time it is not possible to determine all studies to be supported under this contract, but at any particular time 25 to 35 projects are usually under active investigation.

Contract Specialist: Donna Rothberg
RCB, Blair Bldg. Rm. 114
301-427-8888

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