

Special Article

The Department of Defense Congressionally Directed Medical Research Program: Innovations in the Federal Funding of Biomedical Research^{1,2}

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Abstract

In response to the lobbying efforts of the women's advocacy movement, in 1993 Congress authorized funds for a substantial increase in support of new and promising research aimed at the eradication of breast cancer. This appropriation resulted in a major expansion of the United States Army Medical Research and Materiel Command, Department of Defense Breast Cancer Research Program. The Office of Congressionally Directed Medical Research Programs was established within the United States Army Medical Research and Materiel Command to facilitate the management of the expanded extramural research program. Since that time, the programs have grown to include not just breast cancer but also prostate cancer, ovarian cancer, and neurofibromatosis. The unique appropriations to the Office of Congressionally Directed Medical Research Programs has resulted in a number of programmatic innovations. These include development of unique mechanisms of grant support, inclusion of consumer advocates on peer and pro-

grammatic review panels, and the introduction of criteria-based evaluation and scoring in peer review. This article describes these novel scientific management strategies and outlines their success in meeting program visions and goals.

Introduction

Cancer remains the second leading cause of death in the United States (1) despite a decade of unprecedented advances in the understanding of its etiology and progression. Unfortunately, this knowledge has been slow to translate into routine clinical practice (2), depriving many patients of potentially life-saving or life-sustaining treatments. Additionally, some populations have not fully benefited from research findings because of their under-representation in studies or because of variations in access to care (3).

Consumer activists have long voiced their concerns about this apparent scientific bottleneck (4). The breast cancer consumer community has been particularly effective in raising public and legislator awareness of these gaps in research and practice. Their advocacy resulted in a national campaign to change this situation and, in 1993, the National Breast Cancer Coalition presented President Clinton with a 2.6-million signature petition for "a comprehensive plan to end the breast cancer epidemic (5)."

Congress responded by appropriating funds targeted specifically toward winning what came to be known as "The War on Breast Cancer." Responsibility for these funds was given to the DOD,⁸ which in turn created the CDMRP to develop, direct, and manage an innovative agenda for breast cancer research. Located within the USAMRMC, CDMRP has administered a total of \$2.24 billion as of fiscal year 2002 (Fig. 1). Funding is currently provided for extramural research grant programs targeting not just breast cancer but also prostate cancer, ovarian cancer, and neurofibromatosis.

This new research initiative within the DOD and the Army possessed several features unique to research funding organizations at the time. These features included: (a) a history of flexibility enabling a quick response to change; (b) a history of performing research targeted to a specific problem; (c) a willingness to engage scientists, clinicians, and consumers in the design of the program; and (d) a location outside of the tradi-

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⁸ The abbreviations used are: DOD, Department of Defense; CDMRP, Congressionally Directed Medical Research Program; USAMRMC, United States Army Medical Research and Materiel Command; IOM, Institute of Medicine; IP, Integration Panel; BCRP, Breast Cancer Research Program; PCRP, Prostate Cancer Research Program; OCRP, Ovarian Cancer Research Program; NFRP, Neurofibromatosis Research Program; SAIC, Science Applications International Corporation; ASI, Analytical Sciences Incorporated.

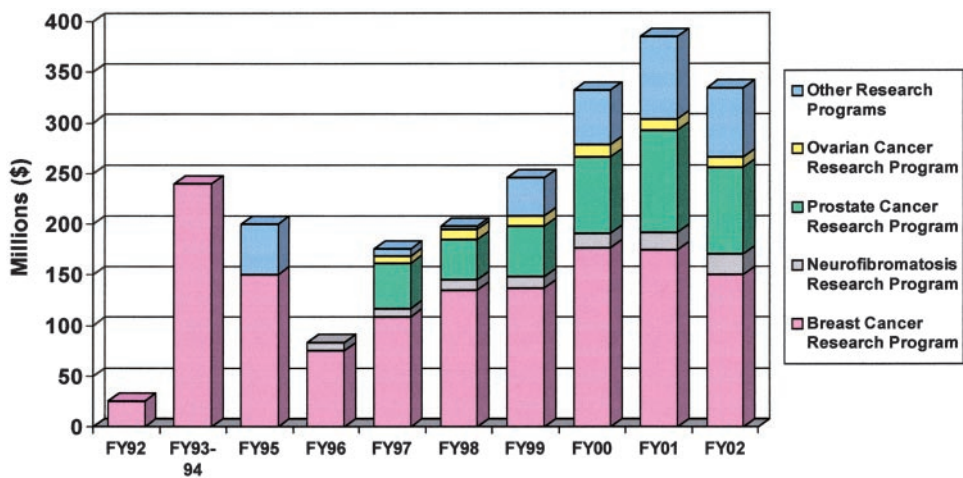


Fig. 1 Summary of funding for CDMRPs per fiscal year of congressional appropriation.

tional federal medical research organization, permitting the design of a research program different from but complementary to those already existing. The DOD was willing, where others were not, to design “a battleship that could turn on a dime (6).” This report describes the evolution of the CDMRP and some of the programmatic innovations developed to fulfill its stated mission: “to advance health care solutions in areas identified by Congress and the DOD by funding excellent research, recognizing and mobilizing untapped opportunities, creating partnerships, and guarding the public trust.”

Evolution of Program Structure

To ensure the establishment of a scientifically sound program that could address the needs of the consumer, and clinical and research communities, in 1993 the DOD sought advice from the National Academy of Sciences IOM. The IOM was specifically asked to comment on: (a) an investment strategy for the wisest expenditure of the funds; and (b) an appropriate review system for the evaluation of competitive proposals. A blue ribbon committee of the IOM studied these major considerations and issued a report (7).

The IOM recommended a traditional peer review of proposals submitted, an approach similar to the NIH model (8). The IOM report concluded that to ensure both scientific excellence and programmatic relevance, a two-tiered peer-review system was needed. The first tier would be panel peer review for scientific and technical merit (similar to a NIH Study Section). This would be followed by a second tier review of all of the proposals for program relevance, to be performed by an IP (similar to a NIH Advisory Council). The combined review process was designed to balance the most meritorious science across many disciplines and offer the highest promise for fulfilling programmatic goals. However, unlike the NIH model, the report advised that the IP should be given much greater flexibility to seek a broad portfolio of grants across all disciplines and give preference to those proposals that involve interdisciplinary or collaborative research, even if this resulted in funding proposals that may not have scored as well in peer review but that addressed a program priority. Furthermore,

the report advised that preference should be given to projects that most closely meet the objectives outlined in the vision statements developed annually by the IP for each program. The USAMRMC accepted and implemented the 1993 IOM recommendations (9).

Program Development

Unlike other federal agencies of which the budgets for biomedical research are assured on a continuing basis, Congress appropriates funds for the CDMRP yearly. Additionally, Congressional language may identify targeted research initiatives for a particular year. Thus, it is not possible to conduct long-term program planning; instead planning occurs 1 year at a time. This arrangement has proved to be more an asset than a drawback. With each new funding cycle, the CDMRP can create new research opportunities and focus funding on the most recently recognized research gaps or controversies. To identify important research areas in need of support, the CDMRP depends on three sources of advice and counsel: the community of stakeholders, the IPs, and the scientists and consumers who participate in peer and programmatic review. The program development process is described below.

When Congress appropriates funds for the initiation of a disease-specific program, the goals and priorities of the new program are established in a stakeholders’ meeting. Stakeholders represent an interdisciplinary group of key scientists and consumers in a given field, drawn from leading government, academic, private, and consumer advocacy organizations.

Once the overall program focus is established, an IP is convened. IP members are selected for their interest and expertise in the areas of research identified by the stakeholders’ meeting. On an annual basis, this panel of scientists, clinicians, and consumers recommends a program vision and research investment strategy, develops award mechanisms appropriate for stated research goals, and advises the CDMRP on plans for the dissemination of information on program progress. The IP also performs the programmatic review, as described below.

After the IP has outlined the program vision, investment strategy, and award mechanisms, a program announcement is

developed and disseminated to the scientific community. Proposals initially undergo a scientific peer review to evaluate their scientific merit using criteria published in the program announcement. Proposals are considered primarily in single discipline panels and are reviewed for their scientific innovation, rationale for and feasibility of the research, relevance of the research to program goals, and qualifications of the investigator. As with the stakeholders meetings and IPs, members of peer-review panels include a mix of researchers, clinicians, and consumers appropriate for the specific program area and topics of interest.

The programmatic review, conducted by the IP, is the second tier of the review system. This review of all projects considered eligible for funding by the peer reviewers is a comparison-based process in which proposals from multiple research areas compete in a common pool. Those projects deemed to have the highest relevance and importance to the CDMRP mission and specific program vision are recommended for funding. Thus, unlike many other agencies that support research, proposals are not funded strictly "in order" of scientific merit. Proposals with low programmatic relevance are less likely to be funded.

Program Components

Presently the CDMRP encompasses four core programs in breast cancer, prostate cancer, ovarian cancer, and neurofibromatosis. Brief descriptions of these programs follow. Current funding opportunities for each program are presented in Table 1. For more detailed information, visit the CDMRP website.⁹

BCRP

The BCRP is the oldest and largest CDMRP component. The mission of this program is to eradicate breast cancer. Within this context, the objective of the BCRP is to fund a balanced portfolio of research on the prevention, detection, diagnosis, and treatment of breast cancer. To date, BCRP appropriations have totaled \$1.22 billion and have supported almost 3200 research projects.

PCRP

The PCRP was begun in FY97 with an overall vision of conquering this disease. Its present mission is to fund research that will result in substantial improvements over current approaches to preventing, detecting, diagnosing, and treating prostate cancer. Appropriations for FY97–01 total \$310 million. Approximately 650 projects have been supported by these funds.

OCRP

Begun in 1997, the vision of this program is to eliminate ovarian cancer. Presently, the OCRP is focused on building a sound research foundation that will enhance studies on the prevention of ovarian cancer. Appropriations to date have

Table 1 Fiscal year 2002 CDMRP funding opportunities

Breast Cancer Research Program—\$150 M

The Program Announcement I was released in February 2002, with preproposal receipt in April 2002. This announcement calls for proposals in the following mechanisms:

- Clinical Translational Research (CTR) Awards
- Biotechnology Clinical Partnership Awards
- Collaborative-CTR Awards
- Breast Cancer Center of Excellence Awards
- Historically Black Colleges and Universities/Minority Institutions Partnership Training Awards

The Program Announcement II was released in March 2002, with proposal receipt in June 2002. This announcement calls for proposals in the following mechanisms:

- Innovator Awards
- Exploration Awards
- Idea Awards
- Predoctoral and Postdoctoral Traineeships
- Clinical Research Nurse Training Awards
- Physician-Scientist Training Awards
- Undergraduate Summer Training Programs
- Breast Cancer Center of Excellence Awards

Prostate Cancer Research Program—\$85 M

The Program Announcement was released in February 2002, with proposal receipt in May 2002. This announcement calls for proposals in the following mechanisms:

- Postdoctoral Traineeships
- Health Disparity Training—Prostate Scholar Awards
- Health Disparity Research—Prostate Scholar Awards
- New Investigator Awards
- Idea Development Awards

Ovarian Cancer Research Program—\$10.2 M

The Program Announcement was released in March 2002, with receipt of proposals due in June 2002. This announcement calls for proposals in the following two new mechanisms:

- Idea Development Awards
- Institutional Training Grants

Neurofibromatosis Research Program—\$21 M

The Program Announcement was released in March 2002, with receipt of proposals due in June 2002. This announcement calls for proposals in the following mechanisms:

- New Investigator Awards
- Idea Awards
- Career Development Awards
- Investigator-Initiated Research Awards
- Therapeutic Development Awards
- Clinical Trial Awards

totaled \$51.5 million supporting approximately 45 research projects.

NFRP

The NFRP was begun in FY96 to address gaps in the knowledge and treatment of these devastating but little-studied disorders. Awards are designed to enhance the infrastructure of the neurofibromatosis research community while addressing problems that cause patient morbidity and mortality, and diminish the quality of life of persons with the disease. Total appropriations through FY01 are \$69.3 million. Approximately 85 projects have been supported with these funds.

Innovative Program Features

The CDMRP has not only sought to fund innovative research but has also sought innovative approaches to research

⁹ Internet address <http://cdmrp.army.mil>.

Table 2 Summary of unique CDMRP processes

FEATURE	CDMRP INNOVATION
Flexible science management	Investment strategy and program emphases developed annually by each Integration Panel Research dollars are set aside in the year the proposal is funded
Award mechanisms	Emphasis on innovation, rewarding competition and progress, building infrastructure and fostering partnerships Periodically assessed for utility and outcomes
Applications	Requires both scientific and lay abstracts Tailored to meet intent of award mechanism
Advisory panel participants	Consumers as full voting members on all advisory and review panels
Peer review panels	Exclusive use of Ad Hoc panels
Peer review procedures	Published evaluation criteria initiated in 1993 Scoring of evaluation criteria initiated in 1996
Peer review meetings	Panels meet at the same time on specific dates Orientation sessions for consumers, scientific reviewers, and staff at each series of meetings
Summary statements	Includes both the scientific and lay abstracts verbatim Criteria-related format and narrative
Programmatic review	Comparison-based Proposals discussed individually on the basis of published criteria
Public disclosure	Annual report released each fiscal year since 1996 Program fact sheets available at CDMRP website
Dissemination of research findings	Multidisciplinary meeting where funded investigators report their findings to the public Research highlights reported at CDMRP website

administration. Many of these have subsequently been adopted by other federal and private research funding agencies. Others remain unique to the CDMRP programs. Some of the features that distinguish this program from parallel efforts in other granting agencies are summarized below and in Table 2.

Priority Setting

Setting program priorities is an integral and ongoing part of CDMRP activities. The annual budget appropriation implies that Congress can mandate a shift in program emphasis or even the creation of entirely new condition-specific programs on a yearly basis. This, along with the focus on funding innovative research that will fill identified gaps in knowledge and treatment, has resulted in the development of methods for ongoing evaluation and, where necessary, revision of program vision, goals, and support mechanisms.

The principle instrument of this flexible, responsive system are the IPs. The main responsibility of the IPs is to integrate member knowledge of the state of science or care for their respective disease area with information about current programs, project portfolios, and accomplishments, and congressional directives. Using this combined information, the IP formulates the program-specific vision, recommends any changes or additions to funding or program management mechanisms, and evaluates peer-reviewed proposals for their relevance to the programs and their visions.

Other federal funding agencies have outside expert groups that evaluate program direction, relevance and effectiveness, and oversee funding recommendations. However, there are often several disparate groups for different functions and, with the exception of standing advisory boards, these are frequently ad

hoc committees. Moreover, recommended changes in program direction or activities often take the form of large reports that must be developed into implementation strategies by yet other outside expert groups. Such reports and implementation plans often take several years to complete. In contrast, the CDMRP IP members serve a multiyear term, and are involved in both proposal review and program priority-setting activities. They work closely with program staff to formulate recommendations and implementation strategies, which can then be quickly executed by CDMRP management.

Looking at Scientific Peer Review in a New Way

This "hands-on" role of outside experts in shaping CDMRP programs and priorities has necessitated the development of a very specific system of proposal review criteria. Since 1993, the CDMRP has used published evaluation criteria, matched and adjusted to the research or training mechanism under review, to notify applicants of the key factors that will be used to judge their applications. The evaluation criteria are intended to provide the applicant, the IP, and the CDMRP with a more informed measure of the strengths and weaknesses of various elements in the proposal. Reliance on specific criteria has the advantage of reducing ambiguous and subjective factors that can unfairly influence reviewer recommendations. Beginning in 1998 the NIH adopted a similar approach to the review of competitive research grants.

The uncertainty of annual appropriations and directing Congressional language prevents the use of standing peer review panels. Ad hoc panels are established for each annual program competition. This has the great advantage of creating panels that can differ from year-to-year and be tailored to the

scientific content of the applications received. The consistency and stability of the review panels and process are maintained in that approximately two-thirds of panel reviewers are invited to return from a previous year and agree to do so.

Expanding the Role of the Consumer in Research

The role of consumer advocates in the instigation of the DOD cancer research initiative resulted in a level of involvement of this important stakeholder group unprecedented in other research funding organizations. At first active only in the BCRP IP, consumers now participate in all levels of program development and are full voting members of all of the peer review panels. Although the value of the consumer perspective has been increasingly recognized within the research community, there were no models for their participation when CDMRP first included them in 1993. Thus, the CDMRP developed guidelines for the selection, screening, and participation of consumers, and has evaluated these efforts on an ongoing basis (10). Consumers are now fully integrated into the activities of all of the CDMRP programs, and several CDMRP funding mechanisms now require consumer involvement.

Novel Award Mechanisms

CDMRP award mechanisms vary by condition-specific program and over time. Most of the mechanisms fund either basic or clinical research (*e.g.*, Idea Awards, New Investigator Awards, and Center Initiation Awards), whereas other mechanisms support clinical research exclusively (*e.g.*, Clinical Translational Research Awards and Clinical Trial Awards). There are also a number of training mechanisms (*e.g.*, Pre- and Post-doctoral Fellowships and Career Development Awards), some of which provide support for investigators at historically black colleges and universities and minority institutions (*e.g.*, Partnership Training Awards).

No matter what the mechanism, each is designed to fulfill individual programmatic objectives and to address the overarching CDMRP goal of hastening the transfer of knowledge from research to patient care. Some of the novel award mechanisms developed by the CDMRP are described below.

Focusing on Innovation. Idea Awards were first instituted by the BCRP in FY96. This award mechanism rewards innovative approaches to research that may be untested but that may reveal breakthroughs or new avenues of investigation. In this manner, the BCRP has invigorated traditional research development. The Idea Award continues to be the hallmark of the BCRP and has been adopted by other CDMRP programs. The Concept Award was introduced by the BCRP in FY99 in an effort to capture ideas that were still in the conceptual development phase. Fast-track proposal submission, review, and negotiation processes were used to fund initial concepts or theories that could give rise to future testable hypotheses. The Innovator Award was offered by the BCRP for the first time in FY01. Open to established scientists in any field, this award was designed to facilitate creative thinking and imaginative application of ideas to this disease. The focus was on the individual rather than on a specific project; the applicant submitted an essay about how he/she would use the award to pursue creative breast cancer investigations. It is hoped that this funding mech-

anism will provide the freedom to pursue creative, potentially breakthrough research that could ultimately accelerate the eradication of breast cancer.

Rewarding Competition and Success. The PCRCP used a unique two-phase funding mechanism in FY99, the Dual Phase Awards, in an attempt to encourage innovative research ideas and approaches. Phase I supported studies designed to explore the viability of novel concepts. If the Phase I projects were successful, investigators were encouraged to apply for Phase II funding, which was structured to provide support to position awardees for competition in traditional funding arenas.

Building Infrastructure. The paucity of information about the natural history of neurofibromatosis has limited the abilities of scientists to develop more effective diagnostic and treatment strategies for this disease. Hence, an initial goal of the NFRP was to promote research directed at gaining a better understanding of the circumstances under which neurofibromatosis develops and progresses. The Natural History Study Award focused specifically on this question, supporting collaborations of scientists for the purpose of providing normative quantitative data on which future studies could be based.

Fostering Partnerships. There is a well-recognized need within the cancer community to design new models for clinical trials that can be completed in less time and can enroll a greater number and variety of patients. The BCRP Collaborative-Clinical Translational Research Award mechanism was created to address this issue. Based on a consortium model that includes academic centers, community-based practices, consumer/survivor groups, and private industry, these awards support the study of multiple novel treatments or technologies developed in the private sector.

Program Successes

Despite its relative youth, the CDMRP has achieved a remarkable level of success. Evidence of this can be found in the growth of the program from its focus on a single disease area to the current emphasis on multiple conditions, with frequent new initiatives requested by Congress. The pioneering work done in consumer involvement is a strong feature of the CDMRP, now emulated by several other funding organizations, including NIH. In addition, several innovative award mechanisms developed within CDMRP have been adopted or adapted by other agencies, including the signature Idea Award, which is now offered by the National Cancer Institute as the Insight Award. The scientific output of grantees has been prodigious. Within the BCRP alone, the 2000 Era of Hope conference resulted in more than 750 presentations or posters outlining findings from CDMRP-funded studies. The OCRP Investigators' Forum, held in 1999, similarly showcased the research of funded scientists. The CDMRP commitment to increase the number of scientists working in its program areas has resulted in the training of thousands of pre- and post-doctoral students, and increased support for minority researchers. Established scientists working in other fields have been encouraged to expand their research to areas where gaps in knowledge and limited treatment options exist.

As with other successful extramural biomedical research support programs, a solid partnership with the scientific community is an essential requirement. Since the beginning of the

program, there have been more than 250-peer review and programmatic panel meetings involving input from more than 2500 members of the scientific community and approximately 200 consumer advocates. It is noteworthy that a 1997 blue ribbon committee of the IOM reexamined the progress of the largest of the CDMRP programs, the BCRP, and fully endorsed its continuation (11).

Future Directions

The CDMRP moves to the future directed by their vision: to be the preferred and responsive source for accessible research funding, shaping the future of health care to prevent, control, and cure disease. The bar has been set high. As a relatively new source of biomedical research funding, the CDMRP has paved the way by establishing new processes for setting priorities and investment strategy, expanding of the role of consumers in research and research administration, implementing innovative review procedures, and mobilizing untapped opportunities. The CDMRP will continue to listen and respond to the individuals it serves. Proposal application processes will become more facile, review processes will become more efficient and transparent, and relationships with the research and consumer communities will be nurtured.

Conclusion

In the management of an extramural biomedical research grant program of relatively modest size, the CDMRP has been able to introduce unique policies and procedures. From its beginning in 1992, the CDMRP has continued to challenge the status quo in research administration. It has matured while adopting the mantle of innovation in almost every facet of its activities. The CDMRP represents an alternative to the traditional model of funding scientific research. It is hoped that this model will lead to faster development and adaptation of novel prevention, diagnostic, and treatment strategies that are practical and acceptable to patients and clinicians.

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