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DCPC Begins Reassessment Of Year 2000 Goals; Advisors Discuss A 'More Dynamic Model'

NCI's Div. of Cancer Prevention & Control and its Board of Scientific Counselors have begun an assessment of the "Year 2000" goals developed in 1986 to established nationwide cancer control objectives. "This would seem to be a good point to take a look at where we are and whether modifications in the goals or NCI activities would be useful," DCPC Director Peter Greenwald said to the board at its recent meeting. In 1986, NCI published a monograph titled, "Cancer Control Objectives for

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In Brief

NBA, NCI Sign Agreement On Content Of PSAs; Broder Talks To NBA Wives; ASCO Honors Frei

NATIONAL BASKETBALL Assn. and NCI have signed an agreement on scientific content of materials and public service announcements the league is developing on cancer early diagnosis. As a result of an initiative by National Cancer Advisory Board member **Irene Pollin**, NBA has produced a television PSA that is being shown during NBA games this month. Teams around the country have developed projects under the intiative; some players and their wives are speaking to community groups, and many are raising funds to help underserved women get breast cancer screening. . . . **"I CAN'T GO** to any NBA city without some NBA wives coming up to talk to me," NCI Director **Samuel Broder** told the NCAB. "In Boston last week, I was surrounded by wives of Celtics players after a talk." . . . **EMIL (TOM) FREI,** chief, Div. of Cancer Pharmacology and physician-in-chief emeritus of Dana-Farber Cancer Institute, will receive the American Society of Clinical Oncology's first Distinguished Service Award at the annual meeting next week. The award recognizes exemplary contributions to the field of oncology and outstanding longterm service to ASCO. Frei is a past president of ASCO and 12th annual Karnofsky Award Lecturer. . . . **NEW STAFF** members in NCI's Div. of Cancer Prevention & Control: **Claudette Varricchio**, nurse consultant in the Commuity Oncology & Rehabilitation Branch; **Ronald Lubet**, health science administrator in the Chemoprevention Branch; **Richard Bragg**, public health advisor in the Special Populations Studies Branch; **Mark Garfield**, chemist in the Biomarkers & Prevention Research Branch. . . . **CORRECTION:** Bernard Fisher was misquoted in the May 8 issue of **The Cancer Letter** regarding risk of endometrial cancer with tamoxifen therapy. Fisher's quote should have read, "our conclusion is that the risk is no greater than what would occur following estrogen replacement therapy."

Year 2000 Goals Were Valuable, Need Reassessment, Advisors Tell NCI

(Continued from page 1)

the Nation: 1985-2000." The report stemmed from work by four committees convened by the DCPC Board of Scientific Counselors at the request of then-NCI Director Vincent DeVita.

"The objectives were very motivating and useful, but they were wishful thinking," board Chairman Alfred Haynes said. "They did not have rigorous analysis."

Since 1986, he said, "there has been improvement toward achieving the goals, but there are limitations to what can be done by the year 2000."

At a workshop held during the board's recent meeting, participants discussed developing a "more dynamic model" that would not be limited to the year 2000.

"The biggest breakthroughs can be achieved by applying what we already know," Haynes said. "Our role might be to define the best strategies and show what time frame might be required to achieve them."

Since achieving the goals depends to a great extent on nationwide changes in behavior, a dynamic model "could be altered as new knowledge comes in," Haynes said. "We don't want to be stuck with a set of objectives written in 1990."

NCI Goals Emphasize Mortality

"I feel the early goals were valuable," Greenwald said. "They did bring into focus our prevention efforts. Having something to shoot for, ambitious as it may be, is useful."

In 1991, HHS, in a report called "Healthy People 2000," set forth "National Health Promotion and Disease Prevention Objectives" for the department. NCI had the key role in developing the cancer section of the report, many aspects of which are similar to NCI's 1986 objectives, Greenwald said.

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"There may be advantages to NCI using the department objectives and not a maintaining a separate set," he said. "First of all, we are part of the department and need to be sure our goals mesh. We have worked very hard to assure this. Second, department goals make clear it is a broad effort involving many agencies, the public sector at all of its levels, and the private sector. This is obvious if, for example, you look at objectives related to smoking prevention or diet modification. Third, the HHS objectives give strong focus to risk factors and behaviors.

"I have been concerned that people have tended to focus on the mortality projections made with the NCI objectives, rather than on the necessary societal effort directed toward the behavioral change needed to impact those outcomes," Greenwald said.

What gains have been made regarding the leading causes of cancer death? Greenwald discussed trends in lung, colorectal, and breast cancers. Following are his remarks:

Lung cancer: The HHS objective calls for reducing smoking to a prevalence of no more than 15 percent among people aged 20 and older; and to reduce the initiation of cigarette smoking by children and youth so that no more than 15 percent have become cigarette smokers by age 20. NCI objectives were the same.

--Smoking among adults (18 years and older) declined from approximately 33 percent in 1980 to 25.4 percent in 1990. Nonetheless, nearly 50 million adults continue to use cigarettes, or about the same absolute number as 15 years ago.

--Smoking among adolescents remained essentially unchanged during the decade of the 1980's. Approximately 12 percent of all youth 12-18 currently use cigarettes regularly. By age 18, between 20 and 25 percent of youth are smokers.

--Price of cigarettes has increased nearly 3-fold since 1980, from slightly less than $.60 a pack to $1.60 in 1991. Surprisingly, this increase is almost entirely due to price increases passed on to consumers from the manufacturer and not from increases in federal or state cigarette excise taxes.

--Cigarette consumption is down. Per capita consumption per adult is expected to fall below 2,700 cigarettes in 1992 and total cigarette sales will probably be below 500 billion.

--Consumption of both snuff and chewing tobacco increased in 1991. While snuff has increased annually over the past 15 years, the increase in chewing tobacco is the first such increase in several decades.

--In terms of lung cancer statistics, we have seen a

topping out of incidence rates in white men, but have not yet seen that for white women or minorities.

Colorectal Cancer: While rectal cancer has been gradually declining, colon cancer rose gradually until 1985, when it peaked. That was the year President Reagan was diagnosed as having colon cancer. Since then, we have had four consecutive years of declining incidence. Possible factors contributing to this decline are early detection and dietary changes, particularly a move away from saturated fat intake. We do see black-white racial disparities in these trends, which need continued attention in terms of research to understand the trend and actions to change it. Some other recent highlights include:

--The evidence grows stronger on the adverse role of saturated fat and the benefits of dietary fiber (especially wheat fiber), vegetables and fruits. Calcium and other micronutrients also may be beneficial and are under study.

--Chemoprevention studies continue to show great promise. Particularly intriguing was the recent report by Thun et al of the American Cancer Society suggesting that colon cancer death rates among people who took 16 or more aspirin tablets per month was 40 percent lower than people who did not take aspirin (NEJM 325:1593, 1991).

--An epidemiologic study of screening sigmoidoscopy by Selby et al (NEJM 326:653, 1992) showed a 59 percent reduction in colorectal cancer deaths, after adjusting for potential confOunding, for those screened. The benefit was limited to cancers within reach of the sigmoidoscope.

--Randomized clinical trials have documented the efficacy for selected patients of adjuvant therapies for reducing colorectal cancer mortality.

Greenwald also noted that the U.S. Dept. of Agriculture finally came out with a new "food pyramid" that emphasizes grains, fruits and vegetables, and de-emphasizes meats and fats.

Breast Cancer: The DCPC-Breast Cancer Prevention Trial was launched recently. This study, being conducted by the National Surgical Adjuvant Breast and Bowel Project, is designed to see if women at increased risk for breast cancer will benefit from taking tamoxifen. The trial is starting at 270 sites across the U.S. and Canada. Sixteen thousand women will participate. On another front, the NIH Women's Health Initiative and the related NCI feasibility trial in minority and underserved women is progressing well. Together, these trials should provide the information to help women make informed choices about reducing breast cancer and other disease risk.

--Mammography screening rates have jumped from below 15 percent screened in 1982 to 40 percent screened in the last two years in 1990. These increases indicate earlier detection of breast cancer, which suggest reductions in breast cancer mortality several years from now.

--As we continue to get questions about cancer screening in 40-49 year old women, I would like to show the incidence and mortality trend for this age group. From 1973 to 1989, the mortality rate has declined by 13 percent for white women. For black women, it rose by nearly 7 percent. These time trend data indicate possible contributions of mammography screening to the decline in mortality, but the evidence is circumstantial and the data may also be explained in part by other factors including etiology and treatment factors. The HIP trial and BCDDP demonstration projects provide some evidence of benefit for screening 40-49 year old women, while other trials have not. We believe it is good medical judgment to stay with our present screening guidelines, and only consider changes if trials in progress present compelling new evidence in the future.

--Recent meta-analyses of clinical trials utilizing combination chemotherapy and hormonal therapy continue to support potential reductions due to treatment, particularly among post-menopausal women.

'Only Modest Mortality Decreases' Projected

"Overall, I think we have made and are making substantial progress, but certainly have many areas where we need a continued broad research effort," Greenwald said. "The overall mortality figures indicate very little decrease thus far from these behavioral changes, and I believe at this point we have to project only modest mortality decreases during this decade based on these known factors.

"However, full application of current knowledge would still have a substantial impact eventually, but the rate of adoption would have to be much more rapid than we anticipate to have a mortality impact in this decade. Finally, there are many vital research leads under study; for example, the chemoprevention trials and studies of new therapies, which at some point could dramatically change this picture."

The workshop participants spent some time discussing the existing public policy barriers to full implementation of the prevention objectives. For example, Haynes noted, one arm of government promotes tobacco farming subsidies while another arm discourages smoking.

Another topic what exactly what measurements to include in a model. "We agreed on survival, incidence,

morality and the process [to achieve the goals]," Haynes said. "And you have to express all that in lay terms, because prevention will not succeed unless it reaches the lay public."

Board member Harmon Eyre said NCI should try into include other agencies setting new goals, such as the Centers for Disease Control and the American Cancer Society.

Board member Robert Greenberg said age-adjusted mortality is "not a valid scientific measurement of progress" because it tends to hide information specific to population subgroups and does not provide information about ethnic groups or genders.

DCPC Deputy Director Edward Sondik noted that Congress has felt that "the bottom line is mortality."

Board Fumes Over Prevention Budget Cut

At the same time the advisors were considering how NCI could improve its prevention goals, they were fuming over the President's proposed FY93 budget for NCI, which would cut $15 million from the prevention and control line.

In an unintended understatement, NCI Deputy Director Daniel Ihde told the board that, "This will necessitate some hard choices for us in the area of cancer prevention and control."

"Can you tell us the rationale for the cut?" board member Carol D'Onofrio asked.

"I can assure you that NCI did not suggest it," Ihde said. He said the reduction was made somewhere along the line in NIH, PHS, HHS, or at the White House Office of Management & Budget.

The Cancer Letter has learned that the cut most likely was made at NIH, which has upset some NCI executives, staff, and advisors. When the White House cuts the budget, it expects criticism from Congress. But NIH officials appear to have unwittingly invited criticism from Congress and prevention advocates alike by seemingly arbitrarily erasing a $15 million increase that Congress provided especially for the prevention and control line last year.

"I think [the cut] can have a devastating effect on prevention and control," Greenwald said. "In FY 1992, we used the increase to start important prevention trials. Once you start a trial, you can't back off on the obligations. So the impact on some of our other programs could be major, such as the smoking program. I don't understand at all why the cut was made."

One major program that will be hurt by the cut is the American Stop Smoking Intervention Study (ASSIST), a collaborative effort with the American Cancer Society. The ASSIST budget will be held to the FY92 level, though the program originally called for a 40 percent increase in FY93.

HHS Secretary Louis Sullivan personally announced the start of ASSIST last fall, stating that a major goal of the department is "to do everything possible to have a smoke-free America in sight by the year 2000."

'I've Written My Congressman'

"The Administration chants a chant about prevention, from Dr. Sullivan on down," board member Helene Brown said. "Committee after committee has emphasized the importance of prevention, and NCI has the same concerns. So this, to me, is a puzzlement. I have written my Congressman about this. I think it is awful."

"The message is not getting across," board Chairman Alfred Haynes said.

"We don't even know who it's not getting across to," said Brown. "We don't know who made the cut."

"Are there prospects for increasing the share of the R01 pool for prevention and control?" board member Robert Greenberg asked.

"That depends on investigators," Greenwald said. "There is always the opportunity for people in every field to come in for R01 grants, and we've tried to encourage that." He noted that the large contract-driven trials, such as ASSIST, or CCOP trials, "are tied very much to the prevention and control line."

Ok's Statement on Tobacco, New Task Force

The board approved in principle a statement also approved by the Div. of Cancer Etiology Board of Scientific Counselors asking the federal government to discourage the export of tobacco products abroad. Board members made suggestions on strengthening the statement, noting that a third of cancer deaths are related to tobacco and that lung cancer is the leading cause of cancer death worldwide. The board decided to seek the input of the Coalition on Tobacco or Health as to the exact wording of the statement and where to send it in the federal bureaucracy to have the greatest impact.

"I think we should send it to [U.S. trade representative] Carla Hill, who is promoting international trade in tobacco," said board member Harmon Eyre.

The board also approved in principle a motion by members Helene Brown and Rumaldo Juarez to initiate a federal interagency task force on cancer prevention policies.

"We are worried that the Cancer Institute is developing a lot of projects for cancer prevention, while other departments are distributing high fat food to the low income population and are subsidizing tobacco," Juarez said.

"We can talk all year long about dietary changes

for young children, while through the federal food programs they are getting the wrong food," Brown said.

Greenwald noted that there are some interagency groups already. "It's a reasonable idea, I just don't know what the format should be," he said.

Sondik suggested the group be called a federal "coordinating" task force.

"I'm very sympathetic to the thrust of what you are trying to do," said board member Carol D'Onofrio. "But there seems to be an assumption that agencies have control over their policies. There are constituencies and entitlements and politics."

"You are absolutely right," said Brown. "This is a small step."

DCPC Advisors Ok Four New Grant Programs To Boost Prevention Field

Advisors to NCI's Div. of Cancer Prevention & Control gave concept approval to four new grant programs designed to encourage investigators to submit applications for prevention research.

The DCPC Board of Scientific Counselors committed more than $44 million over the next five years to the new programs. In addition, the board gave concept approval to recompetition of surveillance master agreements and the reissue of a program announcement for small grants.

Also, the board gave concept approval to an interagency agreement that would provide about $3 million to the National Center for Health Statistics for a longitudinal analysis of behaviors related to diet, weight and physical activity as a followup to the National Health Interview Survey.

Following are the concept statements, which were approved unanimously:

Interactive Research and Development Projects in Chemoprevention. Concept for a new RFA (cooperative agreements), $20 million total over five years, three to five awards per year.

The Chemoprevention Branch, Cancer Prevention Research Program, DCPC, invites grant applications to encourage coordinated submissions of related projects from investigators who want to collaborate on studies dedicated to developmental research in chemoprevention. This type of research moves basic findings to applied innovative research with subject and populations. This RFA is targeted to accelerate the identification and initial evaluation of new technologies that will facilitate the transfer of these from the laboratory to the clinic and, ultimately, to determine their usefulness to public health prevention practice.

This RFA proposes to stimulate collaborative research and development activities in chemoprevention. The objective is the development and conduct of studies of cancer inhibition and the evaluation of efficacy of potential interventions in high risk groups.

It is expected that each coordinated submission support a mix of basic, developmental and clinical research grants from investigators who want to collaborate on a particular chemopreventive effort. A minimum of several independent investigators are required to submit concurrent, collaborative, cross-referenced individual grant applications (U01) that will share a common developmental and translational focus. Applications may be from either a single institution or a consortium of institutions. This RFA is not intended to support either basic or clinical research to the exclusion of the other but should include both components. It should have a general focus on outcomes and the application of basic research and development to subjects and populations.

This proposed RFA is to support collaborative preclinical and clinical interactive grants which are directed toward examining the role of various biological and/or biochemical markers in assessing risk or modulation by chemopreventive agents. One or more intermediate endpoints might be evaluated initially to determine baseline parameters, and subsequently to serve as a follow-up after the administration of the preventive measure or the chemopreventive agent in vivo and/or in vitro.

These studies should be developed with preclinical and clinical phases which may include a pilot phase in humans that could later proceed to a full scale intervention. The main emphasis should be on small, efficient studies aimed at improving future research designs providing biologic understanding of what is happening or providing better, more quantitative and more efficient endpoints. After successful completion of the pilot phase (i.e., demonstrated modulation of marker endpoints), subsequent studies could include a clinical trial monitoring the test system, a cancer incidence or mortality endpoint, and a designated agent.

For the initial human phase the proposed study must describe the relevance of the marker test system to clinical or public health cancer prevention, the rationale for the selection of the study population, and potential intervention agent or procedure. The project could result later in the markers and agent being evaluated in a full scale, double blind, randomized risk reduction clinical trial.

Interactive Research Project Grants for Nutrition and Cancer Prevention. Concept for a new RFA (R01s), $12.5 million total over five years, six to nine awards per year.

The Diet and Cancer Branch, Cancer Prevention Research Program, DCPC, seeks to encourage and facilitate formal interdisciplinary collaborations through the coordinated submission of related research project applications that share a common research focus relevant to nutrition and cancer prevention, but do not require extensive shared physical resources or core functions.

The objectives of this concept for Interactive Research Project Grants are 1) to increase the investigator-initiated pool of quality applications in the area of nutrition and cancer research and 2) to stimulate an intermediate level of interdisciplinary collaborative efforts to build stronger research bridges between nutritional science and the disciplines that relate closely to basic and clinical research for the development and evaluation of new approaches to nutrition and cancer prevention research.

A minimum of three independent investigators with related research objectives will be encouraged to submit concurrent, collaborative, cross-referenced individual research project grant applications (R01) that share a common research focus. Applications may be submitted from a single institution or may include arrangements with multiple institutions if appropriate.

The overall goal is to provide more definitive data for developing quantitative dietary guidance and translation into

optimal and desirable eating patterns and food choices that have the potential for a substantial reduction in the risk of diet related cancers in the general population.

Typically, the IRPG approach will be suited to many basic research questions, as well as research to develop and apply innovative technology, or to evaluate intervention strategies in individuals and target subpopulations. The IRPG mechanism is also well suited for pilot studies that propose limited testable research questions or for clinical/metabolic and related correlative laboratory studies.

Use of the IRPG mechanism should benefit applicants by establishing a larger framework of reference for the proposed work, by facilitating formal collaborations tailored to achieving research objectives, by providing a record of independently acquired awards credited to each funded investigator, and by allowing retention of research autonomy by the named PI on each of the interactive grants.

Several examples of research areas relevant to nutrition and cancer prevention in which the IRPG concept may be applied are as follows:

--Metabolic effectors of dietary origin. Basic science projects may be combined that integrate multiple aspects of dietary factors that modulate signal transduction, DNA repair, antioxidants, hormonal regulation and gene regulation.

--Interaction of diet and dietary components with drugs, hormones, metabolites and genes--synergistic and antagonistic effects.

--Development of new and better methods to quantify dietary intake in individuals.

--Further identification and evaluation of overall dietary patterns, foods and food constituents that alter cancer risk and elucidation of their mechanisms of action.

--Identification of markers of dietary exposure and early indicators of risk.

--Quantification of optimal ranges of dietary constituents that affect cancer risk.

--Social behavioral research to identify motivation factors and barriers to changing food habits.

--Nutrition as one component of healthy lifestyle modification. Studies of fundamental relationships between diet, nutrition and cancer and behavioral change affiliated with modification.

Interventions to Enhance Adjustment to Risk Notification or Diagnosis of Cancer. Concept for a new RFA, $8 million total over four years, four to five awards.

The goal of this concept is to enhance the quality of life of persons at increased risk of cancer and newly-diagnosed cancer patients through effective psychosocial counseling. Research objectives comprise development and testing of interventions to promote adjustment to risk notification or diagnosis of cancer and to enhance adherence/compliance with medical recommendations for prevention, surveillance or treatment.

Psychosocial aspects of cancer are receiving increasing attention as a target for further research, both from within NIH and from Congress. The Senate Appropriations Committee has urged NCI to explore the impact on survival and quality of life of cancer patients from counseling services and further, to give greater priority to counseling services as an integral aspect of medical care being offered."

This concept promotes research to develop, implement, and evaluate the efficacy an effectiveness of specific psychosocial counseling interventions on the quality of life persons notified of increased cancer risk or newly-diagnosed cancer patients with good prognosis. Objectives comprise:

(1) To evaluate the efficacy of specific counseling interventions in high risk individuals and newly-diagnosed cancer patients in (a) improving quality of life and (b) enhancing medical compliance.

(2) To identify characteristics of successful interventions. For counseling programs: timing, content, and structure; for study populations: subgroups with greatest need and greatest benefit.

(3) To assess the potential for community implementation: effectiveness in the community setting, costs, and payment mechanisms.

Psychosocial counseling is defined as short-term, time-limited therapy that addresses not only the emotional and adjustment issues of coping with the diagnosis of cancer, but also issues such as the need to comply with initial treatment plans and medical followup. Examples of interventions include informal self-help or mutual support groups, behavioral interventions (such as coping strategies or relaxation techniques), and more intensive individual counseling by psychiatrists and psychologists; psychopharmacologic interventions may be evaluated as adjunctive therapy to counseling components. Applications may incorporate existing but previously untested interventions, adapt existing programs for specific patient groups, or develop new counseling interventions. Interventions should target either persons notified of increased risk of cancer or newly-diagnosed patients with reasonable chance of cure or prolonged survival.

A major objective of this proposed RFA is to determine the impact of the intervention on quality of life and adherence/compliance. Outcome variables should include standard measures that assess the many aspects of quality of life, and medical outcomes assessment using accepted techniques. Evaluations must also assess the timing, content, and structure of the counseling intervention and identify characteristics of patients with most need of and benefit from the intervention. While the proposed research may focus on efficacy and structure of the study intervention, issues of effectiveness of the program in community settings, efficiency of the intervention with respect to use of resources, potential dissemination of the intervention program, cost considerations, and mechanism payment must be addressed. A multi-disciplinary approach including expertise in cancer prevention, clinical oncology, psychiatry/psychology, nursing, epidemiology, and health services research is recommended.

Methodologic Approaches to Quality of Life/Psychosocial Assessment in Special Populations. Concept for a new RFA (cooperative agreements), $3.9 million over three years, six awards.

The goal of this concept is to foster development of methods for assessing quality of life (QOL) in cancer patients from diverse sociocultural backgrounds, for application in cancer prevention and treatment clinical trials and in supportive care research. The major objective is the development, standardization, and pilot testing of techniques or measuring health-related quality of life or specific QOL dimensions such as physical symptoms (including pain), functional status, psychological function, social interaction and other domains in special populations.

As we have developed program strategies for research in symptom control, continuing care, and cancer rehabilitation, implementation has been compromised by lack of methods to measure various aspects of quality of life in special populations. Pertinent examples include:

1. At the January 1992 DCPC Board of Scientific Counselors meeting, board members raised questions regarding practical aspects of including patients from special populations in research on psychosocial aspects of cancer, which included various aspects quality of life as outcome variables, when few instruments

were sensitive to language and cultural needs.

2. Within the Minority-based Community Clinical Oncology Program (MB-CCOP), many patients are diagnosed with advanced disease and have limited treatment options. Lack of appropriate measurement methods has limited their participation in supportive care and cancer rehabilitation research and has hampered NCI efforts to enhance quality of life and transfer of "state-of-the art" cancer care to these groups. Objectives are:

(1) To develop or adapt existing methods for assessing aspects of QOL in cancer patients from special populations that are sensitive to (a) language and dialect; (b) customs, beliefs, and traditions; and (c) education and socioeconomic status.

(2) To standardize methods in the target population: general acceptability reproducibility, construct validity, and responsiveness to change.

(3) To demonstrate applicability of the assessment methods in pilot studies of supportive care interventions in the target population.

Applicants will develop methods for assessing global QOL and/or various components that are sensitive to language and dialect, culture, and socioeconomic status of minority populations. When feasible, translation and adaptation of existing instruments or methodology for use in special populations is encouraged, to allow cross-cultural comparisons. Techniques should focus on measuring global health-related QOL or specific domains or aspects of QOL, such as functional status, disease- and/or treatment related symptoms, emotional or psychological functioning, and social functioning ar support.

Proposals should focus on methods to evaluate within-person change over time (i.e., evaluative versus discriminative or predictive approaches). Instruments or assessment techniques must be sensitive to language and dialect, and to the customs, beliefs and traditions of the target population. Methods must also be appropriate for the educational achievement and socioeconomic status of the target population.

Methods must be evaluated in patients from the target population. Standardization must include demonstration of general acceptability, reproducibility (replicability), construct validity (correlation with expected changes in variables usually used to measure construct), and responsiveness (ability to demonstrate a difference over time when one exists) within the target population. Ease of administration and respondent burden should also be evaluated.

Methods developed through this initiative must be implemented in pilot studies supportive care or cancer rehabilitation interventions. The spectrum of potential applications in clinical trials and research on psychosocial aspects of cancer should also be identified.

Priority will be given to proposals which comprise a broad program of methods development rather than those which develop/adapt a single tool for one population subgroup. For example, applicants are encouraged to focus on use of an instrument method in multiple special population groups; to highlight development/adaptation of a spectrum of instruments for one special population; or to include a predictive approach to enhance application of the evaluative methods. A multidisciplinary approach is recommended. Collaboration with an established cancer clinical trials network for pilot testing is encouraged.

Cancer Prevention and Control Surveillance Master Agreement. Concept for renewal of an RFP, master agreements, $8.4 million total over five years, 15-25 master agreement holders, 7-12 master agreement orders.

The purpose of this concept is to establish a Master Agreement mechanism under which a variety of surveillance activities would be conducted. The goal of establishing the mechanism is to enable the cancer control information to be obtained with a minimum of delay while maintaining the highest standards for surveys and other data collection.

Although developed by the Surveillance Program, use of this concept will be available to the entire division. The following examples reflect the range of potential applications across the division.

A. Rapid response to developing events--Legislative effects of cancer information: Lagging policy and legislative initiatives is the research base to provide specific information about their impact on desired behaviors and, ultimately, cancer. Evaluation studies must be designed and implemented rapidly in response to naturally occurring policy events. Two examples of important trends that lack sufficient empirical investigation:

(1) Mammography: Twenty-three states enacted breast cancer early detection legislation in 1991, including provisions for third-party reimbursement quality assurance, screening programs, public and professional education and notification of screening options. The impact of these legislative actions on breast cancer detection, survival, and mortality. Studies to answer questions about the impact of third-party reimbursement legislation on such issues as screening frequency, adherence to guidelines, mammography cost, screening quality and availability.

(2) Legislation. Of the 33 states enacting cancer registry legislation, only 17 included provisions to use the collected information to plan and evaluate cancer activities. Missing from this picture is empirical information about the impact of such legislation on the establishment of cancer control programs in states, the use of accurate incidence and morbidity data in cancer control planning and for the evaluation of cancer control initiatives, the influence of the availability of such data on the initiation of cancer control interventions and programs by state and other public health agencies, and institution of cancer control within state health departments.

Recent interest in breast implants: Given the enormity of the consequences if breast implants do carry an increased risk of certain health problems, a timely evaluation of this issue is warranted.

Special studies for planning purposes: In the planning of large intervention trials certain aspects of the design may not be well understood. In such cases, it is desirable to be able to rapidly implement a special study to address a specific design issue.

B. Community and regional cancer control--The Community Intervention Trial for Smoking Cessation (COMMIT): The Master Agreement allowed multiple surveys to be conducted over a five year period to collect relevant data to measure the intervention effect on the population and on selected target groups such as women, children and physicians.

The American Stop Smoking Intervention Study (ASSIST) for Cancer Prevention project provides for activities to the COMMIT project and is funded through its own set of contracts. However, it is anticipated that issues will emerge which involve ad hoc studies which span both these projects, and which are outside the scope of planned funding. The Master Agreement would permit the implementation of such studies.

Cancer Control Practices in Communities: practice patterns, cancer detection patterns and both public and professional behavior related to cancer prevention.

C. Special surveillance studies--Areas include: surveillance of cancer control activities; surveillance of screening practices; surveillance of high risk populations; cancer control program tracking; effects of new product formulations; surveillance of nutritional practices; comorbidity and early diagnosis of cancer in the elderly; and the economic burden of cancer.

Cancer prevention and control research small grant program. Concept for a program announcement to encourage small grants of $50,000 each in direct costs. Total funding dependent on number of grants awarded. All investigators deemed via peer review to have sound scientific proposals will be considered for funding.

The Cancer Prevention and Control Research Small Grant Award is designed to encourage investigators from a variety of academic, scientific, and public health disciplines to apply their skills to scientific investigations in the field of human cancer control intervention research. The research may occur in a variety of settings, such as universities, cancer centers, communities, schools, health departments, laboratories, worksites, etc. These investigators will become part of the nationwide group of scientists pursuing cancer control research goals.

The Small Research Grant mechanism (R03) is designed to aid and facilitate the growth of a nationwide cohort of scientists with high level of research expertise in the field of human cancer control intervention research. New as well as experienced investigators in relevant fields and disciplines (e.g., disease prevention and control, medicine, public health, health promotion, applied epidemiology, chemoprevention, social rehabilitation, nursing research, physical sciences, nutrition, health policy, health services research, and behavioral sciences such as social psychology, health education, sociology, and community organization) may apply for small grants to test ideas or do pilot studies.

Since 1984 this mechanism has existed as an RFA with a total of 89 awards being made between 1984-1989. No awards were made in 199O-1991. Each RFA announcement has resulted in 70-115 grant applications per cycle. Many investigators have successfully submitted subsequent R01 applications and/or become project directors on NCI program projects. Multiple publications and presentations have resulted from work conducted with small grant funding. Grants have not yet been received for the RFA announced in January 1992. Application deadline is May 6.

Within the Small Grant program, investigators may choose among the full range of cancer control phases in their work. Many studies and research designs may contribute to the design, implementation or evaluation of future phase III-V studies, e.g., descriptive baseline surveys, testing, modification and validation of surveys or program materials for use in the proposed population groups, testing of recruitment or compliance procedures for participants, etc. Investigators must address the specific aims and hypotheses, the background and significance of the proposed work, results of any preliminary studies, experimental design and methods including any relevant theoretical concepts which underlie the research, human subjects involvement and protection, and relevant literature. Direct costs up to $50,000 for the two-year time period are allowed. These are would be non-renewable.

The following cancer control program areas are appropriate for human intervention research grant applications:

--Prevention (e.g., chemoprevention, diet and nutrition, and smoking intervention studies).

--Screening and early detection (e.g., developmental studies of new methods; application of the "NCI Guidelines For Early Detection"; in the area of breast screening and detection, however, studies of breast self-examination as a single modality will not be accepted).

--Cancer control sciences (e.g., studies to change current behaviors and/or institute new behaviors or health promotion interventions effective in reducing incidence, morbidity or mortality from cancer).

--Laboratory and clinical research related to cancer prevention (e.g., biological assessment of dietary fiber intake, analysis of human data on chemoprevention and cancer).

--Smoking prevention and cessation (e.g., pilot studies targeted at improving utilization of current technologies in target populations or organizations are encouraged. Minor enhancements of existing technology are not encouraged).

--Applications research (e.g., modifying, feasibility testing, and adopting proven, state-of-the-art intervention programs and strategies from other research projects (e.g., screening, smoking prevention, etc.) for use in special populations, state and local health agencies, or other organizational and community settings and their evaluation.

--Community oncology (e.g., improving the application of patient management and continuing care research advances into community settings).

--Applied epidemiology studies (e.g., using epidemiologic methods to determine the association between exposure to an intervention and its impact on disease) are acceptable within the above program areas.

Although the specific study proposed may attempt only to obtain preliminary data and/or conduct pilot studies in support of a future, more detailed phase III-V study, it is important that a long term human cancer control hypothesis and supporting scientific justification be presented.

Recompetition Of Support Services For NCI Director's Office Ok'd

The Committee on Information & Cancer Control for the Year 2000, of the National Cancer Advisory Board, has given unanimous concept approval by mail ballot for recompetition of a contract for support services for the NCI director's office.

Following is the concept statement:

Support services for the Office of the Director, NCI. Recompetition of a contract, total $2.242 million over five years.

This support services contract has been in place since the early 1970s to support the Institute in conference/meeting management, and the preparation of planning and reporting documents. The contract primarily supports the Office of the Director, NCI and is limited to providing services that cannot be performed expeditiously by in-house staff.

The contract will assist NCI in rapidly responding to requests for information from a variety of sources. The fluctuations in demand for such services and the range of topics covered by such demands would make it difficult for NCI staff to respond efficiently and effectively to the requirements.

The contract would provide services in four areas:

1. Task administration: preparation of progress reports, task orders, secretarial, clerical, and messenger services.

2. Documentation and presentations: preparation of handouts, slides and other graphics for use in presentations. High speed duplicating with 24-hour turnaround.

3. Conference and meeting management: provision of management and support services for a nominal number of conferences and meetings. Contractor is responsible for providing daily on-site general conference support, which includes maintaining rooms in an orderly manner within the Executive Plaza North facility.

4. On-site typing support: provision of personnel necessary to provide typing/word processing services and related clerical support from hand-written copy, rough-typed copy, dictation tapes, and from regularly used formats or preformed paragraphs.