Addressing Evidence Gaps Reflected in the U.S. Preventive Services Task Force Insufficient Evidence (I) Statements

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National Institutes of Health
Office of Disease Prevention

Outline

- About NIH and the Office of Disease Prevention (ODP)
- ODP's role in addressing prevention research gaps:
  - Identify, Monitor, Disseminate, Coordinate
- ODP USPSTF I Statement Annual Reporting Survey
- ODP dissemination and coordination activities:
  - Prevention Research Needs and Gaps Webpage
  - *Partners for Prevention* annual newsletter
  - Trans-NIH collaborations to address prevention research gaps
- Discussion

The National Institutes of Health (NIH)

- NIH is the largest source of funding for biomedical the world.
- Mission:
  - Seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
- NIH supports thousands of scientists in universities and research institutions in every state across America and around the globe.
- In 2013, NIH support for prevention research was estimated to be about 22% ($6.9 billion) of total NIH expenditures ($30.3 billion).

NIH Office of Disease Prevention (ODP)

- **Mission**: to assess, facilitate, and stimulate research in disease prevention and health promotion, and disseminate the results of this research to improve public health.
- **Strategic Plan** (2014-18): https://prevention.nih.gov/strategic-plan
- **Strategic Priorities include:**
  1. Monitor NIH investments in prevention research and assess the progress and results of that research.
  2. Identify prevention research areas for investment or expanded effort by NIH.
  3. Promote the use of the best available methods in prevention research.
  4. Promote collaborative prevention research projects and facilitate coordination of such project across the NIH and with other public and private entities.
  5. Identify and promote the use of evidence-based interventions.
  6. Increase the visibility of prevention research at the NIH and across the U.S.

Strategic Priority (SP) II: Identify prevention research areas for investment or expanded effort by the NIH

- **Objective 1**: Work with stakeholders to identify needs in prevention research.
- **Objective 2**: Compare those needs to the current NIH portfolio to identify gaps in prevention research (i.e., those areas that are not being addressed or have insufficient funding).
- **Objective 3**: Work with the NIH Institutes and Centers to identify promising/feasible prevention research gaps for investment or expanded effort.

Coordination Activities

- NIH coordinates with AHRQ/USPSTF to ensure that:
  - USPSTF evidence reports and recommendations are informed by the most recent NIH-supported research.
    - AHRQ/USPSTF are users of scientific evidence.
    - NIH is a major generator of scientific evidence.
  - Recommendations are clearly explained to the public.
  - NIH Institutes, Centers, and Offices (ICOs) are aware of "Insufficient Evidence" (I) statements.
- ODP is the NIH liaison to the USPSTF:
  - Work with NIH ICOs to facilitate NIH scientific review and input.
  - Monitor progress on active topics and I statements.

U.S. Preventive Services
TASK FORCE

Enhancing Coordination Among the U.S. Preventive Services Task Force, Agency for Healthcare Research and Quality, and National Institutes of Health

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This paper focuses on the relationships among the U.S. Preventive Services Task Force (USPSTF); Agency for Healthcare Research and Quality (AHRQ); and NIH. After a brief description of the Task Force, AHRQ, NIH, and an example of how they interact, we describe the steps that have been taken recently by NIH to enhance their coordination. We also discuss several challenges that remain and consider potential remedies that NIH, AHRQ, and investigators can take to provide the USPSTF with the data it needs to make recommendations, particularly those pertaining to behavioral interventions.
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Introduction

The papers in this Special Issue describe the U.S. Preventive Services Task Force (USPSTF) and its role in evaluating evidence relevant to preventive services. The USPSTF interfaces with the Agency for Healthcare Research and Quality (AHRQ) and NIH, and this article describes their relationships. This article also highlights some of the challenges of merging evidence-based traditions across disciplines. It includes specific suggestions for steps that NIH, AHRQ, and the research community can take to provide better evidence for use by the USPSTF.

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The U.S. Preventive Services Task Force

The USPSTF is an independent, volunteer panel of national experts in disease prevention and evidence-based medicine; it is composed of primary care providers such as internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and health behavior specialists. The USPSTF commissions systematic evidence reviews that examine the existing body of research on preventive services to be provided by primary care clinicians or referred from primary care. The USPSTF uses these reviews as the basis for its recommendations, carefully assessing the evidence on the benefits and harms of screening tests, counseling about healthful behaviors, and preventive medications for children, adolescents, adults, older adults, and pregnant women. The USPSTF does not formally consider cost in its evaluations.

By examining both potential benefits and harms, the USPSTF makes recommendations that help clinicians and patients make informed, individualized choices based on the best available data.

The primary audience for the USPSTF's work is the primary care clinician. USPSTF recommendations are now considered by many to provide definitive standards for preventive services. In addition, the work of the USPSTF is recognized by the Patient Protection and Affordable Care Act; preventive services with a grade of A or B (www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions) must be covered without cost sharing (e.g., copayment or deductible) under new health insurance plans or policies.[1]

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NIH Institutes and Centers That Provide USPSTF Input

Fogarty International Center	National Institute on Deafness and Other Communication Disorders
National Center for Advancing Translational Science	National Institute of Dental and Craniofacial Research
National Center for Complementary Medicine and Integrative Health	National Institute of Diabetes and Digestive and Kidney Diseases
National Cancer Institute	National Institute of Environmental Health Sciences
National Eye Institute	National Institute of General Medical Sciences
National Human Genome Research Institute	National Institute of Mental Health
National Heart, Lung, and Blood Institute	National Institute on Minority Health and Health Disparities
National Institute on Aging	National Institute of Neurological Diseases and Stroke
National Institute on Alcohol Abuse and Alcoholism	National Institute of Nursing Research
National Institute of Allergy and Infectious Diseases	Office of AIDS Research
National Institute on Drug Abuse	Office of Research on Women's Health
National Institute of Biomedical Imaging and Bioengineering	Office of Behavioral and Social Science Research
National Institute of Arthritis and Musculoskeletal and Skin Diseases	Office of Dietary Supplements
National Institute of Child Health and Human Development	

Opportunities for NIH Input

ODP USPSTF I Statement Reporting Survey

- Purpose:
  - Identify and document NIH involvement in activities to address the research gaps reflected in USPSTF I statements.
- First survey:
  - Completed in spring 2015.
  - Addressed 42 USPSTF I statements.
  - Included four open-ended questions fielded by email.
  - 21 ICO representatives participated from 17 ICOs.
- Second survey:
  - Conducted from late February through mid-May 2016.
  - Addressed 47 USPSTF I statements using a redesigned, Web-based platform.
  - 99 ICO representatives participated from 17 ICOs.

Survey 1 Results: NIH Engagement in Activities Related to USPSTF I Statements—Considerable Activity

Research Gap	Portfolio is Addressing	Current Grants or Contracts	FOAs, Workshops, Meetings	New Publications
1. Screening adolescents, adults, pregnant women for illicit drug use	NIAAA NIDA	Yes, grants	FOAs	Yes
2. Interventions to prevent or reduce illicit drug use in children and adolescents	NIAAA NIDA	Yes, grants	FOAs	Yes
3. Screening for cognitive impairment in older adults	NIA, NINDS, NINR	Yes, grants	FOAs	Yes
4. Primary care interventions to prevent child maltreatment	NICHD	Yes, grants	No	No
5. Screening for suicide risk in adolescents and adults	NIMH	Yes, grants	Meeting	Yes

Updated 2016 ODP I Statement Reporting Survey

- For each I statement:
  - ODP provided a list of research needs/gaps from the I statement.
  - ICO representative was asked to identify relevant activities.
- Relevant activities included:
  - Active grants, contracts, FOAs
  - Plans for new contracts or FOAs
  - Intramural research activities
  - Sponsorship of workshops, conferences, or meetings
  - Collaborations with other ICOs, Federal agencies, or non-Federal organizations
  - Recent scientific articles/reports with new evidence.

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) NIH National Institutes of Health U.S. Department of Health and Human Services

National Institutes of Health
Office of Disease Prevention

Annual Insufficient Evidence I Statement Reporting Survey

Home | I Statement List | Instructions | Amy Lossie (NIH IC)

About the Survey

The Office of Disease Prevention Annual I Statement Survey gathers information regarding how the NIH ICs' research portfolios address the evidence gaps reflected in the U.S. Preventive Services Task Force (USPSTF) "insufficient evidence" or I statements.

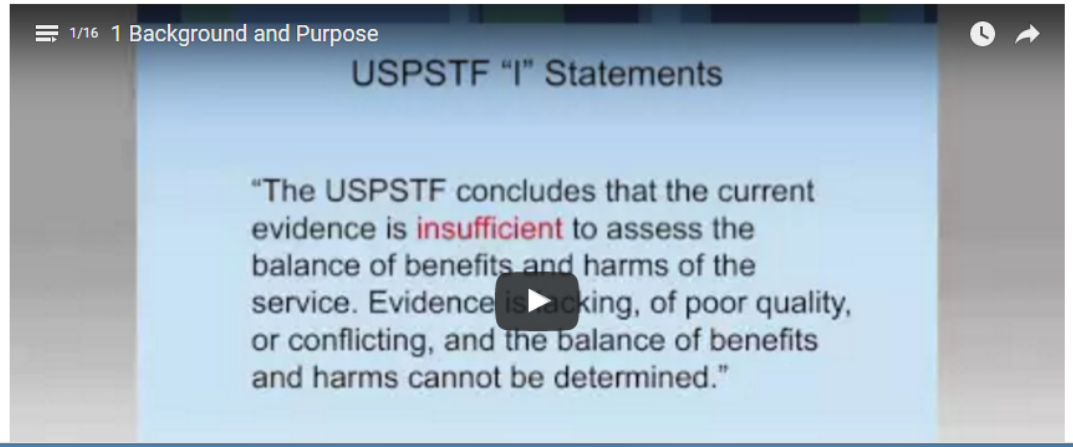
I statements are a conclusion by the Task Force that the current evidence is insufficient to assess the balance of benefits and harms of a preventive service. This may be due to evidence that is lacking, of poor quality, or conflicting.

The survey assists NIH's collaboration with the Agency for Healthcare Research and Quality (AHRQ) in support of the USPSTF. The survey is used to highlight critical research gaps in prevention, monitor progress in NIH activities related to I statement research needs and gaps, and facilitate research collaborations among NIH ICs.

Please complete the survey by April 22, 2016. For more information about the survey or the ODP's coordinating role with AHRQ and the USPSTF, contact Dr. Carrie Klabunde: prevention@mail.nih.gov.

Start the Survey | View Sample Survey | View the Instructions

Instructional Video



David M. Murray, Ph.D.
Importance of this Survey to the NIH
(PDF 78KB)

Quyen Ngo-Metzger, M.D., M.P.H.
Value of the NIH-AHRQ Collaboration
(PDF 95KB)

ODP's Prevention Research Gaps Team

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) NIH National Institutes of Health U.S. Department of Health and Human Services

NIH National Institutes of Health
Office of Disease Prevention

Annual Insufficient Evidence I Statement Reporting Survey

Home | I Statement List | Instructions | Log Out | Maureen Boyle (NIH IC)

Drug Use, Illicit: Primary Care Interventions for Children and Adolescents

Summary of Research Gaps

Assess the balance of benefits and harms of primary care–based behavioral i
nonmedical pharmaceutical use in children and adolescents. This recommenc
already been diagnosed with a substance use disorder.

Drug Use, Illicit: Primary Care Interventions for Children and Adolescents

- Brief interventions.
- Interventions that link screening with tailored interventions.
- Social media, cell phone, and Internet-based interventions to identify novel, effective risk-reduction strategies.
- Studies on diverse populations and the effects of interventions on children and adolescents with different risks, as well as which interventions work best in these subpopulations.
- Effectiveness of behavioral interventions with and without parental involvement.
- Studies that evaluate interventions and address drug use in the context of other substances, including tobacco and alcohol.
- Tools to measure current and past substance use.

Read full statement | Print | Hide

- Active Grants
- Active Contracts
- New Contracts
- Active FOAs
- New FOAs
- Intramural Research
- Recent Meetings/Workshops
- Future Meetings/Workshops
- Collaborations
- Publications
- Other Activities
- Team Members

Active Grants Help

Does your IC have any **active g**

Yes | No

Active Grants Details

For each active grant, pleas

Add the grant information in
file in the box below.

Drop Active Grants or Choose Files to upload

Or add each grant manually below, if you only have a few to add.

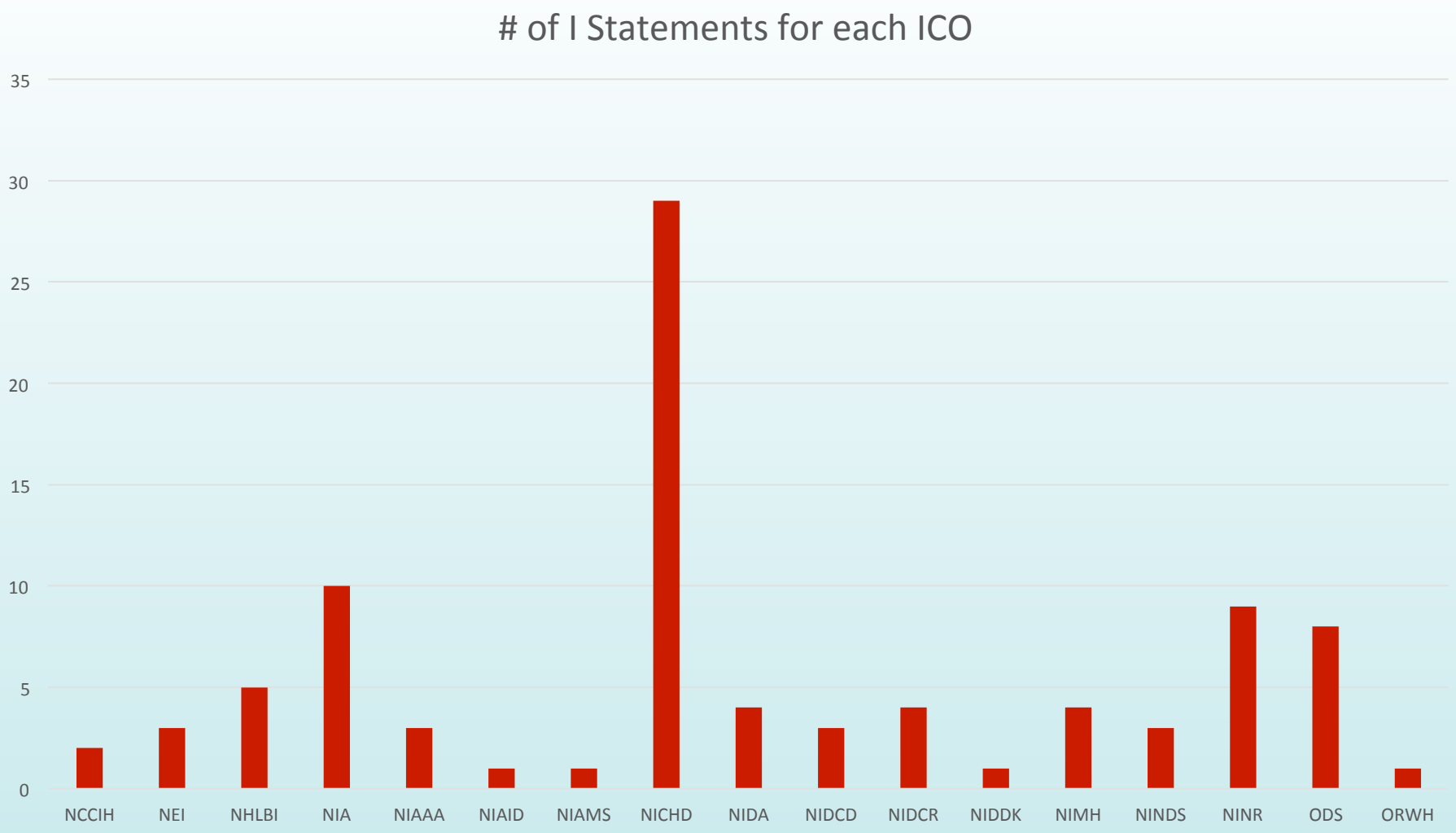
Grant # *

Project Title *

NIH Engagement in Activities Related to USPSTF I Statements: Survey 2 Summary (2016)

- ICOs reported current or planned activities addressing research gaps related to 43 of the 47 I statements (91%).
- For these 43 I statements, the following was provided:
  - 590 active grants
  - 246 active funding opportunity announcements (FOAs)
  - 72 intramural research studies
  - 57 active contracts
  - 42 recent meetings/workshops/conferences.
- Reasons given by ICOs for not currently addressing a particular I statement:
  - #1: Topic is not in the ICO's mission.
  - #2: Topic is not a priority area for the ICO at this time.
  - Study not feasible or study too expensive were not major reasons.

NIH Engagement in Activities Related to USPSTF I Statements: # of I Statements Addressed by ICO



I Statements Being Addressed By 3 or More NIH ICOs

I Statement	Number of ICOs with Relevant Research Portfolios
Cognitive Impairment in Older Adults: Screening	5
Drug Use, Illicit: Primary Care Interventions for Children and Adolescents	4
Tobacco Smoking Cessation in Adults and Pregnant Women: Behavioral and Pharmacotherapy Interventions - Pregnant Women	4
Autism Spectrum Disorder in Young Children: Screening	4
Bacterial Vaginosis to Prevent Preterm Delivery: Screening	3
Blood Pressure in Children and Adolescents: Screening	3
Drug Use, Illicit: Screening	3
Vitamin D and Calcium to Prevent Fractures: Preventive Medication	3
Vitamin D Deficiency: Screening	3

I Statements with the Greatest Amount of Current NIH Activity

I Statement	# Grants	# Contracts	# FOAs	# Intramural Studies	# Meetings/ Workshops
Blood Pressure in Children and Adolescents: Screening	66	0	15	4	0
Gestational Diabetes: Screening	39	9	10	11	1
Drug Use, Illicit: Primary Care Interventions for Children and Adolescents	36	0	6	2	1
Alcohol Misuse: Screening and Behavioral Counseling Interventions for Adolescents	33	0	2	3	0
Tobacco Smoking Cessation in Pregnant Women: Behavioral and Pharmacotherapy Interventions	34	1	2	2	1
Tobacco Smoking Cessation with Electronic Nicotine Delivery Systems (ENDS)	51	2	15	2	1

I Statements with Planned NIH Activity

I Statement	Developing New FOA	Developing New Contract	Planning a Meeting/ Workshop/ Conference
Alcohol Misuse: Screening and Behavioral Counseling Interventions for Adolescents	NICHD		NICHD
Autism Spectrum Disorder in Young Children: Screening			NIMH
Chlamydia and Gonorrhea: Screening	NICHD		
Drug Use, Illicit: Primary Care Interventions for Children and Adolescents	NICHD		
Gestational Diabetes: Screening	NICHD		
Iron Deficiency Anemia in Young Children: Screening			ODS
Iron Deficiency Anemia in Pregnant Women: Supplementation			ODS
Lead Levels in Children: Screening			NICHD
Suicide Risk in Adolescents, Adults, and Older Adults: Screening	NIMH		
Vitamin D and Calcium to Prevent Fractures: Preventive Medication		ODS	

How Survey Results are Used

- The survey:
  - Establishes a repository of NIH activities that facilitates responding to requests from NIH leadership, establishing research collaborations, and monitoring progress.
  - Responds to a Congressional mandate for NIH to improve coordination.
- The ODP:
  - Shares the results of the survey with NIH USPSTF Liaisons, IC Directors, and other senior leaders.
  - Posts the I statements on the ODP website to draw attention to them in the extramural community:
    - https://prevention.nih.gov/resources-for-researchers/prevention-research-needs-gaps
  - Works with specific ICOs to consider new activities (e.g., screening in youth – lipids, autism, lead levels, hip dysplasia).

ODP Dissemination and Coordination Activities

- Dissemination:
  - Staff presentations at NIH and professional association meetings:
    - AHRQ Annual Research Conference, Conference on the Science of Dissemination and Implementation, American College of Preventive Medicine, Society for Prevention Research
  - New ODP Web page: Prevention Research Needs and Gaps
  - Annual Task Force Coordination newsletter: *Partners for Prevention.*
- Coordination:
  - ODP Scientific Interest Groups
  - Leveraging existing collaborative groups
  - Child health/pediatric clinical care and other initiatives.

U.S. Preventive Services Task Force I Statements

The USPSTF utilizes systematic reviews to make recommendations for primary care clinicians and health systems regarding a broad range of clinical preventive services. Often, the evidence base summarized in these systematic reviews is insufficient to enable the USPSTF to make a recommendation for or against a preventive service because the evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms for a clinical preventive service cannot be determined. When this occurs, the USPSTF issues an insufficient evidence, or I statement, along with a description of research needs and gaps.

The list below details 47 I statements, each with a brief summary of research needs and gaps. The list can serve as a resource for prevention researchers and does not necessarily reflect the research priorities of NIH Institutes and Centers.

Abdominal Aortic Aneurysm (AAA): Screening

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for AAA in women ages 65 to 75 years who have ever smoked.

Research Needs/Gaps Summary

A. Randomized controlled or modeling studies assessing the effectiveness of screening for AAA in women who smoke and in men and women with a family history of AAA.

B. Studies, especially those using genetic markers, to assess the validation of risk-scoring tools to identify patients most likely to benefit from screening for AAA.

C. Effectiveness of antibiotics, statins, or other pharmaceutical agents to reduce AAA growth.

D. Interventions that address modifiable risk factors and strategies for smoking cessation.

E. Appropriately powered studies that assess efficacy of treatments on health outcomes.

Read full statement

www.prevention.nih.gov/resources-for-researchers/prevention-research-needs-gaps/uspstf-i-statements

PARTNERS for Prevention

NIH National Institutes of Health
Office of Disease Prevention

Newsletter | January 2016

Introduction

The Office of Disease Prevention (ODP) works to increases the scope, quality, dissemination, and impact of National Institutes of Health (NIH)-supported prevention research through a wide range of activities. This includes forging and maintaining partnerships with organizations, such as the U.S. Preventive Services Task Force (USPSTF) and the Community Preventive Services Task Force (CPSTF), that conduct evidence reviews to identify needs in prevention research, as well as the Healthy People program, which sets benchmarks for promoting high-quality, longer lives free of preventable disease, disability, injury, and premature death.

This is the first issue of what will be an annual newsletter for the ODP's prevention research partners. The goal of the newsletter is to update our partners on the activities the ODP conducts together with the USPSTF, the CPSTF, and Healthy People (and their supporting federal agencies) as part of the ODP's liaison role with these organizations. We will provide a year-in-review progress report, and alert our colleagues about important future meetings and deadlines. More information about our partnerships is available on the ODP website. We welcome input on the content and format of the Partners for Prevention newsletter. Please send your comments to Dr. Elizabeth Neilson at neilsone@mail.nih.gov.

In This Issue

Coordination with USPSTF

Partnership with CPSTF

Collaboration with Healthy People

ODP Staff and Upcoming Events

Task Force Coordination

"Identifying gaps in prevention research is one of the most important activities of the ODP. The work of the USPSTF and the CPSTF serves a very important function in this regard, and the ODP is proud to contribute to that work," said David M. Murray, Ph.D., Associate Director for Prevention and ODP Director.

The ODP serves as the NIH liaison to the USPSTF and the CPSTF. Dr. Carrie Klabunde, Senior Advisor for Disease Prevention, is the NIH lead, and Dr. Elizabeth Neilson, Senior Communications Advisor, is the alternate representative to each Task Force. Drs. Klabunde and Neilson attend quarterly Task Force meetings and manage communication and information dissemination regarding USPSTF and CPSTF activities on behalf of the NIH.

David M. Murray, Ph.D.,

Associate Director for Prevention and ODP Director

Strategic Priority (SP) IV: Promote and facilitate collaborative prevention research projects across the NIH and with other public and private entities.

- **Objective 1**: Identify, document, and share best practices for research collaborations within the NIH and with other stakeholders.
- **Objective 2**: Establish or promote infrastructures and processes to foster research coordination and collaboration across the NIH and with other public and private entities.
- **Objective 3**: Coordinate NIH Funding Opportunity Announcements to address areas of need in prevention research.

Creating New Collaborative Prevention Scientific Interest Groups (SIGS)

- Working within the NIH Prevention Research Coordinating Committee, ODP is establishing five new SIGS that will be discussing how current and future research might address a number of the I statement research gaps:
  - Adult Screening
  - Youth Screening
  - Genetics of Prevention
  - Evaluation of Policy and Legislative Interventions
  - Interventions to Prevent or Delay Comorbid Disease.

Working Within Existing Collaborative Groups

- Some examples of activities that include addressing I statement research gaps:
  - Nutrition:
    - September 2016 workshop addressing research gaps and priorities related to screening and supplementation for iron deficiency in pregnant women and infants.
  - Obesity Research Task Force:
    - Multiple activities related to addressing gaps in evidence related to prevention and control of obesity over the lifecycle.
  - Autism Coordinating Committee:
    - Holding trans-NIH discussions on how current NIH research will address gaps related to autism screening.
  - Health Care System Collaboratory:
    - FOA renewal to be released in the fall will incorporate reference to I statement research gaps to encourage applicants to consider these research gaps in developing proposals.

Child Health and Pediatric Clinical Care

- Extensive gaps in the evidence related to pediatric clinical practice has been highlighted in recent publications and stimulated the Child Health Forum meeting in March 2016.
  - Examples of NIH response:
    - ODP and NICHD staff participated in that forum and are discussing potential next steps for more in-depth efforts to address research gaps in prevention.
    - Dr. Matt Gillman's arrival at NIH to direct the Environmental Influences on Child Health Outcomes (ECHO) Program provides an opportunity to integrate research on gaps related to community interventions with those related to pediatric clinical practice.
    - Discussing NIH role in addressing issues raised in Child Health Forum – i.e., methods workshop related to algorithms for review.
    - Interest in having USPSTF Pediatric Chair meet with NIH staff to discuss perspectives on I statement research gaps for children and youth.

Other Related NIH Activities

- Enhancing data systems for monitoring progress:
  - NIH staff are involved with trans-HHS working groups on evaluating gaps in monitoring progress for HP2020 objectives—such data also provides evidence for what is happening in clinical practice for issues being addressed by the USPSTF.
  - ODP provides co-funding for trans-HHS database enhancements to address data gaps.
- Poor study designs limit research quality and contribute to gaps in evidence:
  - ODP SPIII team focuses on enhancing prevention methods.
  - Mind the Gap Webinars.
  - Pathways to Prevention Workshops address enhancing research methods and data (e.g., suicide prevention, obesity methods).

Summary

- Thanks to the hard work by many staff in ODP, AHRQ, and the NIH ICOs, the work of the NIH and the USPSTF is now better coordinated.
- ODP annual I statement reporting survey has increased awareness of USPSTF I statements and fostered ideas for new or enhanced trans-NIH research collaborations.
- The barrier to moving from an I to an A, B, C, or D is the persistence of one or more evidence gaps.
- ODP will continue to work with AHRQ, the USPSTF, and NIH ICOs to identify opportunities for addressing evidence gaps, monitoring progress, and enhancing coordination.

ODP Strategic Priority Teams II and IV

Team II (Identify Prevention Research Gaps)

Carrie Klabunde

Team Lead

Team Members:

Deepa Chhatwal (IQ Solutions)

Tina Kaur (IQ Solutions)

Deb Langer

Elizabeth Neilson

Rich Panzer (IQ Solutions)

Jennifer Villani

Kate Winseck

Team IV (Promote Collaboration/ Coordination)

Rachel Ballard

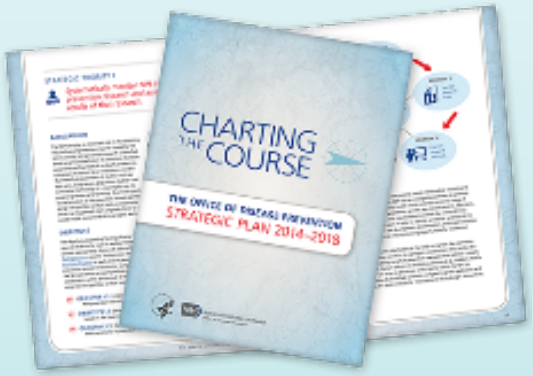
Team Lead

Team Members:

Stephanie George

Andrey Kuzmichev

Keisha Shropshire



For Discussion

- What information about the NIH research portfolio related to I statements is most useful to you?
- Are there I statements that are a particular priority?
- How can NIH and AHRQ/USPSTF improve coordination to better address evidence gaps?