

Prevention Research: Building a Healthier Future

Spotlight on 2021



Message from the Director



David M. Murray, Ph.D. Associate Director for Prevention Director, Office of Disease Prevention

2021 was a notable year, not only because it brought the rollout of multiple safe and effective vaccines for COVID-19, a once-in-a-lifetime pandemic that continues to affect us, but also because it marked the 35th anniversary of the Office of Disease Prevention (ODP). Before reflecting on this past year in our Spotlight on 2021 Report, I would like to recognize all the work that has been done to increase the scope, quality, dissemination, and impact of prevention research at the National Institutes of Health (NIH) since our Office's founding in 1986. Our <u>History of the ODP timeline</u> and our new <u>35th anniversary infographic</u> highlight the major projects and milestones that have brought us to this point.

Focusing now on the last 12 months, the ODP has made considerable progress toward meeting the objectives and goals outlined in our <u>strategic plan</u>.

- We analyzed the NIH prevention research portfolio and identified a need for more intervention research addressing the leading risk factors for death and disability in racial and ethnic minorities and other populations that experience health disparities.
- We made it easier for investigators to find prevention-related funding opportunities from across the NIH.
- We expanded and improved research methods resources to help investigators design and implement more rigorous clinical trials.
- ODP staff published a study characterizing the types of scientific evidence that help upgrade U.S. Preventive Services Task Force insufficient evidence (I) statements to definitive recommendations that allow clinicians and patients to make evidence-based choices about preventive care. We also supported a project to better communicate the research gaps identified in I statements to researchers and funders.
- Scientists funded by the Tobacco Regulatory Science Program developed a special issue of Nicotine & Tobacco Research, which begins to examine the association between respiratory disease and the use of combustible and non-combustible nicotine and tobacco products.

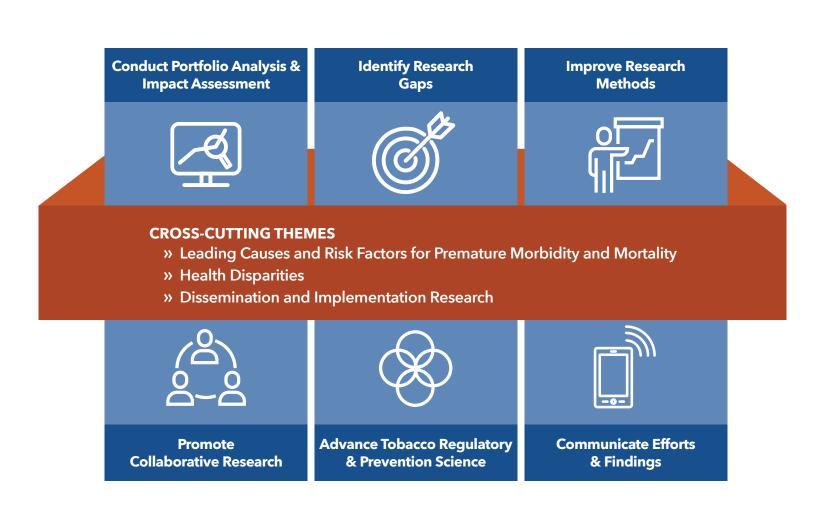
I hope this report gives you a better understanding of our work and collaboration with NIH colleagues and other partners to advance disease prevention and health promotion.

We are looking forward to building on this progress to move prevention research forward in the new year. Notably, the ODP is elevating its commitment to achieving health equity in disease prevention. A critical part of reducing health disparities involves addressing the leading risk factors and causes of death and disability, many of which can be prevented, delayed, or caught and treated early. However, through our portfolio analysis work, we found the NIH has supported limited research on interventions to address these risk factors in populations that experience health disparities in the United States. In response, the ODP is launching a long-term, NIH-wide effort called <u>ADVANCE: Advancing</u> <u>Prevention Research for Health Equity</u>. Through ADVANCE and further efforts in this area, the ODP will work to develop new prevention initiatives and strategies to deliver evidence-based interventions and preventive services in populations that experience health disparities.

in M. Mog

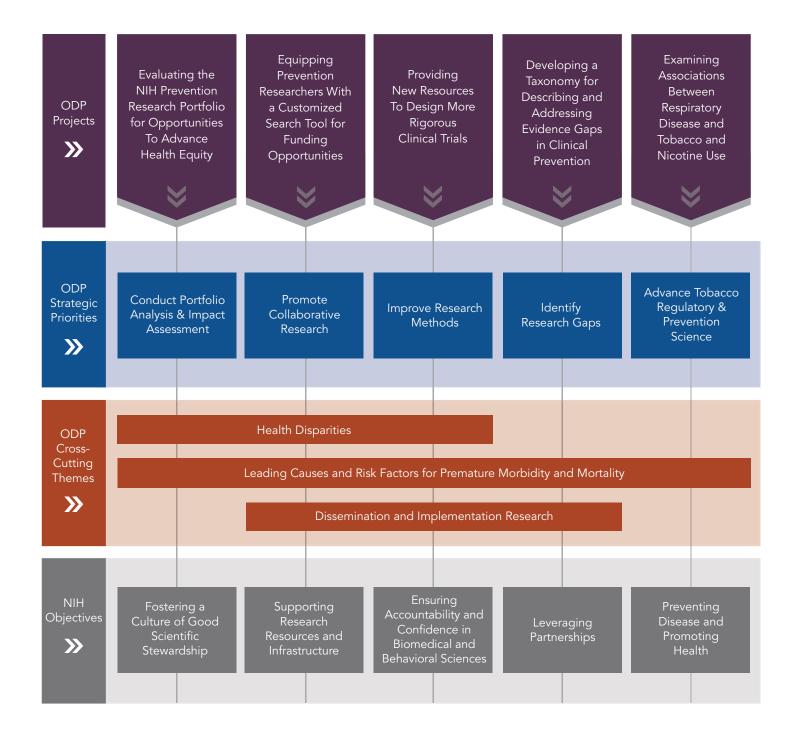
Strategic Priorities and Cross-Cutting Themes

The Office of Disease Prevention (ODP) is the lead office at the National Institutes of Health (NIH) responsible for advancing and disseminating research in disease prevention. Our work to help people in all communities live longer, healthier lives is guided by these interconnected strategic priorities and cross-cutting themes.



Connecting ODP Projects and Priorities with NIH Objectives

Our work makes valuable contributions to NIH's goal of turning scientific discoveries into health. We are dedicated to working closely with our NIH colleagues, as well as other federal and non-federal partners, to address NIH's three strategic objectives.



Spotlight on Progress

The ODP is the lead office at the NIH focused on disease prevention and health promotion. Our work developing, coordinating, and implementing prevention research helps strengthen clinical practice, health policy, and community health programs.

This section highlights a few of our 2021 accomplishments.



ODP Strategic Priority

• Conduct Portfolio Analysis & Impact Assessment

ODP Cross-Cutting Themes

• Health Disparities

• Leading Causes and Risk Factors for Premature Morbidity and Mortality NIH Objective
 Fostering a Culture of Good Scientific Stewardship

Evaluating the NIH Prevention Research Portfolio for Opportunities To Advance Health Equity

Over the last 5 years, the ODP's systematic analyses of the NIH prevention research portfolio have provided broad, high-level assessments of funding allocation and priorities across NIH Institutes, Centers, and Offices (ICs) and prevention topics. Support for new primary and secondary prevention research in humans by the NIH has been shown to be quite stable over the last 8 years, representing approximately 20% of new NIH projects and just over 25% of new research funding.

Recently, the ODP has focused on measuring the NIH's support for research targeting the leading risk factors for death as identified by the Global Burden of Disease Study. These risk factors are linked to nearly 60% of attributable deaths in the United States, but many like tobacco use, diet, and physical activity are modifiable. While prevention could play a critical role in reducing chronic disease and improving health, NIH support for research on these leading risk factors <u>only</u> accounts for less than a third of new NIH projects and funding.

As the ODP looked more closely at the NIH prevention research portfolio, we determined that NIH support for prevention research on leading risk factors that also addresses minority health populations and health disparities is limited. <u>Our findings</u> indicate that roughly 12% of new NIH research projects and 15% of new NIH research funding address populations that experience health disparities, including racial and ethnic minorities, sex and gender minorities, low socioeconomic (SES) populations, and those who live in rural settings. In addition, fewer than 5% of new NIH research projects and funding include interventions—either randomized or non-randomized—to target leading risk factors in these populations, even though studies supporting randomized interventions are critical to the development

of effective strategies for implementing and increasing the uptake of clinical and public health guidelines.

Why does this matter? These risk factors contribute substantially to health disparities. While a combination of socioeconomic and race/ethnicity factors, behavioral and metabolic risk

<1 in 3

prevention projects measured one of the leading risk factors identified by the Global Burden of Disease project

<1 in 9

of the FY19 NIH prevention research portfolio included a randomized intervention to address a leading risk factor

<1 in 19

used an intervention to address a leading risk factor in health disparity populations (racial/ ethnic minorities, low SES, undeserved rural, SGM)

factors, and health care factors has been found to explain much of the difference in life expectancy when looking across counties, overall, the leading risk factors for death account for <u>74% of the variability in county-level life expectancy</u>.

These data make it clear there is an urgent need to develop and use evidence-based strategies that will target leading risk factors in racial and ethnic minorities and other populations that experience health disparities. The ODP is leading the charge to reduce health disparities by working with NIH ICs to stimulate more support to address common risk factors in these populations. The new trans-NIH effort, <u>ADVANCE: Advancing Prevention Research for Health Equity</u>, will focus on encouraging the development and adaptations of preventive interventions and increasing research capacity to reduce health disparities and achieve health equity.

ODP Strategic Priority

• Promote Collaborative Research

ODP Cross-Cutting Themes

- Health Disparities
- Leading Causes and Risk Factors for Premature Morbidity and Mortality
- Dissemination and Implementation Research
- NIH Objective
 Supporting Research Resources and Infrastructure

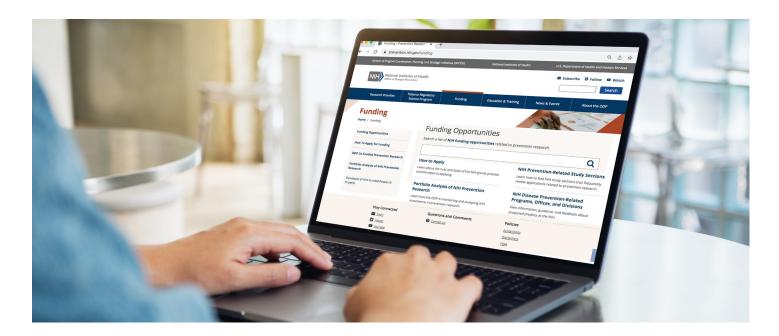
Equipping Prevention Researchers With a Customized Search Tool for Funding Opportunities

As a coordinating office at the NIH, one of the core objectives of the ODP is to bring together prevention researchrelated resources from across the NIH and federal government. We also build new tools specifically for the prevention community to make it easier to develop research concepts and applications, as well as conduct high-quality research.

The ODP's table of <u>funding opportunities</u> is a customized search tool that investigators can use to identify NIH prevention research funding opportunities. We compile funding opportunity announcements (FOAs) and Notices of Special Interest (NOSIs) from across the NIH on a weekly basis so researchers don't need to search the entire <u>NIH</u> <u>Guide for Grants and Contracts</u> (the official publication for all NIH biomedical and behavioral research grant policies, guidelines, and funding opportunities) or navigate multiple NIH Institute, Center, and Office websites to find prevention-related opportunities.

In the past year, we have improved the search tool to make it easier to find prevention-related FOAs and NOSIs on topics of interest. For example, finding a funding opportunity related to COVID-19 is now as straightforward as selecting the new <u>"COVID-19" filter</u> from the predefined list of prevention topics, which also includes research areas like cancer, diet and nutrition, injury and violence, heart disease, and substance use. You can use keywords or phrases in the search box to find funding opportunities by title. The most relevant funding opportunities will be listed first. If you only know the funding opportunity number—e.g., NOT-OD-21-087—you can now use that to <u>search for a specific opportunity</u>, as well. We have also added the ability to narrow your search by the type of funding opportunity (e.g., NOSI, Program Announcement, Request for Application) using the "Type of Funding Opportunities" filters on the left side of the screen.

We have also "pinned" select funding opportunities to the top of the search tool to highlight new or topical opportunities coordinated by the ODP. These change periodically, so we encourage you to take a moment and review the featured opportunities whenever you visit the ODP's website.



ODP Strategic Priority

• Improve Research Methods

ODP Cross-Cutting Themes

- Health Disparities
- Leading Causes and Risk Factors for Premature Morbidity and Mortality
- Dissemination and Implementation Research
- NIH Objective
 - Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences

Providing New Resources To Design More Rigorous Clinical Trials

The ODP launched the <u>NIH Research Methods Resources (RMR)</u> website in 2017 as one of several initiatives by the NIH to enhance the quality, efficiency, accountability, and transparency of clinical research. The site focuses on trials that randomize or deliver interventions to groups or clusters, and after more than 3 years of steadily increasing web traffic, the ODP undertook a top-to-bottom redesign of the site.

In 2021 we released a more modern, easier-to-use version of the RMR website with additional features, including an expanded list of references that can be filtered by year of publication, author, and study design. Most notably, there is now a <u>new sample size calculator for individually randomized group-treatment (IRGT) trials</u>. This new resource makes it easier for researchers using the <u>IRGT trial design</u> to strengthen their sample size and statistical analysis plans.

Inspired by our first <u>sample size calculator for parallel group-randomized trials (GRTs)</u> from the original site, the new IRGT trial sample size calculator can accommodate both cohort and cross-sectional designs. Tutorials are available for each aspect of the calculation, and results can be downloaded to work with offline. New examples illustrate the formulas each sample size calculator uses to arrive at the results, as well.

Though GRTs and IRGT trials are <u>becoming more common</u> in biomedical research, they are often <u>implemented</u> <u>incorrectly</u>. Special methods are required for analysis and sample size when study participants are assigned in groups or clusters (e.g., families, clinics, schools, worksites, communities, counties, states) or when study participants receive some part of their intervention in a group or cluster. However, too often, the analytic plans for these trials may be inappropriate and have inadequate power due to small sample sizes.

By referring to RMR early and often when developing statistical methods, your use of rigorous and reproducible design principles will help promote proper stewardship of NIH-supported clinical trials. Most recently, we launched a third section of the RMR website focusing on stepped wedge group-randomized trials (SWGRTs). These trials have become quite common over the last 15 years, particularly in the evaluation of health care delivery interventions. The SWGRT is a GRT that allows each group to cross from control to intervention at a prespecified time and in a random,

staggered order. The RMR website now includes background material and references on how to use SWGRTs as well as a <u>sample size calculator for SWGRTs</u> that accommodates the three most-used versions of this study design.

The ODP also worked with the NIH Office of Extramural Research to develop standard language for the application guide about special issues that accompany group randomization. NIH funding opportunities that may involve trials that randomize and/or deliver interventions to groups now often encourage investigators to use the information, references, and three custom-built sample size calculators on the RMR website in their research applications. Investigators proposing these types of trials need to satisfy the <u>NIH's clinical research requirements</u> and show that the selected methodology, statistical analysis, and sample size are appropriate.

It is our hope that by referring to the site early and often when developing statistical methods, your use of <u>rigorous and</u> <u>reproducible design principles</u> will help promote proper stewardship of NIH-supported clinical trials.

ODP Cross-Cutting Themes

Research

- Leading Causes and Risk Factors for Premature Morbidity and Mortality
- Dissemination and Implementation

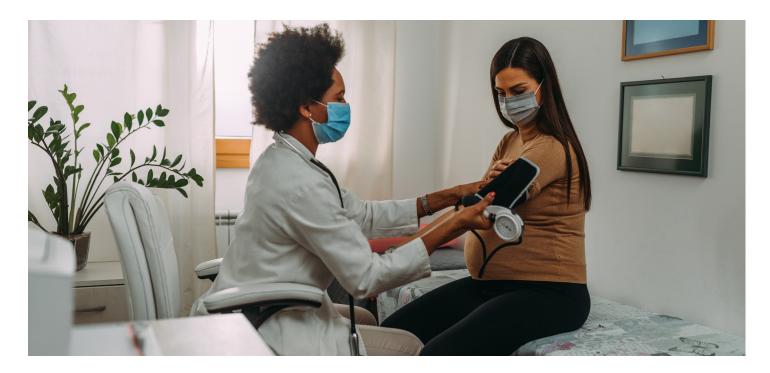
NIH Objective Leveraging Partnerships

Developing a Taxonomy for Describing and Addressing Evidence Gaps in Clinical Prevention

In 2021, ODP staff completed and published a study examining characteristics of the scientific evidence that informed upgraded U.S. Preventive Services Task Force (USPSTF) insufficient evidence (I) statements. These upgrades are important because USPSTF recommendations help primary care clinicians and patients make informed, evidencebased choices about preventive screenings, counseling services, and medications. Between 2010 and 2019, the USPSTF changed 11 I statements to definitive recommendations based on the availability of new, high-quality evidence. We found that the NIH was the largest single funder of that research.

The study also highlighted the need for better ways of describing and communicating the types of research required to address I statement evidence gaps. One way the ODP is working to meet that need is by sponsoring a project with the National Academies of Sciences, Engineering, and Medicine to develop a standardized approach for describing and reporting evidence gaps. In July 2020, the NIH awarded a contract to support a committee of experts that has been examining current challenges in describing and disseminating research gaps in evidence-based clinical prevention. The committee developed a taxonomy for characterizing evidence gaps and applied it to the existing list of gaps identified by the USPSTF. The project is jointly funded by the ODP and Agency for Healthcare Research and Quality (AHRQ), with co-funding from the Office of Behavioral and Social Sciences Research. The committee's report was issued in December 2021.

In 2022, the ODP plans to work with the NIH Institutes, Centers, and Offices and AHRQ to review the committee's recommendations and begin to apply the new evidence gaps taxonomy. The results should also be useful to other national expert groups—such as the Community Preventive Services Task Force—that evaluate evidence to make recommendations for preventive services.



ODP Strategic Priority

• Advance Tobacco Regulatory & Prevention Science

>>> ODP Cross-Cutting Theme

• Leading Causes and Risk Factors for Premature Morbidity and Mortality NIH Objective
 Preventing Disease and Promoting Health

Examining Associations Between Respiratory Disease and Tobacco and Nicotine Use

The use of combustible tobacco products has long been recognized as one of the leading causes of death and disability in the United States. However, the health effects of using newer, non-combustible products like e-cigarettes are not fully understood. As public health emergencies like the COVID-19 pandemic and the e-cigarette, or vaping, product use-associated lung injury (EVALI) outbreak arise, it becomes even more urgent to understand how these products may impact lung health.

Research on the health effects of all tobacco products is an important priority for the <u>Tobacco Regulatory Science Program</u> (<u>TRSP</u>). To address this need, the TRSP-funded Center for Coordination of Analytics, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (U54-DA046060) issued a call for papers examining the influences of tobacco and nicotine products on respiratory health, resulting in a series of publications in this priority area. The culminating <u>supplementary issue of Nicotine & Tobacco Research</u> explores the associations between cigarette and non-cigarette nicotine and tobacco use and respiratory disease. The collection of multidisciplinary studies investigates the effect of tobacco and nicotine use from the cellular level to the population level. The 13 papers include findings from preclinical toxicity studies of electronic nicotine delivery systems (ENDS) and constituents, reports of respiratory symptoms associated with ENDS use, and reports of wheezing symptoms and patterns of tobacco use in the United States.

Highlights of reported findings include:

- Correia-Alvarez and colleagues identified flavorings that were associated with increased cellular toxicity including vanillin, benzyl alcohol, and cinnamaldehyde.
- Williams and colleagues found cytotoxic metals present in e-liquids, atomizers, and in e-cigarette users.
- Examining longitudinal data, Dia and Khan found that compared to non-users, <u>e-cigarette users had higher</u> <u>concentrations of toxicants and risks of subsequent respiratory symptoms</u>, and e-cigarette users who also use other tobacco products exhibited an even higher risk.
- King and colleagues from the Centers for Disease Control and Prevention described <u>the evidence-based</u> <u>approach that identified the primary cause of EVALI</u> and the subsequent actions taken to curb the outbreak.

As Stanton, Tarran, and Mermelstein summarize in their opening editorial, these early studies on the respiratory health impact of e-cigarette and other tobacco product use provide hypotheses and direction for future studies and set the stage for establishing an evidence base to guide regulation and public health practice. Findings highlight the opportunity for policy interventions like bans on specific flavors and constituents in e-cigarettes. The evidence for increased toxicity and respiratory symptoms from e-cigarette use in combination with combustible smoking, point to the need for communication of the harms of polyuse of tobacco products and the continued priority of eliminating combustible tobacco product use.

Office of Disease Prevention 2021 at a Glance

