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Pancreatic Cancer: A trickle of federal funding for a river of need

Why survival rates for pancreatic cancer have remained in the single digits for 40 years

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For 40 years, the survival rate for pancreatic cancer has remained in the single digits – despite an increase in the incidence of the disease, despite the fact that it is the fourth leading cause of cancer death, and despite the progress made on other cancers. Survival rates for pancreatic cancer have remained relatively the same because the federal government's approach to pancreatic cancer has been relatively the same – provide a trickle of research funding in response to a river of need.

EXECUTIVE SUMMARY

As the fourth leading cause of cancer-related death, pancreatic cancer represents a major threat to human health in the United States. Estimates show that more than 43,000 new diagnoses and 36,800 deaths were attributed to pancreatic cancer in 2010. The similarity of these numbers is a stark reminder of the deadliness of this disease: the five-year survival rate is a meager six percent. Pancreatic cancer is currently the only of the top ten cancer killers in the US with a five-year survival rate lingering in the single digits—a grim statistic that has not changed significantly in the past 40 years.

There are many reasons why the clinical outcome for pancreatic cancer patients is so much bleaker than for most other cancer types. There are no reliable methods to detect the disease early, and there are very few effective treatment options.

Researchers and clinicians around the country and the world are endeavoring to improve the odds for pancreatic cancer patients. However, the community of scientists and doctors dedicated to this disease has historically been small, fragmented, and poorly funded. In 2010, the Pancreatic Cancer Action Network conducted an analysis of the US government's pancreatic cancer research program, focusing on the National Cancer Institute (NCI) as the largest federal research funding source, to determine opportunities for improvement, collaboration, and growth.

- Currently, research dedicated to pancreatic cancer receives a mere two percent of the federal dollars distributed by the NCI. By contrast, the other four of the top-five cancer killers in the US (lung, colon, breast, and prostate cancer) received 2.8- to 6.3-fold more NCI funding in 2009 than pancreatic cancer.
- The average dollar amount of basic research (R) grants in pancreatic cancer was 18 to 29 percent less than R grants for lung, colon, breast, and prostate cancers. The R grant mechanisms are the mainstay of scientific discovery in cancer research.
- Training grant (F, K, and T awards) funding in pancreatic cancer decreased by 15 percent from 2008 to 2009, a decline larger than any of the other leading cancers experienced. Pancreatic cancer trainees were awarded between 2.4- and 6.5-fold less grant money in 2009 than young researchers studying the other four top cancer killers. These grants are critical to mobilizing young scientists to study pancreatic cancer.
- American Recovery and Reinvestment Act (ARRA) funding represented a unique opportunity for the NCI to direct research monies toward the deadliest cancers, including pancreatic cancer. Unfortunately, this opportunity was missed, as pancreatic cancer research received only slightly more than one percent of the NCI ARRA budget.

The Pancreatic Cancer Action Network is a nationwide network of people dedicated to working together to advance research, support patients, and create hope for those affected by pancreatic cancer. In order to make clinical progress a reality, it is imperative for the NCI to develop and implement a focused strategic plan to combat this deadliest of cancers. This report looks at pancreatic cancer, the lack of progress made against it, and the problems caused by not having a dedicated national research strategy to build the scientific knowledge and collaboration necessary to speed progress. It also provides a solution, one that includes private investment in research and life-saving government investment in a dedicated national strategy to find better diagnoses, treatments, and cures for pancreatic cancer. After 40 years, a river of need calls out for the watershed solution found in these pages.

INTRODUCTION

Pancreatic cancer recently surpassed prostate cancer as the fourth leading cause of cancer-related death in the United States, preceded only by lung, colon, and breast cancer. The five-year survival rate for pancreatic cancer is a meager six percent, a dismal statistic that has not changed significantly in the past 40 years. According to the American Cancer Society's *Cancer Facts and Figures 2010*, more than 43,000 new cases of pancreatic cancer were diagnosed in 2010, and 36,800 lives were lost to the disease[1]. Progress in the understanding, diagnosis, and treatment of pancreatic cancer is urgently needed.

The majority of pancreatic cancer patients die within a year of their diagnoses. While overall cancer survival rates have improved during the last four decades since the War on Cancer was first declared, pancreatic cancer survival rates have remained bleak and relatively stagnant, largely because there are no early detection tools or effective treatments.

The source of the problem is two-fold: the absence of (1) a well-defined strategic research agenda and (2) a robust, sustained commitment of resources.

Founded in 1999, the Pancreatic Cancer Action Network is dedicated to advancing research, supporting patients, and creating hope for those affected by pancreatic cancer. The organization takes a comprehensive approach, including direct funding of research grants, providing education and support to patients and caregivers, raising money and awareness through community outreach, and advocating for pancreatic cancer at the local and federal governmental levels.

In order to effect change, the federal government's National Cancer Institute must do its part and devise a focused strategic plan to improve the outcomes in pancreatic cancer. An obvious starting point would be an increase in federal funding devoted to pancreatic cancer studies, in the form of the most prevalent and meaningful grant mechanism, the R01, as well as striving to recruit new investigators into the field.

It is critical that these issues be addressed immediately, before the devastating impact of pancreatic cancer becomes even greater. A recently published study in the *Journal of Clinical Oncology* predicts that the number of new pancreatic cancer cases will increase by 55 percent between the years 2010 and 2030[2]. Given the bleak survivability and the shocking projected increase in diagnoses, the time has come for a death-defying strategy.

This report reviews the most critical hurdles in advancing pancreatic cancer research, analyzes the current levels of federal support for pancreatic cancer research, and recommends some specific solutions.

DEFINING A DEADLY PROBLEM

Four decades ago, the five-year survivability for any cancer diagnosis was 50 percent. Today, that number has soared to 68 percent. More than two-thirds of individuals diagnosed with cancer will now live beyond the five-year mark. However, this impressive statistic is not shared by all cancers. The five-year survival rate for pancreatic cancer remains well below the 50 percent mark established 40 years ago. In fact, over that time period, the five-year survival rate for pancreatic cancer has only improved slightly, from three percent to six percent. Sadly, 75 percent of Americans diagnosed with pancreatic cancer do not even live one year. Pancreatic cancer is currently the only of the top ten cancer killers with a five-year survival rate mired in the single digits[1].

There are enormous differences between cancers that present at various sites throughout the body. Of the approximately 200 known forms of cancer, some are quite treatable and pose relatively little threat to long-term health. Others, like pancreatic cancer, are exceptionally difficult to treat and aggressively affect major organs, impacting crucial bodily functions.

With the right combination of highly trained clinical and basic science researchers, ample research funds, innovation, and perseverance, great strides have been made in the treatment of many cancer types. Translating elegant genetic and biochemical analyses from the laboratory to the clinic has allowed for the development of targeted drugs that have revolutionized the course of breast cancer and some forms of leukemia, for example[3, 4]. Today, practically all Americans can tell a story of a loved one who was diagnosed with cancer and lived more than five years.

So, why is pancreatic cancer still a quick and painful death sentence for nearly every patient diagnosed?

One reason is that only a minority of pancreatic cancer cases, approximately 20 percent, are diagnosed early enough to be eligible for surgical resection[5]. Surgery offers the best survival outcome, but is only feasible when the tumor is confined to the pancreas. However, because symptoms of pancreatic cancer are vague and not easily attributable to the pancreas, the disease is frequently diagnosed after the tumor has spread locally or distantly. Those 80 percent of patients whose tumors

have advanced beyond the pancreas are at a great survival disadvantage. Even for those who underwent seemingly successful surgery, the disease frequently recurs due to undetectable microscopic spread to other organs.

Aside from the lack of early detection, pancreatic cancer is also exquisitely resistant to current treatment modalities. Many combinations of chemotherapies, targeted drugs, and radiation have been tested and found to be mostly ineffective. Only three drugs (gemcitabine, erlotinib, fluorouracil) have been specifically approved by the United States Food and Drug Administration (FDA) for the treatment of pancreatic cancer, and they provide minimal survival benefit to patients. Between the lack of early detection and absence of effective treatments, it becomes clearer why pancreatic cancer survival statistics are so dismal. Scientists and clinicians throughout the country strive tirelessly to improve the odds for pancreatic cancer patients. However, more funding and more researchers are desperately needed to make an impact.

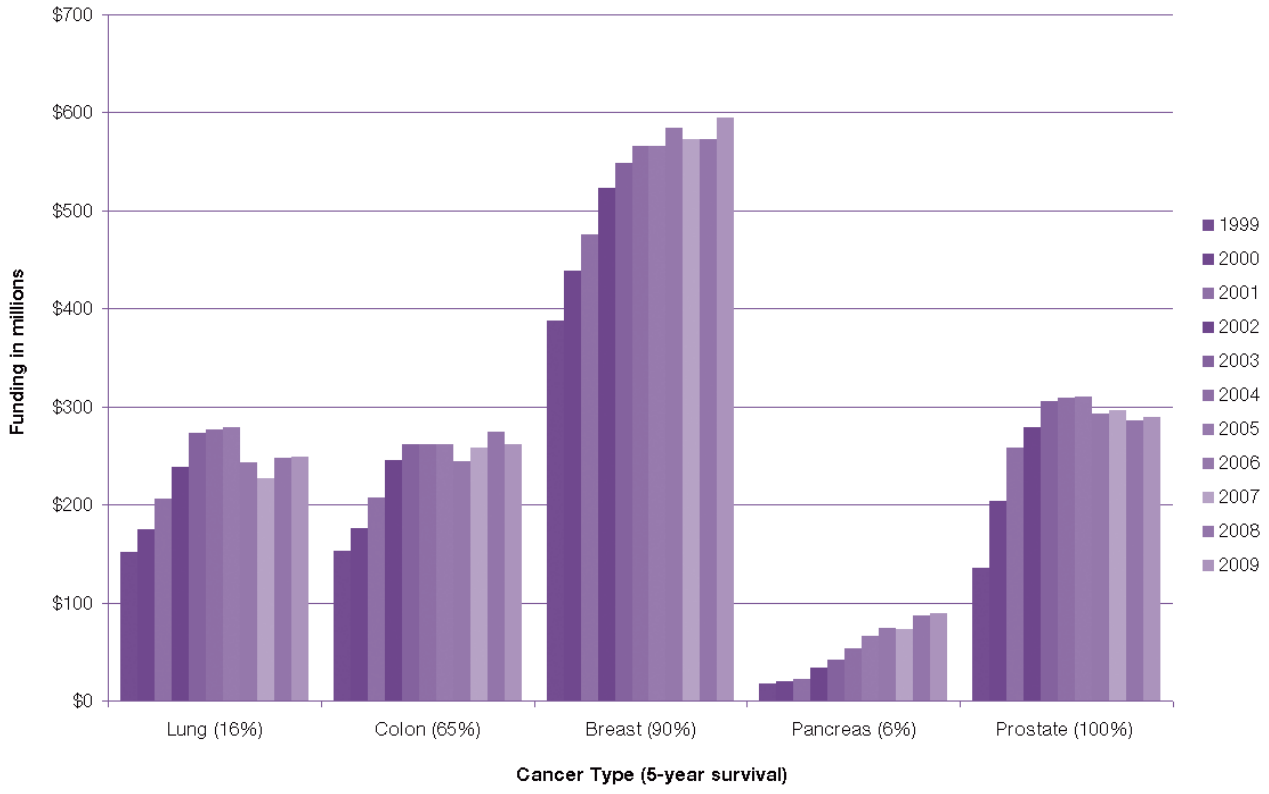
HURDLES TO TRUE PROGRESS

Low Federal Funding

Pancreatic cancer takes a devastating toll on society, yet its study receives only minimal funding (see Figure 1). An adequate and sustained financial investment is an absolute necessity in order to advance research. The vast majority of biomedical basic research dollars in the United States are allocated by the government, via the National Institutes of Health (NIH). Within the NIH, the National Cancer Institute (NCI) funds the vast majority of cancer research studies. For pancreatic cancer, the NCI serves as the primary source of funding, with little or no money coming from other federal sources, such as the Department of Defense.

Unfortunately, the NCI does not have a strategy to address pancreatic cancer and has failed to make research into the disease a priority, despite its tragic societal impact and static survival rates. The lack of a focused strategic plan that includes incentives to build a pancreatic cancer research community

Figure 1: Top Five US Cancer Killers' NCI Funding and Survival Rates



and prioritizes funding to meet clear goals and objectives is the largest hurdle to making progress against pancreatic cancer.

An informal survey of health and scientific professionals conducted by the Pancreatic Cancer Action Network in 2010 reported that the vast majority of responders were either "very dissatisfied" or "dissatisfied" with the current NCI funding for pancreatic cancer, listing shortage of research money as a major barrier to progress in understanding and combating this deadly disease. One responder commented, "In order to attract the best scientists with the most novel and far-reaching ideas to this field of research, there must be a significant pool of funds available. Excellent science with stellar ideas that can ultimately be translated to the clinic requires substantial monetary investments."

Historically, few researchers have focused on studying pancreatic cancer. A 2001 NCI Report of the Pancreatic Cancer Progress Review Group concluded that "urgently needed progress against pancreatic cancer must be achieved through a concerted and significant effort to build a comprehensive research community focused on this disease." There remains a dire need for more researchers to join the study of pancreatic cancer. A major way to support current researchers and expand the research community would be an increase in focused funding for pancreatic cancer studies.

In late 2010, the NCI released two documents entitled *Investment in Pancreatic Cancer: Action Plan for Fiscal Year 2011* and *Pancreatic Cancer: A Summary of NCI's Portfolio and Highlights of Recent Research Progress*. These documents represent a commendable and critical first step in drawing attention to the dismal survival statistics and urgent necessity for research progress in pancreatic cancer. The Action Plan lists currently funded projects that will continue to be supported in the upcoming fiscal year, while mentioning Emerging Areas of Focus that could narrow the gaps in research knowledge between pancreatic and other cancer types. However, these initiatives will require sufficient funding and resources in order to be put into effect. The document highlighting Research Progress asserts that, "NCI's efforts in pancreatic cancer research have increased our understanding of the biological basis for pancreatic cancer, developed potential means to reduce morbidity and mortality associated with the disease, and expanded pancreatic cancer research capacity." Although there have been promising clinical and scientific findings related to the field, the stagnant survival statistics clearly indicate that true progress remains elusive.

The NCI's Research Progress document also states that the research investment towards pancreatic cancer has increased by "311 percent" between fiscal years 2001 and 2009. Despite these encouraging improvements, funding allocated to pancreatic cancer remains disproportionately and tragically low. The NCI Funded Research Portfolio[i] for 2009 reveals that, of the nearly $4.5 billion of non-ARRA (American Recovery and Reinvestment Act) funds distributed by the NCI in 2009, pancreatic cancer research received $89 million, or a meager two percent. Funding allotted to the other of the top five cancer killers (lung, colon, breast, and prostate) eclipsed that awarded to pancreatic cancer studies. As a dramatic comparison, almost $595 million was allocated to breast cancer research, making up about 13 percent of the NCI budget. Prostate cancers researchers were awarded nearly $290 million in 2009. Thanks in large part to historically high levels of NCI funding, the current five-year survival rates of breast and prostate cancer are 90 and 100 percent, respectively[1]. Recall that this statistic is six percent for pancreatic cancer. For pancreatic cancer researchers to achieve similar clinical success, a much higher level of financial resources is needed.

Insufficient Support of Pancreatic Cancer R01 Grants

The NCI allocates its money via multiple grant mechanisms. The most frequently awarded category of grants is the "R" research grants, designed to support major experimental aims within each laboratory. Almost all laboratories depend on some R funding, most often R01 grants, for their financial livelihood, and thus for their research productivity. Although there are eight distinct grant mechanisms at the NCI, the R grants account for 40 to 50 percent of the total grant money awarded to each of the five top cancer killers in the US. Therefore, these grants are of utmost importance to the effectualness of cancer research laboratories.

Looking at NCI statistics from 2008 and 2009, the number of funded R grants focused on pancreatic cancer actually increased, from 216 to 231. However, the addition of these 15 grants was accompanied by a decrease in money allotted,

i) Methodology:
The NCI Funded Research Portfolio (NFRP) is available at http://fundedresearch.cancer.gov/, allowing analysis of the allocation of funding by cancer type or by available fiscal year. For 2009, the first fiscal year affected by funding from the American Recovery and Reinvestment Act (ARRA), NFRP differentiates between non-ARRA and ARRA funding. All grants that represented administrative expenses (e.g., grants for extramural support) were removed from the analysis. Grants with $1 or less in relevant funding were also excluded.

from $49.1 million to just over $48.1 million, a fall of about two percent. Not only do pancreatic cancer researchers see fewer grants and less overall funding than the other top five cancer killers, but pancreatic cancer awardees also tend to receive a smaller amount of money per grant. Looking at the all-important R grant mechanism, the average dollar figure for a grant focused on pancreatic cancer was 16 to 22 percent smaller than the average one supporting lung, colon, breast, or prostate cancer.

Within the R category, the majority of money is distributed via R01 grants, funding major projects conducted in each laboratory. In fact, for lung, colon, breast, and prostate cancers, funding for R01 grants makes up 82 to 86 percent of each disease's total R allotment. By contrast, only 67 percent of the funding within the R mechanism dedicated to pancreatic cancer goes towards R01 grants (Figure 2). R01 grants are the most basic and common research grants, and the productivity and stability of individual researchers' laboratories are dependent upon their funding. Importantly, R01 grants are available for competitive renewal, allowing an investigator to hold the same R01 award for many years. This sustainable source of funding is imperative for scientists to accomplish their experimental goals and answer important research questions. R01 grants are most often the catalysts for scientific discovery and therefore must play an integral role in any concerted effort to widen the scientific knowledge base surrounding pancreatic cancer.

Figure 2: Uneven Distribution of NCI Funding Within R Mechanism, 2009

Figure 2a: R Grants for Pancreatic Cancer

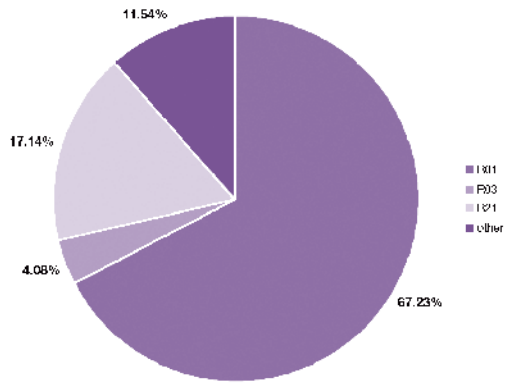
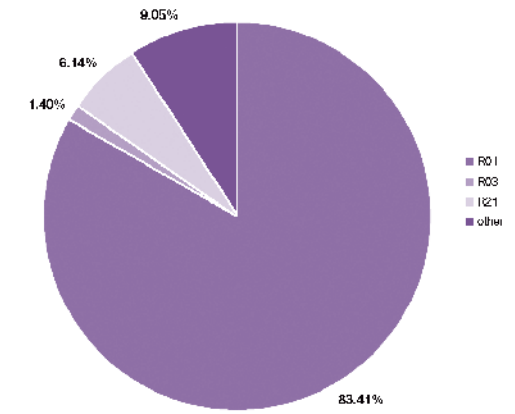


Figure 2b: R Grants for Other Four Deadliest Cancers



In order to secure funding, an R01 grant application must propose feasible, hypothesis-driven ideas, and provide sufficient preliminary data to prove the merit of the project. Compared to other cancer types, the depth of basic scientific knowledge about pancreatic cancer is limited. Some progress has been made in understanding the causative genetic aberrations responsible for pancreatic cancer, but substantial work is still needed. Specifically, little progress has been made towards determining a means for early detection of pancreatic cancer, and very few therapeutics have shown promise. Because of these factors, it is very difficult for a pancreatic cancer researcher to write a fundable R01 application, competing with researchers studying much better understood fields of cancer biology. In fact, responders to the 2010 Pancreatic Cancer Action Network survey of health and scientific professionals repeatedly urged the NCI to "establish a study section strictly for submissions related to pancreatic cancer research," because it is "difficult to compete in the translational realm with diseases such as colon, breast, etc, where there are … abundant preliminary public data."

Other available grant mechanisms bypass the requirement for extensive preliminary data, by inviting innovative proposals. R03 and R21 grants are dedicated to novel scientific projects that involve a creative hypothesis and/or experimental approach. These grant mechanisms can be especially attractive for those studying pancreatic cancer, where there are so many gaps in knowledge, and innovative approaches are sorely needed. Encouragingly, pancreatic cancer received 67 percent more R03 grants in 2009 than 2008, going from 15 to 25 awards. In this case, the funding followed the same pattern as the number of grants, with a 71 percent increase in total R03 grant money. Funding from the other innovative grant mechanism, R21, did not change substantially for pancreatic cancer studies between 2008 and 2009. The allotment of NCI funding to pancreatic cancer R03 and R21 grants was comparable to three of the four other top-five cancer killers. Overall, the funding towards innovative studies represents the most positive evidence of the

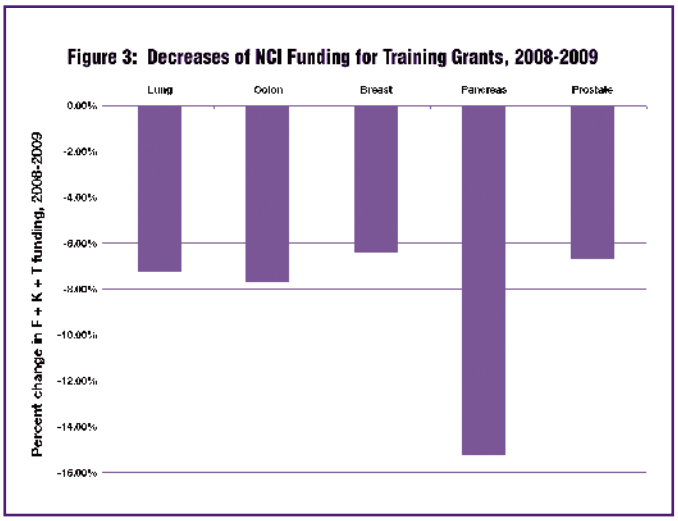
NCI's focus on pancreatic cancer in 2008 and 2009, and the fairest distribution of money. However, R03 and R21 awards remain only a very small fraction of the money allotted from the NCI.

The average R01 grant amount awarded to the study of lung, colon, breast, pancreatic, and prostate cancers in 2009 was over $280,000 per grant, whereas R03 and R21 grants were, on average, about $75,000 and $178,000, respectively. The R03 and R21 grant mechanisms are not designed to sustain a laboratory's productivity for any significant amount of time, and therefore rarely lead to substantial experimental findings. R03 and R21 grants are useful, but cannot replace the value of one or more stable R01 grants.

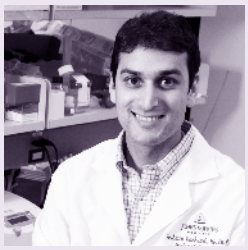
Failure to Train the Future of Pancreatic Cancer Research

While the R grant described above is typically awarded to the principal investigator of a laboratory, other funding mechanisms exist for early-career scientists within a laboratory, at the pre-doctoral or post-doctoral level. The NCI grant mechanisms devoted to trainees include F (fellowship), K (career), and T (training) awards. Besides supporting some of the principal investigator's lines of research and strengthening the trainee's résumé, these training grants can also provide young researchers with the confidence and experience necessary to eventually run their own laboratories. Oftentimes, a newly appointed assistant professor will establish an independent laboratory following in the research footsteps of his or her postdoctoral mentor. Pancreatic cancer desperately needs young investigators to dedicate their research focus to this deadly disease.

Looking at the F, K, and T categories in sum, there is an appalling lack of grants and funding awarded to young scientists studying pancreatic cancer. In 2009, pancreatic cancer research received a staggering 15 percent less funding in F, K, and T awards than awarded in 2008, a far more significant relative decrease than any of the other top five cancer killers (Figure 3).



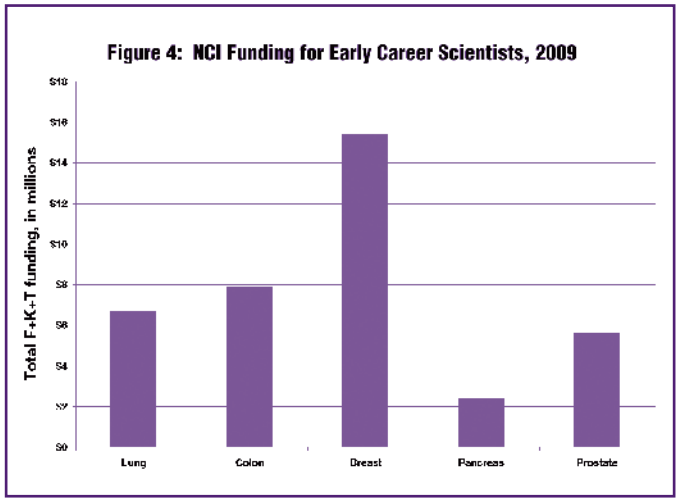
PANCREATIC CANCER ACTION NETWORK RESEARCH GRANTS PROGRAM



Zeshaan Rasheed, MD, PhD. 2010 Tempur-Pedic® Retailers – Pancreatic Cancer Action Network – AACR Path-way to Leadership Grant

Since the inception of the research grants program in 2003, the Pancreatic Cancer Action Network has distributed 56 awards for $7.1 million to scientists and clinicians across the country. The grants are administered in partnership with the American Association for Cancer Research to ensure a stringent peer-review process and funding of the highest quality science. Annually, the Pancreatic Cancer Action Network receives nearly 200 applications for research grants, emphasizing these researchers' struggles to secure funding from federal sources. Grants awarded by the Pancreatic Cancer Action Network are specifically dedicated to support researchers early in their careers (Fellowship, Career Development, or Pathway to Leadership Awards) and those taking a somewhat unconventional research approach (Innovative Awards). Funding efforts made by the Pancreatic Cancer Action Network comprise a small, focused portion of the national pancreatic cancer research investment, with the NCI acting as the largest funder.

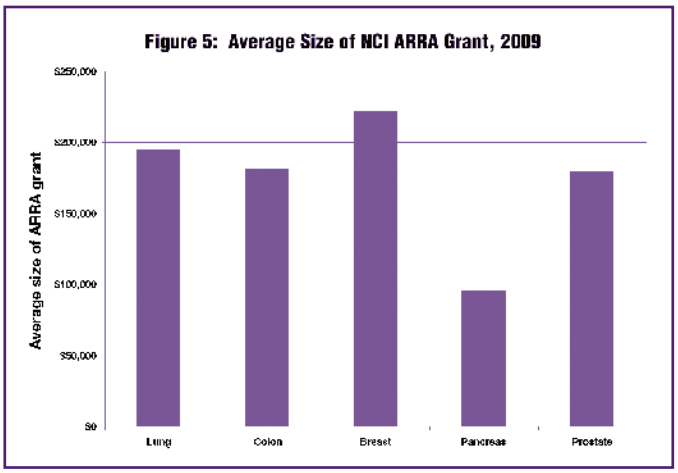
In 2009, pancreatic cancer researchers were given 24 training awards for about $2.4 million. The F, K, and T awards allotted to the other of the top five deadliest cancers – lung, colon, breast, and prostate – amounted to between 2.4 and 6.5-fold more money than awarded to pancreatic cancer (Figure 4). Because pre- and post-doctoral trainees represent the future of cancer research, it is especially distressing to see these discrepancies between pancreatic and other major cancer types.



A principal investigator with stable funding may expand and improve upon his or her laboratory's breadth of research, personnel, and experimental outcome. Without sustainable NCI funding, usually in the form of one or more R01 grants, researchers will be unable to mentor and train young scientists to pursue their same study focus. This trickle-down effect then yields fewer trainees applying for and receiving these F, K, and T awards in the subject of pancreatic cancer, to the great disadvantage of progress in the field. It is a vicious cycle that must be specifically addressed.

American Recovery and Reinvestment Act Funding: A Missed Opportunity

In 2009 alone, the NCI was also provided funding from ARRA, the American Recovery and Reinvestment Act[ii], to award to researchers. The NCI website states that, "Recovery Act funds enable NCI to move closer to its strategic vision of accelerating cancer research and advancing innovations that will make a difference in the lives of those affected by cancer." The availability of ARRA money represented a prime opportunity for the NCI to narrow some of the gaps in research funding through creative and strategic allotment of these additional funds. The NCI released a list of ARRA Requests for Applications (RFAs) for challenge grants that invited proposals focused on particular topics. Disappointingly, only one of more than 100 challenge grant RFAs specifically mentioned pancreatic cancer. Overall, pancreatic cancer was awarded only slightly more than one percent of the NCI ARRA budget. In addition, the largest ARRA award given to a pancreatic cancer researcher was approximately $650,000. In stark contrast, the maximum funding amount given to researchers in each of the other four top cancer killers ranged from $2.8 million to $4.6 million. With the ARRA funding, the NCI had a unique opportunity to direct research monies towards the neediest, deadliest cancer types. Sadly, this opportunity was missed (Figure 5).



ii) According to the www.recovery.gov website, the three goals of the American Recovery and Reinvestment Act (ARRA) are:
- "Create new jobs and save existing ones.
- Spur economic activity and invest in long-term growth.
- Foster unprecedented levels of accountability and transparency in government spending."

The National Cancer Institute was allotted almost $840 million to distribute to cancer research projects.

POLICY RECOMMENDATIONS

Significant advances have been made against many cancer types, providing ample evidence that well-targeted, sustained resources are the starting place for better diagnostic tools and improved treatments for patients. For pancreatic cancer, however, persistently low funding has effectively turned away distinguished senior scientists and discouraged bright young researchers from entering this field of study – all but guaranteeing that tens of thousands of Americans will lose their lives each year. Some progress can be made by studying scientific frontiers common to many cancers, such as signaling pathways or metastases (mechanisms of cancer spread). However, scientific history has strongly demonstrated that focused attention and adequate funding are imperative to achieve true results. We therefore call on our nation's policymakers to take the following steps:

- Require the NCI to develop a comprehensive five-year strategic plan that describes specific areas of study and action steps needed, including incentives that encourage researchers to join and build the pancreatic cancer research community.
- Assign pancreatic cancer research a priority by:
  - Increasing federal research funding for this disease, particularly in the category of R01 grants;
  - Establishing a discrete pancreatic cancer research grant program.
- Ensure that pancreatic cancer grants submitted to the NCI are reviewed by pancreatic cancer research experts.
- Increase overall funding for the NCI so that there is more money available to pursue new areas of research.

CONCLUSIONS

Pancreatic cancer was predicted to kill more than 36,000 people in the United States in 2010. The number of cases diagnosed is forecasted to increase by 55 percent over the next 20 years. Despite tireless efforts by researchers, clinicians, the Pancreatic Cancer Action Network, other advocacy organizations, and passionate constituents throughout the country, improvements in survival rates have been elusive. It is time for the NCI to come forward and create a focused, strategic plan to address pancreatic cancer. Clinicians and scientists need the appropriate financial support and resources to conduct effective research, promote breakthroughs, and train future scientists to continue to focus on this devastating and extremely challenging disease. This redirection in funding priorities is also justifiable since any breakthroughs in the diagnosis or treatment of pancreatic cancer may translate to better care for other cancer types where the disease is particularly aggressive or in advanced stages.

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