



DoD CDMRP FY2018 Request

Peer-Reviewed
Young Adult,
Adolescent and
Pediatric Cancer
Research Program

By Dean Crowe

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ABSTRACT

The Department of Defense (“DoD”) Congressionally Directed Medical Research Program’s (“CDMRP”) mission is to target critical gaps and transform healthcare through groundbreaking biomedical research in response to its stakeholders—the American public, the military and Congress.¹ The National Institutes of Health (“NIH”) defines adolescent and young adults (“AYAs”) as persons between the ages of 15-39 years old.² The #1 disease killer of AYAs and children is cancer.³ According to the U.S. Census Bureau, the AYA and pediatric populations comprise more than half (53%) of the American public.⁴ According to the DoD, 2.1 million AYAs make up 86% of the active population serving in the U.S. military. When you factor in their spouses and children, more than 90% of America’s active military members and their families fall into the AYA and pediatric population.⁵

According to the NIH, AYA and pediatric cancers are significantly under-researched, leading to poor outcomes including high morbidity and mortality.³² The CDMRP FY16 \$1 billion budget features line items for prostate cancer, ovarian cancer and lung cancer totaling \$110 million,⁶ for these cancers, with a median diagnosis age of 66 years old.⁴² The median age of AYA and the pediatric population fighting cancer is 20 years old.⁷ The average age of children dying from cancer is 8 years old,⁴⁵ who lose an average of 71 productive life years.⁸ Yet there is not a specific program in the CDMRP for AYA and pediatric cancer, the #1 disease killer of America’s young active military service members and their families.⁶

The NIH states that AYA and pediatric cancers differ in type and biological behavior from cancers diagnosed in older adults,² yet funds to support cancer research in these unique cancers and patient populations are lacking. When it comes to cancer research, this population has fallen through the cracks. The DoD CDMRP is in the unique position to make groundbreaking, transformative discoveries that positively impact the healthcare for 90% of our nation’s active military forces⁵ and 53% of the American population⁴, filling the critical gap by investing in research for cancers that specifically affect AYAs and their children. The NIH says there is a need for basic science, epidemiology and clinical trials to improve survival rates for AYAs and children fighting cancer.⁴⁴ We are asking the DoD CDMRP to include a \$30 million line item specifically for Peer-Reviewed Young Adult, Adolescent and Pediatric Cancer Research.

The National Institutes of Health defines adolescent and young adults (“AYAs”) as persons between the ages of 15-39 years old. The #1 disease killer of AYAs and children is cancer.

In the U.S. military, 2.1 million AYAs make up 86% of the active population. More than 40% of the active military are 25 years old or less.

Currently, the CDMRP does not have specific line item for young adult, adolescent and pediatric cancer research.

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SUMMARY KEY POINTS

KEY POINT #1: Cancer is the #1 disease killer of young adults, adolescents and children in the United States, according to the National Institutes of Health (NIH).⁹

KEY POINT #2: More than 90% of all active military personnel and their families fall into the pediatric, adolescent and young adult (AYA) population comprised of ages 0-39.⁵

KEY POINT #3: The Department of Defense (DoD) Congressionally Directed Medical Research Program (CDMRP) mission is to transform healthcare through innovative and impactful research.¹⁰ The CDMRP FY 2016 budget was \$1 billion.⁶ Currently, the CDMRP does not have specific program for young adults, adolescents and pediatric cancer research.¹¹

KEY POINT #4: The NIH says that evidence suggests that cancers in the AYA population have unique genetic and biological features. Research is needed to identify molecularly targeted therapies for the unique biology of these cancers.²

KEY POINT #5: The DoD CDMRP is in a unique position to make a groundbreaking transformation in healthcare for 86% of our nation's active military forces⁵ and 53% of the American public⁴ by filling the critical cancer research gap for this population. For this reason, we respectfully request \$30 million for a Peer Review Young Adult, Adolescent and Pediatric Cancer Program.

Most Common Cancers by Age Group

Birth-39 Years Old

Children (Birth-14)

- Blood cancer
- Brain cancer
- Soft tissue cancer
- Nerve cell cancers

Adolecents and Young Adults (15-24)

- Blood cancer
- Germ cell tumors,
- Thyroid cancers

Adolecents and Young Adults (25-39)

- Breast cancer
- Melanoma



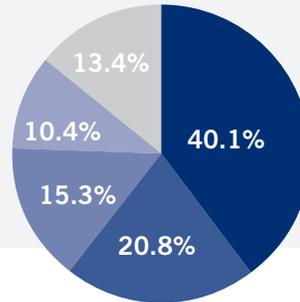
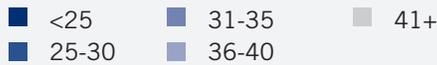
POPULATION DEFINED

The National Institutes of Health (“NIH”) defines adolescents and young adults (“AYA”) between the ages of 15-39 years old,² and the pediatric population consists of all persons from birth to 14 years of age.¹² According to the NIH, the #1 disease killer of AYA and children is cancer.⁹ According to the U.S. Census Bureau, the AYAs and pediatric populations comprise more than half (53%) of the American public.⁴ According to the DoD, AYAs make up 86% of the active population serving in the U.S. military. When you factor in their spouses and children, more than 90% of America’s active military members and their families fall into the AYA and pediatric population. This does not include the 865,019 civilian personnel.⁵

A deeper analysis of the statistics reveals that the total Active Duty, Reserve and Guard personnel from all branches of the DoD, the Department of Homeland Security (DHS) and Coast Guard was 2,668,155 with 86.3% of the military personnel ages 40 or younger. A further breakdown reveals that 40.1% are 25 years and younger; 20.8% are 26-30; 15.3% are 31-35; and 10.4% are 36-40. The total number of military

family members is 2,783,141. Of that number, 1,012,251 are spouses and 1,758,365 are children. Of the Active Duty members, 41% have dependent children. The average age of active military personnel at the time of the birth of their first child is 26 years old and 37% of their children are five and younger.⁵

Active Military Personnel Age Distribution



THE PROBLEM

ADOLESCENTS AND YOUNG ADULTS

War is war. Whether it is war with another country, the war on terror or the war on cancer, casualties are suffered along with debilitating injuries. Each year in the United States, approximately 70,000 AYAs are at war with cancer.² America is known as an international superpower with a highly trained military that allows our troops to have the best chance of securing a victory and survival. The DoD invests heavily in research and development (R&D) so that our troops will have the best equipment and training. The ultimate goal of this R&D is to secure victory with minimal casualties. AYAs make up the vast majority of the troops in the trenches during war⁵ and we send them in equipped for victory, yet they wage their war with cancer without the best treatments and outcomes available to them.¹³ These citizens who faithfully serve our country fall through the cracks when it comes to scientific advancements in the diagnosis and treatment of their cancers. It has been 40 years since AYA cancer survival rates have improved.¹⁴ R&D is needed in the AYA war against cancer.

Adolescents and young adults diagnosed with cancer face a unique set of challenges.¹³ While the names of some AYA cancers may be the same as a pediatric or adult cancer, the biology and behavior of these cancers are often quite different and must be studied separately.² Clinical trials specific to this population of patients are needed to improve treatments for these brave young service men and women.¹⁵ There is also a shortage of treatment centers specializing in the treatment of this age demographic.¹³ Other issues unique to this population include fertility preservation, psychological and psychosocial needs, and ongoing support and survivorship, including the management of complications from the late effects of treatments.¹⁶

Stuart Siegel, M.D.; Children's Center for Cancer and Blood Diseases; Children's Hospital Los Angeles explains, "There has been very little attention paid by medical researchers and clinicians to this group as a distinct entity. A lot of attention to children with cancer, a lot of attention to older people with cancer, but very little attention until recently to the young adult group. The kinds of cancer they have, the treatments they respond to, all these issues are important."² Although AYAs make up the vast majority of active U.S. military personnel,⁵ when it comes to the war with cancer, they enter that battlefield with the least amount of evidence-based treatment plans and therapies of everyone fighting cancer.¹³

The most common cancers in the AYA population are lymphoma, leukemia, germ cell tumors, melanoma, sarcomas, breast cancer, cervical cancer, liver cancer, thyroid

cancer and colorectal cancer.¹³ The AYA cancer population is unique in that the types of cancers this population gets varies according to their age. The AYAs between the ages of 15-24 are more likely to get leukemia, lymphoma, germ cell tumors, and thyroid cancers.² Leukemia has many forms, but the two most common are acute lymphoblastic leukemia and acute myeloid leukemia.¹⁷ Lymphoma also has two forms: Hodgkin and non-Hodgkin.¹⁸ Germ cell tumors are either ovarian germ cell tumors that originate in the egg cell of the ovary or testicular germ cell tumors which originate in the testis.¹⁹ These are not the same as ovarian cancer, which originates in the fallopian tubes or tissue lining the abdominal walls⁴⁸ and has an average diagnosis age of 62 years old,⁴⁹ or prostate cancer, which is found in the gland below a man's bladder⁵⁰ and has an average diagnosis age of 66 years old.⁵¹ Older AYAs between the ages of 25-39 are more likely to get breast cancer and melanoma.² Unfortunately, breast cancer tends to be more aggressive in AYAs than in older women.⁵² There is a significant increase in active military AYAs being diagnosed with thyroid cancer verse the general population.⁵³ There is a 65% greater diagnosis of melanoma in the active military than the general population.⁵⁴

Although some of the AYA cancers do share the same names as pediatric and older adult cancers, AYA cancers typically have unique genetic and biological characteristics.² Take for example acute lymphoblastic leukemia ("ALL"). Doctors are aware that there are different biological characteristics in ALL in young children, compared to that of the same disease found in older children, that lead to a worse prognostic subtype.²⁰ Children diagnosed with ALL have a 91% survival rate, but adolescents between the ages of 15-19 years old only have a 78% survival rate.²¹ Furthermore, the survival rate falls to less than 50% for young adults diagnosed with ALL.²² Studies are needed to understand the differences in biology in AYA ALL to determine the best treatment and to improve outcomes for the patients. The same is true for neuroblastoma, a cancer that affects nerve cells. The disease behaves very aggressively in AYA compared to young children, indicating there is a very different biology at work. In addition, distinct biology may exist in breast and colon cancer diagnosed in AYAs compared to older adults.²³

Due to the unique biological and genetic differences found in AYAs,² translational research and clinical trials, which are the keys to developing better treatments and improving survival rates, are needed.²⁴ Evidence-based research is the gold standard in all care,²⁵ and this population lacks access to clinical trials that provide the evidence-based intel. Dramatic improvements have occurred in survival rates for children diagnosed with cancer in the past 50 years. Fifty years ago, a child diagnosed with cancer had less than a 10% chance of surviving,²⁴ but today this statistic is closer to 86%.²⁵ One of the main reasons for the improvement in survival rates for pediatric cancer patients is the increased number of clinical trials available to children diagnosed with cancer.²⁶

More than 60% of pediatric cancer patients, ranging in age from birth to 14 years, participate in NCI-sponsored clinical trials.⁴³ Contrast this statistic with the fact that fewer than 10% of 15-19 years old are involved in clinical trials; this participation percentage drops to about 1% for patients who are 20-25 years old.²⁷ Survival rates for AYAs diagnosed with cancer have remained stagnant since 1985.

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Researchers believe the lack of clinical trials available to AYAs in the past 31 years has greatly contributed to the lack of progress in survival rates. It is not that AYAs do not want to participate in clinical trials; it is the fact that clinical trials are, for the most part, unavailable to this population.²⁴ It has been 40 years since AYA cancer survival rates have improved.¹⁴

In addition to the above obstacles to effective treatment, the AYA population does not have a cooperative group, such as the Children's Oncology Group, that is dedicated to specifically studying cancers and conducting clinical trials in this population.²⁴

AYAs are in "no man's land" when it comes to diagnosis and selecting a treatment center. Diagnosis is often delayed because physicians are not looking for cancer in this population, which often delays treatment.²⁸ AYAs don't necessarily fit into a pediatric hospital environment, and they certainly don't fit into a hospital with elderly patients being treated for cancer. Many AYAs are diagnosed with a pediatric type of cancer but are too old to be treated at a pediatric hospital. Often, adult oncologists treat the AYA patients who are diagnosed with a pediatric cancer. These adult oncologists are neither familiar with the pediatric types of cancers nor the best treatment protocols for pediatric cancers.⁴⁶ These limitations in knowledge and treatment options are unfair to both the physician and the AYA patient. Nita Seibel, M.D.; Cancer Therapy Evaluation Program, National Cancer Institute explains, "When we talk about AYA cancers, we are referring specifically to the group of patients that are between ages 15-39. This group of patients has sort of fallen through the cracks, not only from a medical standpoint of their treatment for cancer, but also from giving them the necessary support they need."²

Necessary support speaks to the AYAs unique psychosocial needs. Adolescents and young adults are naturally becoming more independent. As they form their own worldviews, they begin to determine their futures, making decisions about college, graduate school, career, dating, marrying, and starting a family. AYAs diagnosed with cancer are faced with their own mortality; they often feel isolated and alone, and they gain wisdom and perspective on life that their peers do not have. Dr. Lori Wiener who heads the Psychosocial Support and Translational Research Program at the National Institute of Cancer explains, "Training pertaining to the developmental needs of adolescents and young adults is still in its infancy and requires a lot of attention and research. But the need for it has been recognized and heard."²⁹

One unique issue faced by the AYA population is fertility preservation.¹⁶ Younger AYAs who are not in serious relationships or married often don't think to ask about fertility preservation. Those who ask about fertility preservation are often told by their oncologists that saving their lives takes priority over preserving fertility. The NIH strongly supports educating oncologists on the importance of having a conversation with AYAs about the options available to them for fertility preservation. But a survey revealed that more than half of the oncologists treating AYAs felt inadequate to discuss fertility preservation, indicating that more training is needed.³⁰

PEDIATRIC CANCER

Children are our country's future and greatest resource. According to the U.S. Census Bureau, in 2015, children made up 12.9% of the population.⁴ According to the DoD, 41.2% of active U.S. military personnel have dependent children.⁵ Childhood cancer is the #1 disease killer of America's children³ and has increased 24% during the past 40 years.⁸ Approximately 17% of all children die within five years of diagnosis³¹ and on average, 71 productive life years are lost⁸ each time a child cancer patient dies at the average age of death, eight years old.⁴⁵ The NCI is a proponent of childhood

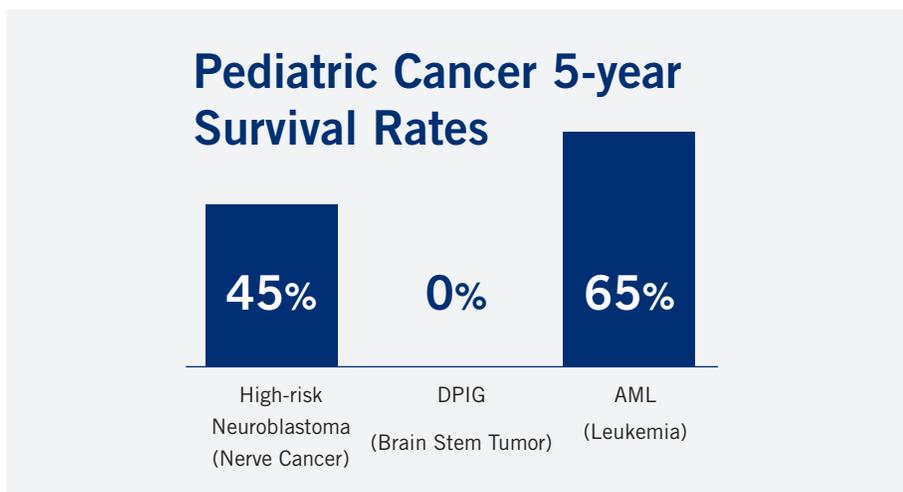
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cancer research focusing on biomedical research, basic research to understand cancer biology, clinical trials for the development of more effective and safer treatments, and survivorship research.³²

Similar to the differences between AYA and adult cancers, most pediatric cancers are very different from adult cancers.³³ According to the NCI's Surveillance, Epidemiology, and End Results Program ("SEER") the most commonly diagnosed cancers in older adults are prostate, breast, lung and colorectal (colon and rectal) cancer,³³ all cancer types that almost never occur in children. Children are most commonly diagnosed with blood, brain, soft tissue and nerve cell cancers.³⁴ The NCI recognizes that not only do adult and pediatric cancers differ in types but also in biological behavior.²

Pediatric clinical trials have greatly improved outcomes and the five-year survival rate, calculated from the day of diagnosis, for many pediatric cancers.⁴⁷ For example, in the 1970s, a child diagnosed with acute lymphocytic leukemia ("ALL") had a 60% chance of survival.³⁵ Today, due to research and clinical trials, a child diagnosed with ALL has a 91% chance of surviving.²¹ Unfortunately, the same cannot be said for all childhood cancers; there are still many pediatric cancers with very low five-year survival rates.³ Pediatric cancers are made up of 16 major types and more than 100 subtypes.⁸

Leukemia is the most common childhood cancer with many subtypes.³⁶ Both ALL and acute myeloid leukemia ("AML") are subtypes of childhood leukemias.³⁵ A child diagnosed with standard-risk ALL has a 91% survival rate,²¹ yet a child diagnosed with AML has five-year survival rate of only 65%.³⁷ While survival rates are excellent for low-risk neuroblastoma (a nerve cancer), patients with high-risk neuroblastoma, which is typically seen in older children and AYAs, have a 45% five-year survival rate.³⁰ Unfortunately, children with a brain stem glioma (diffuse intrinsic pontine glioma or DIPG) have a 0% chance for survival.⁸ The unique biology of these cancers desperately needs to be better understood so that effective treatments can be offered.



The NIH recognizes the need for survivorship research for pediatric cancer survivors.³³ Children that survive five years beyond their diagnosis dates have an eight times greater mortality rate due to the toxic side effects from current treatments, and 18% will die within 30 years of diagnosis due to the late effects from their cancer treatment. In addition to their increased risk of developing secondary cancers, childhood cancer survivors have a higher risk of heart and liver disease.³² More than 95% of childhood cancer survivors suffer from chronic to moderate to mild side effects from treatment.³⁹

By the Numbers

Birth-14 Years Old

12.9% of the U.S. Population are children

41.2% of the active U.S. Military personnel have dependent children

#1 Childhood cancer is the the #1 disease killer of America's children

24% Childhood cancer has increased 24% during the past 40 years.

17% Approximately 17% of all children die within five years of diagnosis

8 years old is the average age of child cancer patient death⁴⁵

71 is the average years of productive life lost each time a child cancer patient dies at the average age of death

95% of childhood cancer survivors suffer from chronic to moderate to mild side effects from treatment.

Since 1980, only three new drugs have been approved specifically for pediatric cancers,⁴⁰ and only four additional drugs have been approved for use in both children and adults. Treatment protocols for many of the 16 major types of pediatric cancer are nearly identical to those developed in the 1970s.³³ Contrast these limited developments in childhood cancer drugs with the hundreds of drugs that have been approved for adult cancers.

Peter Adamson, M.D., Chair of the Children's Oncology Group and Professor of Pediatrics & Pharmacology at the University of Pennsylvania School of Medicine, testified at the U.S. House Childhood Cancer Caucus stating, "We are entering an era of unprecedented discovery of the underlying molecular bases of childhood cancers. The research tools that we have today and the current pace of discovery were difficult to imagine as recently as five years ago. Yet if we are not able to turn these discoveries into better treatments for children with cancer, then we run the risk of failing the next generation of children with cancer that we are called upon to care for."⁴¹

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PROPOSED SOLUTION

Slightly more than 90% of the active military⁵ and 53% of Americans citizens comprise our country's adolescent, young adult and children population.⁴ The diagnosis of cancers in this specific population is biologically different than cancers in older adults,² yet specific cancer research for this population is lagging. It has been 40 years since AYA cancer survival rates have improved¹⁴ and the average age of death for a child who dies from cancer is eight years old.⁴⁵ The positive societal impacts and the productive life years gained for each child or AYA cured of cancer are immeasurable. These citizens and consumers will rally as advocates for this line item.

The Department of Defense (DoD) Congressionally Directed Medical Research Program (CDMRP) has already established an excellent system for receiving grant applications. The CDMRP also strongly supports collaboration among researchers, as do the physicians and scientists who represent this community. Finally, the CDMRP excels in the two-tier peer review process for research grants that are submitted. Once a grant is awarded, the CDMRP also has an outstanding reporting system as to the progress being made and how the funds are being spent. This well-established system highlights the unique position of the DoD CDMRP to afford brilliant researchers the opportunity to bring home great victories in the war against cancer for the AYA population and their children.⁶

The CDMRP's mission is to manage collaborative research that discovers, develops and delivers health care solutions for Service Members, Veterans and the American public.¹ The CDMRP transforms healthcare through innovative and impactful research.¹⁰ The CDMRP can have a high impact and lead to groundbreaking, transformative cancer research discoveries for the 86% of the active military currently serving in our nation's armed forces.⁵ Cancer is the #1 disease killer of AYAs, who are the most productive active military age group, and also of children.³

The CDMRP FY 2016 budget was \$1 billion and features line items for prostate cancer, ovarian cancer and lung cancer, totaling \$110 million.⁶ According to the NIH, all of these cancers have a median diagnosis age of 66 years old.⁴² Currently, the CDMRP does not have a specific program for AYA or pediatric cancer research.⁶ To improve survival rates and quality of life for these brave men and women who defend our nation, as well as their families, innovative and impactful research in basic science, epidemiology and clinical trials is needed.

WE RESPECTFULLY REQUEST

Program Title: Peer-Reviewed Young Adult, Adolescent and Pediatric Cancer Research Program

Funding Request: \$30 million

Bill: Department of Defense Appropriations Act, FY 2018 under the Defense Health Program in Research, Development, Test and Evaluation

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