Meeting the Moment:

Aligning ORAU capabilities with the federal government's priorities to end cancer as we know it

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Introduction

When President Richard M. Nixon signed the National Cancer Act (National Cancer Institute, 2021) into law on December 23, 1971, he delivered the opening salvo in the "war on cancer." War was an arguably appropriate metaphor, as the act was signed as the Vietnam War was raging in the background.

Among other things, the National Cancer Act provided for a significant increase in funding for the National Cancer Institute, a branch of the National Institutes of Health. Much of the funding was directed at basic research to reduce cancer incidence, mortality and morbidity. This funding and the cancer act itself were revolutionary in their time, and the research conducted laid the foundation for what we know today of modern molecular biology, genomics, immunology and precision medicine that are driving today's treatment protocols.

Still, in retrospect Nixon's goal was grand and ambitious. Using President's John F. Kennedy's moonshot of the 1960s as a blueprint, Nixon expected the war on cancer to be won in five years. Yet here we are, more than 50 years later, still grappling with the class of diseases people fear most.

There is no doubt progress against cancer has been made (National Cancer Institute, 2021). Treatments like chemotherapy that once were nearly as deadly as the disease itself have become more tolerable. Advances in genomics, immunology and precision medicine have made treatment of some cancers more like chronic diseases rather than deadly ones. And there have been cures. Treatment of some forms of childhood leukemias lead to lifelong remissions. Medications like Gleevec and others also have the power to put some forms of cancer in remission.

Death rates from cancer have declined steadily since 1990 (American Cancer Society, 2022), which means more people are surviving cancer than ever before. As of this writing, more than 18 million people are living as cancer survivors. This is good news to be sure, but cancer survivors have unique physical and mental health needs that are not consistently accounted for or treated in today's health care system. Post Traumatic Stress Disorder, depression and other mental health issues are often prevalent in survivors. The toxicity of chemotherapy agents and the impacts of radiation therapy have long-term effects on the health of survivors that isn't uniformly discussed.

While progress has surely been made, that progress is faltering. One in two men and one in three women will be diagnosed with cancer in their lifetime. While cancer death rates are declining, cancer remains the second leading

cause of death in the United States, for adults and children alike (American Cancer Society, 2022).

Some cancer incidence rates are on the rise, particularly among people under age 50 and among underserved and underrepresented individuals. Colorectal cancer incidence and mortality rates are particularly alarming. Colorectal cancer is on track to be the number one cancer killer among people under the age of 50 by 2030 (Siegel, et al, 2023). Prostate cancer (Hinata & Fujisawa, 2022) and lung cancer rates are disproportionately higher among Black people (Giaquinto, et al., 2002). Why is this happening? More research is needed to answer that question.

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President Joseph R. Biden reignited his Cancer Moonshot Initiative in 2022. The initiative, originally funded through the 21st Century Cures Act of 2016, focuses on the goals of reducing the age-adjusted death rate from cancer by at least 50% over the next 25 years. "This includes developing and deploying effective ways to prevent, detect, and treat cancer through new breakthroughs and ensuring existing tools reach more Americans equitably," according to



a July 22, 2022, White House memo to the heads of executive departments and agencies across the federal government (Young & Nelson, 2022).

The memo further urges government agencies to prioritize and collaborate on laboratory, clinical, public policy, public health, and environmental health research programs across five focus areas:

- Close the Screening Gap: Catch up on the nearly 10 million cancer screenings that were missed during the COVID-19 pandemic.
- Understand and Address Environmental and Toxic Exposures: Decades of public health
 and healthcare messaging has focused on an individual's responsibility to reduce their risk of cancer by eating healthy foods, exercising regularly and getting age-appropriate cancer screenings and
 vaccinations. But what role does exposure to environmental contaminants and toxic chemicals have
 in increased risk of cancer, and how can those exposures be prevented?
- Decrease the Impact of Preventable Cancers: The above-mentioned messages have proven
 effective at reducing the burden of preventable cancers. What additional approaches can be taken
 to continue to reduce the cancer burden?
- Bring Cutting Edge Research Through the Pipeline to Patients and Communities: The
 development and deployment of new ways to prevent, detect, and treat cancer will be necessary to
 increase cancer survival rates. FLASH Radiology, which is discussed later in this paper, along with
 the development of Multi-Cancer Early Detection blood tests, are leading the way in cutting edge
 treatment.

Support Patients and Survivors: Cancer can be overwhelming and affects not just the patient
receiving the diagnosis but family members and others in the patient's orbit. Making treatment and
survivorship easier through palliative care team planning, telehealth, survivor care planning and
more has the potential to close care gaps and improve overall patient outcomes.

The Cancer Moonshot is a whole-of-government approach to ending cancer as we know it. Several agencies have a role in the fight against cancer, including the National Institute of Health, the National Cancer Institute, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention, and the U.S. Department of Health and Human Services.

This paper examines the federal government's cancer-related priorities as outlined in the National Cancer Institute Annual Plan and Budget Proposal for Fiscal Year 2024, the CDC's National Comprehensive Cancer Control Program Priorities, the National Cancer Plan, and the White House Cancer Cabinet (aka Cancer Moonshot) and weighs those priorities against ORAU's history and capabilities in the cancer space. This examination is additionally informed by the federal legislative priorities of two national cancer advocacy organizations, the American Cancer Society Cancer Action Network and the National Coalition for Cancer Survivorship.

From this examination of federal agency priorities, advocacy organization priorities, and ORAU history and capabilities, the following recommendations are being made (in no particular order) for the pursuit of contractual work or organizationally funded research. Details about each recommendation are explored following the ORAU History section of this document.

- 1. **Develop** an ODRD-funded research project focused on improving cancer screening rates among underserved populations, especially the black and LGBTQIA+ communities.
- **2. Develop** an ODRD-funded research project to study and improve the processes for collecting patient-reported outcome measures between treatment visits.
- 3. **Develop** an ODRD-funded research project to identify best practices for communication to improve the uptake of low-dose CT for lung cancer screening.
- **4. Develop** an ODRD-project focused on cancer-related stigma and the preference for or against using militaristic language (e.g. war on cancer, personal fight, etc.) to describe a patient's cancer treatment experience.
- Develop an ODRD-funded research project focused on ensuring inclusion of the special needs of cancer patients in disaster preparedness guidelines.
- **6. Develop** an ODRD-funded research project to develop and test messaging to patients who may wish to request a blood test to screen for colorectal cancer rather than submit to a colonoscopy.

About the Author



Michael Holtz, APR, MPRCA, is senior communications and marketing specialist for ORAU. He is the host of two company podcasts, Further Together: The ORAU Podcast and the ORISE Featurecast. He serves as associate editor of the company's annual report, ORAU Story, is the content champion for orau.org and leads the company's media relations programs.

Holtz is an 11-year survivor of an aggressive rectal adenocarcinoma, diagnosed as stage-3b, who underwent oral chemotherapy (Xyloda) combined with 28 rounds of radiation treatment, surgery that resulted in a permanent colostomy, and six months of adjuvant infused chemotherapy (FOLF-OX) over the course of 11 months from March 2012 to February 2013. The author was declared NED (No Evidence of Disease) in May 2013.

About the Author (cont.)

Holtz was diagnosed with cancer while working for the American Cancer Society Cancer Action Network, left the organization in 2014 and returned as a volunteer advocate in March 2015. He served as Tennessee State Lead volunteer for seven years and is currently a member of ACS CAN's 14-member National Ambassador Team and the LGBTQIA+ and Allies Engagement Group. He is also a member of the National Coalition for Cancer Survivorship Cancer Policy Advocacy Team and was a 2023 National Ambassador for Fight Colorectal Cancer.

In his role as a cancer advocate, Holtz regularly meets with federal, state and local lawmakers or their staff members to discuss policy issues relevant to cancer patients and their families, including increasing federal research funding, patient quality of life issues, early detection and prevention, and survivorship care issues. He has spo-

ken at two Congressional research briefings, and regularly appears in the media to discuss cancer advocacy issues.

Additionally, Holtz has served as a patient/consumer reviewer for the U.S. Department of Defense Congressionally Directed Medical Research Program and the Cancer Prevention and Research Institute of Texas. He is a member of the American Society for Radiation Oncology Rectal Cancer Guidelines Focused Update Task Force, which is working on updating guidelines for using radiation for the treatment of rectal cancer. He is national volunteer fundraising leader for Man Up to Cancer, an organization that offers online and in-person group support for men who have been diagnosed with cancer, are cancer survivors, or caregivers for a loved one with cancer.

ORAU History

ORAU has been engaged in the fight against cancer in various ways for more than 70 years.

In 1950, ORINS, the Oak Ridge Institute for Nuclear Studies (now ORAU), opened a 30-bed cancer hospital. It was one of three facilities across the country developed at the urging of the Atomic Energy Commission after the end of World War II and the Manhattan Project to explore the use of radioisotopes in cancer treatment. The other hospitals were located near Argonne National Laboratory in Chicago and Brookhaven National Laboratory in Upton, New York (Pollard, et al., 1980).

In the 24 years during which the ORINS Medical Division cancer hospital admitted patients, 3,500 people were treated. All had been diagnosed with cancer and nearly all of them were considered terminal.

The ORINS cancer hospital is credited with laying the foundations for nuclear medicine research, pioneering the use of chemotherapy, immunotherapy, teletherapy and brachytherapy, and the de-



velopment of machines that were precursors to today's linear accelerators and positive emission tomography scanners.

The first patient admitted to the cancer hospital was a woman with extensive thyroid cancer (Andrews, 1980). Thyroid cancer became an early focus of the ORINS Medical Division's work. Marshall Brucer, M.D., the first director of the ORINS Medical Division, developed thyroid phantoms, devices that simulated the human neck and thy-

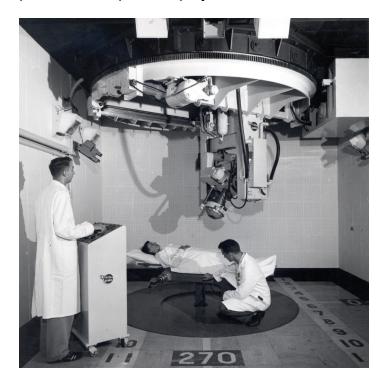
roid and were used for equipment calibration in thyroid uptake studies. These studies were crucial in evaluating thyroid function. The thyroid phantoms Brucer developed were created from department store mannequins named "Abigail, Bridget, Chloe, Drucilla, Euphemia and so on through Rhoda with a special one for a difference purpose named Anne Boleyn." These mannequins, which contained approximately a metal Dixie-cup's worth of mock iodine in artificial thyroid glands that were inserted in their necks, were sent around the world to train medical personnel in their use for equipment calibration.

That mock iodine referenced above was developed by the medical division team in 1954-55. Radio-active iodine, or iodine-131, has long been used to detect and diagnose thyroid cancer but has an extremely short half-life of just eight days. The ORINS medical team created a carefully proportional mixture of barium-133 and cesium-137, which gave nearly the same gamma spectrum appearance as iodine-131. Its longer half-life made it an ideal source for calibrating thyroid uptake machines before they were used on patients.

Members of the ORINS medical team were involved in the development of several radiotherapy treatment machines. In one case, Brucer and team participated in a cooperative project with M.D. Anderson

Cancer Center to develop an efficient Cobalt-60 teletherapy machine. Space had to be specially built at ORINS for the device. After testing at ORINS, the device was moved to M.D. Anderson for clinical trials.

Another example of ORINS medical professionals developing a cutting-edge cancer radiation treatment device was the development of an early linear scanner. In collaboration with Oak Ridge National Laboratory, scientists worked to improve the resolution of two-dimensional maps of the human body that were produced by a "radiation head on a cantilevered arm which moves back and forth over a patient." This scanning device was used to determine how radioisotopes were distributed and how they behaved in patients receiving diag-



nostic or therapeutic doses of radioisotopes. The linear scanner was first introduced at the University of California, but the improvements made during testing by the Oak Ridge team were incorporated in commercial models developed for cancer treatment centers around the country.

The ORINS Medical Division was on the forefront of many advances in cancer treatment, including but not limited to the following:

- Advancement of bone marrow transplantation. ORINS' Gould Andrews, M.D., studied the effectiveness of bone marrow transplantation in the treatment of victims of radiation accidents.
- **Development of gallium-67 as a radiopharmaceutical.** ORINS medical staff first developed gallium-67 as a scanning agent for locating soft-tissue tumors. Then, in the early 80s, ORAU staff determined how it could be used in a diagnostic procedure for finding postoperative infections. Gallium-67 has wide use in nuclear medicine to this day.
- **Development of carbon-11-labeled amino acids as radiopharmaceuticals.** ORAU staff synthesized and purified carbon-11-labeled amino acids for use in positron emission computerized tomography (what we call PET scans today). These amino acids could be used for differential diagnosis of pancreatic diseases and detection of solid tumors.
- **Development of cobalt teletherapy.** Brucer was a major contributor to the development of teletherapy using cobalt-60. Cobalt-60 became the most widely used teletherapy source across the world.
- **Development of cesium teletherapy.** Brucer was also a key contributor to the development of cesium teletherapy, in which cesium was used in place of cobalt.

- Creation of cesium teletherapy machines. Brucer helped develop machines like the 1540 curie cesium-137 unit, which targeted diseased tissue and reduced impact on healthy tissue. Leonard G. Grimmett, Ph.D., at MD Anderson Cancer Center in Houston was co-developer.
- **Development of total body irradiation.** Drs. Brucer and Andrews developed an approach for delivering a uniform whole-body dose of radiation and used it to treat some forms of cancer, particularly leukemia and lymphoma. Employing whole body irradiation with significantly higher doses than those used at ORAU became established medical practice for treatment of blood and other cancers.

In addition to these important advancements in cancer treatment, the ORINS Cancer Hospital was a pioneer in the field of nuclear medicine. The treatment advancements were remarkable, to be certain, and the hospital also created the early workforce for this new field of medicine. In addition to Drs. Brucer and Andrews, other medical professionals who worked at the forefront of this emerging field included Frank Comas, M.D., Ph.D., radiation therapist; Ralph Kniseley, M.D.; George LeRoy, M.D., who led studies of lanthanum as part of tracer studies for gastrointestinal absorption; Clarence Lushbaugh, Ph.D., who lead the Total Body Irradiation program; Karl Hubner, M.D., hematologist; Ray Hayes, Ph.D., who led the development of radionuclides and radiopharmacy; Fred Snyder, Ph.D., who was in the lipid program; Helen Vodopick, M.D., Frank Goswitz, M.D., Nazareth Gengozian, Ph.D., who developed experiments for use in immunology; Lowell Edwards, M.D. chief clinical investigator; and the many nurses, technologists and other personnel who were required for the operation of the hospital.

The cancer hospital was closed in 1974 after the U.S. Department of Energy determined that the fields of nuclear medicine, oncology, and others were thriving in world outside of the government department. The Medical Division continued work well into the 1990s, including research on cotton-top tamarins, the only other mammal besides human beings that spontaneously develops colorectal cancer.

When the cancer hospital closed, many of the doctors on staff envisioned the establishment of the Radiation Emergency Assistance Center/Training Site (REACTS), which would provide emergency response and subject matter expertise on the medical management of radiation incidents. REAC/TS was established in 1975 and moved to its current location on the campus of Methodist Medical Center

in Oak Ridge. (ORAU, 2006) Today, REAC/TS is a world renowned U.S. Department of Energy (DOE) asset, situated under DOE's Oak Ridge Institute for Science and Education (ORISE), which is managed by ORAU.

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While neither the research hospital nor the Medical Division exists today, ORAU has built on its legacy by continuing to demonstrate its capabilities in the cancer space. These capabilities include epidemiology and exposure science, radiation studies, peer review and health communications. Among the highlights of this work over the years:

Epidemiology & Exposure Science

1994

In 1994, the ORISE Center for Epidemiologic Research completed a second medical survey of workers assigned to the Centrifuge Program at the K-25 site, also known as the Oak Ridge Gaseous Diffusion Plant, and found no increase in bladder cancers over an initial medical survey of workers in 1989 (Bonee & West, 2013).

1995

In 1995, an ORISE study revealed a significant relationship between death from leukemia and occupational radiation exposure of workers at the Savannah River site. The study built upon a previous project from 1988 that examined the mortality through 1980 of workers employed at the site between 1952 and 1974. The 1995 study involved an additional six years of follow-up through 1986 and included dosimetry data for 99 percent of the study population. Similar studies produced varied results, and ORISE recommended further research be conducted.

1996

The ORISE Center for Epidemiologic Research reported on death rates of males who were hired at DOE's Feed Materials Production Center in Fernald between 1951 and 1981. The results showed a significant increase in lung cancers with high levels of external radiation received by their workers.

Energy Secretary Richardson proposed legislation to compensate current and former contract employees at uranium enrichment facilities for cancers resulting from exposure to radioactive contaminants. Sites included Paducah, Kentucky; Oak Ridge, Tennessee; and the Portsmouth plant in Piketon, Ohio. Richardson's proposal would lead to the creation of the National Institute for Occupational Safety and Health (NIOSH) Dose Reconstruction Program, which ORAU began managing in 2002, in collaboration with MJW Associates and Dade Moeller and Associates. The NIOSH Dose Reconstruction Program helps ensure that energy workers who develop cancer because of their work are compensated for their losses by policies established by the U.S. Department of Labor. Since 2002, the NIOSH team has completed and submitted more than 66,000 dose assessments for NIOSH Review (ORAU, 2004).

2003

Since 1992, more than 1,100 former Rocky Flats radiation workers have been tested and monitored for DOE in the Former Radiation Worker Medical Surveillance Program, a program initially managed by ORISE beginning in 1998. The surveillance program was expanded to become the National Supplemental Screening Program (NSSP), which was established by DOE in 2005 and is managed by ORAU. The NSSP The program offers free, customized medical tests to thousands of former site employees who may have been exposed to hazardous substances at work. The screenings are designed to identify occupational diseases, such as chronic beryllium disease, hearing loss, kidney or liver disease, and some forms of cancer. (Bonee & West, 2013)

2004

ORISE began managing DOE's Radiation Exposure Monitoring System (REMS) and NRC's Radiation Exposure Information and Reporting System (REIRS). Today, REMS tracks nearly 4.5 million radiation exposure records on more than 800,000 monitored individuals from 94 reporting organizations at all 33 DOE sites. REIRS tracks more than five million radiation exposure records on more than one million monitored individuals from 1,800 Nuclear Regulatory Commission licensees, reactor and nonreactor licensees.

ORISE and ORNL published results from a study, begun in 2000, of 6,675 Rocketdyne, Inc., employees. Rocketdyne built engines for rockets such as the Apollo space craft. ORISE managed the computerization of radiation occupational exposure data from electronically scanned records (ORAU, 2005).

2007

ORISE released the DOE Worker Health Summary, 1994-2004, and a companion summary version, Worker Health at a Glance, 1994-2004, a nine-year ORISE health summary of 120,000+ workers from 14 DOE sites (Bonee & West, 2013)

2008

Providing long-time support for DOE, NRC and other federal agency worker health programs, ORISE had conducted health studies and maintained data and records involving a combined total of more than 1.1 million workers at more than 500 sites. As DOE's data center for worker health, ORISE manages DOE's Radiation Exposure Monitoring System database, Human Subjects Research Database and the Beryllium Active Workers Registry, as well as NRC's Radiation Exposure Information Reporting Database, all housed in one location.

2010

ORAU was contracted by the Tennessee Valley Authority to conduct independent comprehensive evaluations of more than 200 Roane County resident impacted by a coal ash spill that occurred at TVA's Kingston Fossil Plant. More than 5.4 million cubic yards of fly ash leaked into Melton Lake and land surrounding the plant. The comprehensive medical evaluation included health history, medical examination, breathing test, chest x-ray, routine urinalysis, blood count, blood test and biological monitoring tests. While the initial evaluation found that study participants showed no adverse health impacts because of the fly ash spill, repeat tests could whether any change in health was related to the spill.

ORISE epidemiologists, in collaboration with Vanderbilt University, DOE, NRC, NASA and EPA, were selected to help design and execute the largest-of-its-kind study in the U.S, on the effects of long-term worker exposure to low-dose radiation involving more than one million workers. In its first full year, the Million Worker Study finalized project scope to include creating a registry that will capture 70+ years of radiation worker data, dating from 1942. The precedent-setting study also will include an assessment of internal organ dosage – the first of its kind – that will incorporate internal and external exposure to derive an overall organ dose.

2013

ORISE published its final Worker Health Summary, a ten-year report of DOE complex-wide occupational health data collected on more than 136,000 individuals through the DOE Illness and Injury Surveillance Program. Over the 20 years of the program's existence 217,000 DOE workers were assessed.

2019

Thanks to funding from the ORAU-Directed Research and Development program, researchers from ORAU and Texas A&M University to evaluate the feasibility of developing a preliminary set of reference models to address the need to speed up the process to make the dosimetry calculations needed to determine risk estimates for various jobs. Data from the U.S. Department of Energy's Radiation Exposure Monitoring System (REMS) and the Nuclear Regulatory Commission's Radiation Exposure Information Reporting System (REIRS) (ORAU, 2019).

Radiation Studies

1994

In 1994, ORISE scientists initiated precedent-setting work on internal dosimetry that improved the understanding of the beneficial uses of radionuclides as diagnostic and therapeutic tools. Staff at the ORISE Radiation Internal Dose Information Center developed a systematic computer model that allows physicians to determine how much of a radiolabeled compound a patient needs to effectively treat a malignant tumor without damaging health tissue. (Bonee & West, 2013)

1996

The ORISE Radiation Internal Dose Information Center was a key contributor to release criteria for patients receiving radiopharmaceuticals, specifically including guidelines for breastfeeding mothers who were being treated with nuclear medicine.

2017

Dr. Balajee teamed up with researchers at the University of Tennessee to study how ionizing radiation causes chromosomal breakages in cell nuclei and how these chromosomes translocate or reattach to other nearby chromosomes. These translocations cause chromosomal abnormalities and mutations that could be the underlying cause of many disease, including cancer. The results of this study appeared in the Journal Health Physics in 2018 (ORAU, 2017).

2023

Dr. Adayabalam Balajee and researchers at Columbia University Medical Center are working on an ODRD-funded research project to test FLASH radiation for treatment of some cancers. FLASH radiation uses a single beam of high-dose radiation precisely targeted at the tumor to kill cancer cells and preserve healthy surrounding tissue with minimal to no side effects (Holtz, 2023).

Peer Review

2003

Peer Review assisted the Pennsylvania Department of Health in allocating more than \$41 million in grants to health researchers in areas such as cancer, infectious diseases, cardiovascular disease, and mental illness. The grants were funded through Pennsylvania's share of tobacco Master Settlement Agreement funding (ORAU, 2003).

Health Communication

2006

The health communication team developed CancerSPACE (Cancer: Simulated Planned Approach to the Collaborative Experience) for the National Cancer Institutes. CancerSPACE was an interactive learning tool that uses cancer clinics' spirit of collaboration in sharing experience and knowledge to increase rates of cancer screening, especially among underserved populations (ORAU, 2006).

2007

The National Cancer Institute called on the Health Communications team to create EPEC-O, Education on Palliative Care and End-of-Life Care Oncology, a CD-ROM and DVD education tool to help palliative care workers meet the unique physical, emotional and spiritual needs of the terminally ill cancer patient that was provided concurrently with therapy throughout the entire spectrum of disease (ORAU, 2007).

CancerSPACE (Simulating Practice and Collaborative Education) was developed as an interactive web-based application for training clinical staff to screen patients for breast, cervical and colon cancers. This e-learning application gamified education and facilitated self-directed learning (ORAU, 2008).

2012

ORAU health communications staff began work on a two-year project for the CDC's National Center for Immunization and Respiratory Diseases to implement a health communication and social marketing campaign to promote uptake of human papillomavirus (HPV) uptake for girls and boys ages 11-12. HPV is a sexually transmitted virus linked to several types of cancer among women and men. The campaign included radio and digital media advertising and targeted website and social media messaging. An important component of the project was conducting focus groups of parents and adolescent boys and girls, and health care workers to collect data on knowledge and attitudes and beliefs about the HPV vaccine. Additionally, ORAU worked with the CDC to develop educational materials about the importance of HPV vaccination (ORAU, 2013).

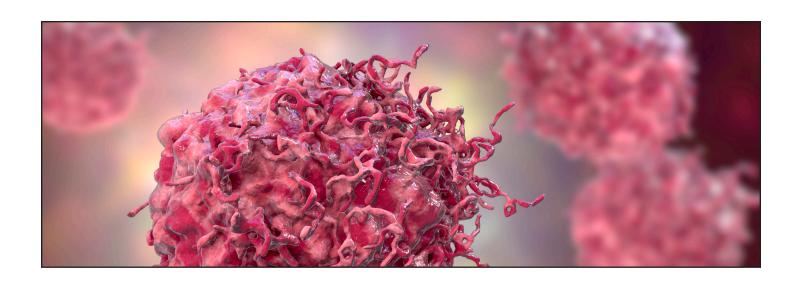
2014

In collaboration with the University of Tennessee College of Nursing, ORAU worked on two separate projects investigating occupational, environmental, and genetic risk factors in the development and survivability of cancer. In the first project, ORAU investigated occupational exposures to chemotherapeutic drugs among oncology nurses. The goal of the study was to identify ways to better handle chemotherapeutics and communicate their potential risk, thus minimizing exposure threats to these critical caregivers. In the second study, ORAU worked with Pikeville Medical Center in Kentucky to investigate and assess environmental and genetic risk factors among a cohort of cancer patients diagnosed with specific cancers who were surviving longer than expected (ORAU, 2014).

ORAU partnered with Ogilvy Public Relations to win a two-year contract to support the CDC with its Young Women and Breast Cancer Social and Digital Media Education Campaign. During the campaign, ORAU health communications experts conducted formative research, developed and conducted continuing education activities for health care providers, and provided technical assistance and developed training for CDC staff, partner organizations, grantees, and the Federal Advisory Committee on Breast Cancer in Young Women. ORAU also supported Bright Pink with the development and launch of the Know BRCA clinical decision support tool that used a statistical model based on family history and other factors to determine a woman's risk of developing breast cancer (ORAU Annual Report, 2014).

2018

ORAU helped the CDC evaluate its Living Beyond Breast Cancer pilot program. LBBC trains nurses about the unique survivorship issues faced by women diagnosed with breast cancer and equips them to lead survivorship education programs at their cancer treatment centers (ORAU, 2018).



Based on ORAU's history and capabilities outlined above, as well as on analysis of federal agency cancer-related priorities and the legislative priorities of key advocacy groups, the following recommendations are being made for the pursuit of contractual work or ODRD-funded research projects:

Recommendation One:

Develop an ODRD-funded research project focused on improving cancer screening rates among underserved populations, especially the black and LGBT communities.

Black and individuals who identify as LGBTQIA+ are at higher risk for several cancers, especially those caused by the Human Papilloma Virus, as well as colorectal cancer and prostate cancer. "In the United States, age-standardized overall death rates for cancer are highest for non-Hispanic Black people, followed by American Indian and Alaska Native people. Other populations, such as people with disabilities and sexual and gender minority individuals, also suffer disparities in cancer care outcomes," according to the National Cancer Plan.

The American Cancer Society reports that Black individuals have a disproportionately higher cancer burden, including the highest mortality and lowest survival of any ethnic/minority group for most cancers. Additionally, individuals who identify as lesbian, gay, bisexual, and queer may have a higher risk of getting cancer than those who identify as heterosexual or cis gender. The reason for this disparity is largely due to discrimination. LGBTQ individuals are more likely to be unemployed, uninsured and lack access to quality health care (Charlton, 2022).

Because of fear of discrimination, LGBTQ individuals are less likely to disclose their sexual identity to their health care provider, if they indeed have a provider. Individuals who have a health care provider who knows their sexual identity are more likely to have been encouraged to get cancer screenings than individuals who have not disclosed their identity.

The current Congress is considering legislation, the PSA Screening for HIM Act (Congress.gov, 2023),

that would expand insurance coverage for prostate cancer screening to men who are at high risk of prostate cancer because of family history but who may fall outside current screening guidelines.

An ODRD-funded project focused on reducing these health disparities through communication of audience-appropriate cancer screening messaging, including the development of focus groups to help determine effective messages, and tools to reach underserved populations could be the catalyst for research further funded by the Department of Health and Human Services, Center for Disease Control and Prevention, National Cancer Institute or other agency tasked with reducing disparities in cancer incidence and mortality.

Recommendation Two:

Develop an ODRD-funded research project to study and improve the processes for collecting Patient Reported Outcome Measures between treatment visits.

Oncology practices increasingly recognize and rely on Patient Reported Outcome Measures to improve quality of patient care and measure treatment adherence. PROMs are typically collected between oncology visits, say midway between a two-week interval between chemotherapy treatments and again the day before chemotherapy.

"Patients receiving oncologic care are predisposed to disease and treatment-related issues, many of which have shown to be preventable through proactive monitoring and management," according to a study from Ochsner Health.

As research on the importance PROMs increases, investigators report challenges in getting this data from patients. Often, data is collected through existing health system patient portals, which can be difficult to navigate, require use of a login and password, and sometimes require inputting credit card data for payment of co-pays and other medical charges.

Telehealth is an important means of collecting PROMs between treatment visits. Digital technology is another means. Veris Health, for example, offers a digital hub that daily prompts oncology patients

to step on a scale, provide a temperature reading and a blood pressure reading and heart rate, and report any side effects like rashes, neuropathy, headaches, etc. via a telehealth call. Ochsner has piloted use of Chemotherapy Care Companion and reports an increase in patient satisfaction scores and improves in reports of overall care because of use of digital vital sign collection devices (Larned & Pierce, 2023).



An ODRD-funded research project could pilot digital technology designed to improve PROMs, and thereby improve patient satisfaction measures and perception of improved quality of care. Such a project could be conducted with any number of our university consortium partners if they are interested.

Recommendation Three:

Develop an ODRD-funded research project to identify best practices for communication to improve the uptake of low-dose CT for lung cancer screening.

Lung cancer continues to cause more cancer deaths in the United States than any other cancer among men and women. The National Cancer Institute estimates 127,070 people will die of lung cancer this year (National Cancer Institute, 2023). Tobacco use remains the biggest cause of lung and other cancers. Additionally, tobacco use is one of the primary causes of cancer-related health disparities, as tobacco use disproportionately impacts people by race, ethnicity, sexual identify, gender identity, disability status, mental health, income, education level and geographic location (ACS CAN, 2023). While tobacco use is generally on the decline across the country, tobacco use continues above the median average in thirteen primarily Midwest and Southern states, including Tennessee.

The use of low-dose CT has been proven effective at diagnosing lung cancers early and is covered by most insurance companies, yet screening rates remain alarmingly low. Only 5.8 percent of people eligible for a low-dose CT underwent the screening (American Lung Association, 2022). There could be a several causes for this, including the fact that guidelines for recommending lung cancer screenings are complicated. Unlike mammograms or colon cancer screenings, which are age dependent, lung cancer screenings are recommended based on a somewhat complicated formula. U.S. Preventive Service Task Force guidelines say that individuals eligible for low-dose CT have a 20-pack year or more smoking history (a pack year is defined as smoking a pack of cigarettes a day for a year), smoke now or have quit within the last 15 years and be between 50 and 80 years old (USPSTF, 2021).

An ODRD-funded research project could develop, create and test effective evidence-based methods for communicating the importance of lung cancer screenings and improve understanding the screening guidelines, and be focused on helping reduce the tobacco-related health disparities at the same time.

Recommendation Four:

Develop an ODRD-funded research project focused on cancer-related stigma and preferences for or against using militaristic language to describe a patient's cancer treatment experience.

When Nixon launched the "war on cancer" he may have unwittingly ushered in the use of battle metaphors to explain the treatment of cancer. Patients are often considered to be in a pitched battle with the disease and asked to visualize radiologic and chemotherapy agents as doing combat against the enemy within. For some patients, battle metaphors are energizing. For others, they can be despairing, especially in cases where the disease is terminal. Patient who pass away are spoken of as simultaneously having lost or won their battle with cancer, depending on the perspective of their loved ones or their spiritual/religious perceptions.

There are real challenges when it comes to using militaristic language. Has a patient given up if they decide to forego further treatment and enter hospice care, for example?

On the one hand, use of militaristic language can give patients and their medical teams a feeling of control over the situation. Using words like "battle" and "fight" raise the specter of the attitude a patient has toward their illness. A positive attitude is a good tool in the arsenal, so to speak, and a patient's family and friends expect that positivity. T-shirts and social media posts bearing hashtags like #TeamMichael and #HoltzStrong are both accepted and expected by and large (McEachern, 2022).

But what of patients who aren't comfortable using militaristic language. Patients report perceiving treatment to be more difficult when using violent or warfare-infused metaphors. If treatment isn't working or a patient isn't feeling well, which is completely normal and natural for patients in treatment, use of "fight" metaphors can make them feel dispirited, disempowered, even guilty or weak.

Phrases like "cancer journey" and "cancer experience" are offered as replacements for militaristic language. Is this language specific enough or effective enough? Ultimately the choice of language is best left to the patient.

In a post COVID-19 world where medicine is equally focused on mental health, an ODRD-funded study of communicating cancer metaphors would be worth pursuing. Because of ORAU's previous work around stigma and substance use disorder, a study of cancer-related stigma would be interesting as well. Patients are expected to have a positive attitude through the course of treatment. "Attitude is everything" for those of us in the cancer advocacy community, those of us who experience survivor's guilt often face shame from fellow advocates. In my own experience as a patient, I often found myself in the role of making other people comfortable with the face that I had stage-3b cancer by leaning into my positive attitude and sense of humor, or by forcing a smile and a positive word even on days when chemotherapy made me so weak I could barely function. Patients everywhere could benefit from new or better ways to talk about their illness.

Recommendation Five:

Develop an ODRD-funded research project focused on ensuring inclusion of the special needs of cancer patients in disaster preparedness guidelines.

Disaster preparedness and response is one of ORAU's critical capabilities. Our organization has more than three decades of experience supporting preparedness and response programs, including the Ebola virus outbreaks in the United States and West Africa, and the worldwide coronavirus pandemic.

Our expertise includes automation of emergency management processes, community capacity building, emergency response support and training, strategic planning, preparedness products like toolkits and guidance, medical countermeasures planning, and medical surge planning.

Recently, our preparedness and health communications experts worked with the Centers for Disease Control and Prevention Office of Readiness and Response to develop discussion guides for planners to use in preparedness activities around five social determinants of health topics: economic stability, education access, health care access, neighborhood and built environment, and social and community context.

While the CDC's ready.gov website includes some preparedness information for cancer patients and their families (CDC.gov, 2023), a more robust guide could be helpful to cancer patients who are dealing with all of the physical, mental and emotional stressors of their illness combined with the stressors of preparedness in the case of an emergency situation. An ODRD-funded research project to develop such a guide would be beneficial.

Recommendation Six:

Develop an ODRD-funded research project to develop and test messaging to patients who may wish to request a blood test to screen for colorectal cancer rather than submit to a colonoscopy.

While colorectal cancer remains one of the most preventable forms of cancer, incidence and mortality of the disease is on the rise. In fact, colorectal cancer is on track to be the number one cancer killer of people under age 50 by 2030. (Fight Colorectal Cancer, 2023)

Colonoscopy remains the gold standard for colorectal cancer early detection and prevention screening, but colonoscopy is an invasive procedure that requires preparation in advance to clean out the colon to get an accurate screening. Colonoscopy prep is often a barrier to screening for some people. Still, 71.8% of adults aged 50 to 75 who were eligible for a colonoscopy got one in 2021. (NCI, 2023) That year, the United State Preventive Services Task Force changed its colorectal cancer screening guidelines, urging people age 45 and older to talk to their doctor about getting screened. This followed the American Cancer Society, which changed its guidelines in 2018.

Other colorectal cancer screening tests available include a virtual colonoscopy, which also requires cleaning out the colon, and flexible sigmoidoscopy, which is another invasive test. Non-invasive screening tests are available, including fecal occult blood tests, fecal immunochemical (FIT) tests, and FIT DNA tests like Cologuard. Positive results of these tests may lead to referral for a colonoscopy. Companies like Knoxville-based New Day Diagnostics are working to develop blood tests to detect colorectal and other cancers early. Tests for specific cancers as well as multi-cancer early detection (MCED) blood tests are in development by New Day, GRAIL, and a host of other companies. Cancer advocacy groups like the American Cancer Society Cancer Action Network are working toward passage of legislation that would pave the way for Medicare approval of these tests, so that when the Food and Drug Administration approves MCED tests Medicare recipients have access to them as soon as possible. (ACS CAN, 2023)

As single cancer blood tests gain FDA approval limiting language requiring that these tests be offered

only after a patient has refused a colonoscopy may be included. An ODRD-funded research project could help educate patients on how to request these blood tests in place of a colonoscopy if that is their preference.

Conclusion

Since the end of the Manhattan Project and the opening of the ORINS Medical Division cancer hospital, ORAU has always had a place in the nation's fight against cancer. Our capabilities have shifted over time and our current capabilities in epidemiology and exposure science, radiation studies, health communications and preparedness afford ORAU opportunities to continue to have a significant impact in the cancer space. Where our capabilities align with federal priorities, we can do great things and impact cancer risk, survivorship, early detection and prevention, and quality of life for cancer patients and their families. There is so much we can do, further together.

Appendix

The following table categorizes the cancer-related priorities of Federal government agencies, including the White House, U.S. Department of Health and Human Services, U.S. Center for Disease Control and Prevention, National Institutes of Health, and National Cancer Institute. Additionally, the federal legislative priorities of two cancer advocacy organization, the American Cancer Society Cancer Action Network, and the National Coalition for Cancer Survivorship, are included. Labels for the priority areas were determined by the author.

White House Cancer Cabinet (aka, The Cancer Moonshot)

Priority Area	Focus
Research	Decrease the impact of preventable cancers. Research efforts should
	focus on fully understanding and developing additional approaches to reach people with cancer prevention tools to include, for example:
	cancer-related vaccines, effective treatments for cancer-causing infectious agents, techniques to address and treat pre-cancer (like
	we do with colonoscopies today) and approaches to decrease the impact of nutrition- and tobacco-related cancers. Efforts are also needed to expand access to cancer-prevention approaches through
	evidence-based public health and community health efforts to ensure these preventative tools are reaching all U.S. populations.

Priority Area	Focus
Research	Understand and address environmental and toxic exposures. Studies
	have shown that exposure to environmental contaminants and toxic
	chemicals can lead to a higher risk of certain types of cancer. A
	robust scientific and regulatory agenda should be pursued to enable
	increased understanding of the impact of environmental exposure in
	the effort to better prevent and mitigate cancer-related exposures.
Research	Bring cutting edge research through the pipeline to patients and
	communities. The development and deployment of new ways to
	prevent, detect, and treat cancer will be necessary to increase cancer
	survival rates. Focus should be given to fundamental research that
	supports precision medicine, increases understanding of how to
	target effective treatments to patients, improves cancer
	survivorship, and speeds progress on some of the deadliest and rare
	cancers, including childhood cancers. Emphasis should be given to
	driving innovation, from discovery to patient treatment, by
	accelerating trial accrual and enrolling populations that reflect the
	diversity of those diagnosed with cancer in America. Agencies should evaluate ways to use, expand, and share Federal datasets, some
	already rich with diverse patient populations, to drive investigations.
Early Detection, Prevention,	Close the screening gap. Americans missed nearly 10 million cancer
and Treatment	screenings ad compared to prior years during to the COVID-19
	pandemic. The development of innovative approaches to cancer
	screening and early detection, including more precise, less invasive,
	and even at-home methods, should be prioritized to reduce that
	deficit and expand equitable access to effective cancer early
	detection going forward.

Priority Area	Focus
Patient Care and Survivorship	Support patients and caregivers. Cancer can be overwhelming to any person or family and gaps in support can lead to gaps in positive outcomes. In order to make the experience around cancer from screening, to getting a diagnosis, to treatment, care and surviving easier on those living with cancer and their caregivers, evidence based, and scientifically sound public health approaches should be pursued. That means making it easier for people to access screening and diagnostics, bringing trials and quality care closer to home, including through the use of telehealth, providing patients and caregivers with the data and knowledge they need to make informed care decisions, and giving people with cancer and the people who care for them, a seat at the table in order to improve our cancer research and development system.

National Cancer Plan – U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute

Priority Area	Focus
Research	Prevent Cancer. All people and society adopt proven strategies that
	reduce the risk of cancer.
Early Detection, Prevention,	Detect Cancers Early. Cancers are detected and treated at early
and Treatment	stages, enabling more effective treatment and reducing morbidity
	and mortality.
Early Detection, Prevention,	Develop Effective Treatments. Effective treatment, with minimal side
and Treatment	effects, is accessible to all people with all cancers, including those
	with rare cancers.
Health Equity	Eliminate Inequities. Disparities in cancer risk factors, incidence,
	treatment side effects, and mortality are eliminated through
	equitable access to prevention.
Health Equity	Engage Every Person. Every person with cancer or at risk for cancer
	has an opportunity to participate in research or otherwise contribute
	to the collective knowledge base, and barriers to their participation
	are eliminated.
Patient Care and Survivorship	Deliver Optimal Care. The health care system delivers to all people
	evidence-based patient-centered care that prioritizes prevention,
	reduces cancer morbidity and mortality, and improves the lives of
	cancer survivors, including people living with cancer.
Data Collection and	Maximize Data Utility. Secure sharing of private-protected health
Evaluation	data is standard practice throughout research, and researchers share
	and use available data to achieve rapid progress against cancer.
Workforce Development	Optimize the Workforce. The cancer care and research workforce is
	diverse, reflects the communities served, and meets the needs of all
	people with cancer and those at risk for cancer, ensuring they live
	longer and healthier lives.

National Cancer Institute Annual Plan and Budget Proposal for FY24

Clinical Trials	Expand and modernize clinical trials and the enterprise for supporting them.
Research	Continue to invest in basic and translational research to ensure a continuous stream of new approaches to cancer prevention, diagnosis, and treatment.
Early Detection, Prevention, and Treatment	Undruggable cancer targets.
Early Detection, Prevention, and Treatment	Cell therapy to treat cancer
Health Equity	Ensure equitable health care delivery of current and new standards of care.
Health Equity	Persistent poverty and cancer.
Multi-cancer Early Detection	Asymptomatic multi-cancer detection.
Workforce Development	Expand and enhance the diversity of the cancer research workforce.

U.S. Centers for Disease Control and Prevention National Comprehensive Cancer Control Priorities

Early Detection, Prevention, and Treatment	Emphasize primary prevention of cancer. Increase vaccination for HPV and HBV, promote tobacco-free living, improve nutrition and physical activity in communities, worksites, and schools; promote sun safety, reduce exposure to artificial UV sources.
Early Detection, Prevention, and Treatment	Support early detection and treatment. Increase use of recommended cancer screenings, support appropriate treatment, address financial barriers, provide emotional support, improve access to clinical trials, use patient navigators and community health workers,
Health Equity	Promote health equity.
Health Equity	Implement policy, systems and environmental approaches.
Patient Care and Survivorship	Address the public health needs of survivors. Offer survivorship programs, promote survivorship care plans, educate, and provide information to survivors, caregivers, providers)
Data Collection and Evaluation	Demonstrate outcomes through evaluation.

American Cancer Society Cancer Action Network 2023 Federal Legislative Priorities

Clinical Trials	Diversifying Investigations Via Equitable Research Studies for
	Everyone (DIVERSE) Trials Act.
Research	Increased funding levels for cancer research and prevention.
Early Detection, Prevention	Legislation and regulatory policies to reduce death and disease
and Treatment	caused by commercial tobacco.
Early Detection, Prevention	FDA's issuance of marketing denial orders for menthol-flavored e-
and Treatment	cigarettes.
Health Equity	Collect and make available detailed demographic data to reduce
	disparities in cancer prevention, detection and treatment.
Health Equity	Prostate-Specific Antigen Screening for High-Risk Insured Men (PSA
	Screening for HIM) Act.
Health Equity	Increased funding for Indian Health Services
Multi-cancer Early Detection	Medicare Multi-Cancer Early Detection Screening Coverage (MCED)
	Act
Patient Care and Survivorship	Palliative Care and Hospice Education and Training Act
Data Collection and	Verifying Accurate Leading-edge IVCT Development (VALID) Act
Evaluation	

National Coalition for Cancer Survivorship

Patient Care and Survivorship	Comprehensive Cancer Survivorship Act. This legislation would
	include coverage of cancer care planning and coordination services;
	cancer survivor employment assistance grants; and an adult cancer
	survivorship longitudinal study.

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