DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

January 10, 2017

TO: James M. Anderson, M.D., Ph.D.
Director
Division of Program Coordination, Planning, and Strategic Initiatives
National Institutes of Health

Donna Jones
Chief Financial Officer
National Institute on Drug Abuse
National Institutes of Health

Judit O'Connor
Chief Financial Officer
National Institute on Alcohol Abuse and Alcoholism
National Institutes of Health

FROM: /Gloria L. Jarmon/
Deputy Inspector General for Audit Services

SUBJECT: Independent Attestation Review: National Institutes of Health Fiscal Year 2016 Detailed Accounting Submissions and Performance Summary Report for National Drug Control Activities and Accompanying Required Assertions (A-03-17-00352)

This report provides the results of our review of the attached National Institutes of Health (NIH) submissions as follows:

- detailed accounting submissions, which include the tables of Fiscal Year 2016 Actual Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2016, submitted by NIH's National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA), respectively, and

- the Performance Summary Report for National Drug Control Activities and management's assertions for the fiscal year ended September 30, 2016, submitted by NIH for NIDA and NIAAA, collectively.

NIH management is responsible for, and prepared, the detailed accounting submissions and Performance Summary Report to comply with the Office of National Drug Control Policy

Circular *Accounting of Drug Control Funding and Performance Summary*, dated January 18, 2013 (the ONDCP Circular).

We performed this review as required by 21 U.S.C. § 1704(d)(A) and as authorized by 21 U.S.C. § 1703(d)(7) and in compliance with the ONDCP Circular.

We conducted our attestation review in accordance with attestation standards established by the American Institute of Certified Public Accountants and the standards applicable to attestation engagements contained in *Government Auditing Standards* issued by the Comptroller General of the United States. An attestation review is substantially less in scope than an examination, the objective of which is to express an opinion on management's assertions contained in its report. Accordingly, we do not express such an opinion.

Based on our review, nothing came to our attention that caused us to believe that NIH's detailed accounting submissions and Performance Summary Report for fiscal year 2016 were not fairly stated, in all material respects, based on the ONDCP Circular.

NIDA's and NIAAA's detailed accounting submissions and NIH's combined Performance Summary Report are included as Attachments A, B, and C, respectively.

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Although this report is an unrestricted public document, the information it contains is intended solely for the information and use of Congress, ONDCP, and NIH and is not intended to be, and should not be, used by anyone other than these specified parties. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Amy J. Frontz, Assistant Inspector General for Audit Services, at (202) 619-1157 or through email at Amy.Frontz@oig.hhs.gov. Please refer to report number A-03-17-00352 in all correspondence.

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

MEMORANDUM TO: Director
Office of National Drug Control Policy

THROUGH: Sheila Conley
Deputy Assistant Secretary of Finance
Department of Health and Human Services

FROM: Donna Jones Donna M Jones
Chief Financial Officer
National Institute on Drug Abuse 11-16-16

SUBJECT: Assertions Concerning Drug Control Accounting

In accordance with the requirements of the Office of National Drug Control Policy Circular "Accounting of Drug Control Funding and Performance Summary," I make the following assertions regarding the attached annual accounting of drug control funds:

Obligations by Budget Decision Unit

I assert that obligations reported by budget decision unit are the actual obligations from the NIH financial accounting system for this budget decision unit after using NIDA's internal system to reconcile the NIH accounting system during the year.

Drug Methodology

I assert that the drug methodology used to calculate obligations of Prior year budget resources by function for the institute was reasonable and accurate in accordance with the criteria listed in Section 6b(2) of the Circular. In accordance with these criteria, I have documented data which support the drug methodology, explained and documented other estimation methods (the assumptions for which are subject to periodic review) and determined that the financial systems supporting the drug methodology yield data that present fairly, in all material respects, aggregate obligations from which drug-related obligation estimates are derived (See Exhibit A).

Obligations of prior year drug control budgetary resources are calculated as follows:

FY 2016 actual obligations were determined by identifying NIDA support for projects that address drug prevention and treatment. Projects for inclusion in the ONDCP budget are identified from the NIDA coding system and database known as the "NEPS" system (NIDA Extramural Project System). Data are entered into this system by program staff. NIDA does not need to make any assumptions or estimates to isolate its total drug control obligations as the total appropriation is drug control.

As the supporter of most of the world's research on drug abuse and addiction, the National

Institute on Drug Abuse (NIDA) provides a strong science base for our Nation's efforts to reduce the abuse of drugs and their consequences. NIDA's comprehensive research portfolio addresses a broad range of drug abuse and addiction issues, ranging from the support of fundamental neurobiology to community-based research. As our Nation looks for science-based approaches to enhance its prevention and treatment efforts, NIDA's broad portfolio and its continuing efforts to work with other Agencies and NIH Institutes on a variety of transdisciplinary issues will provide the tools necessary to move these efforts forward. Research serves as the cornerstone of NIDA's efforts to disseminate research information and educate health professionals and the public, especially our Nation's youth, about the factors influencing drug use, its consequences, and about science-based and tested treatment and prevention techniques. These research and dissemination efforts to develop, test, and disseminate information on the basis of addiction, its consequences, and enhanced therapeutic techniques support the ONDCP Goal 3 (treatment). Efforts to enhance the science base and disseminate information on the factors that inhibit and facilitate drug use and its progression to addiction and other health consequences, and on science-based approaches for prevention interventions support the ONDCP Goal 1 (prevention).

NIDA obligations are allocated between prevention and treatment research based on the professional judgment of scientific program officials on specific grant and contract projects. These scientists review the grant application, project purpose and methodology, and/or progress report to determine whether the project meets NIDA's criteria for categorization as prevention or as treatment research. Projects are coded and entered into the NEPS system prior to funding.

The FY 2016 total of NIDA's budget from the FY 2017 Congressional Justification was $1,050,550,000. There was a Secretary's Transfer in the amount of $1,491,294. NIDA obligated $1,048,971,037 and $87,669 lapsed.

Application of Methodology

I assert that the drug methodology described in the preceding section was the actual methodology used to generate the table required by Section 6a. NIDA has not modified its drug methodology from the previous year. The difference between NIDA's actual obligations and the National Drug Control Strategy Budget summary number for FY 2016 are for the same reasons described above for the FY 2016 column of the FY 2017 CJ.

Reprogrammings or Transfers

I assert that the obligation data presented are associated against a financial plan that, if revised during the fiscal year, properly reflects those changes, including ONDCP's approval of reprogrammings or transfers affecting drug-related resources in excess of $1 million that occurred during the fiscal year.

Fund Control Notices

I assert that the obligation data presented are associated against a financial plan that complied fully with all Fund Control Notices issued by the Director under 21 U.S.C. 1703(f) and with section 9 of the ONDCP Circular *Budget Execution*, dated January 18, 2013.

ATTACHMENT

Exhibit A

(1) **Drug Methodology** – Actual obligations of prior year drug control budgetary resources are derived from the NIDA Extramural Project System (NEPS) and the NIH nVision Balance of Accounts Report.

(a) **Obligations by Budget Decision Unit** – NIDA's budget decision units have been defined by ONDCP Circular, Budget Formulation, dated January 18th, 2013. NIDA reports its entire budget to ONDCP. This unit is referred to as:

- National Institute on Drug Abuse

(b) **Obligations by Drug Control Function** – NIDA distributes drug control funding into two functions, prevention and treatment:

- Research and Development Prevention
- Research and Development Treatment

(2) **Methodology Modifications** – none

(3) **Material Weaknesses or Other Findings** – none

(4) **Reprogrammings or Transfers -** The obligation data presented are associated against a financial plan that, if revised during the fiscal year, properly reflects those changes, including ONDCP's approval of reprogrammings or transfers affecting drug-related resources in excess of $1 million that occurred during the fiscal year.

(5) **Other Disclosures** - none

NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON DRUG ABUSE
FY 2016 Actual Obligations
(Dollars in Thousands)

I. RESOURCE SUMMARY

	FY 2016 Actual
Drug Resources by Decision Unit:	
National Institute on Drug Abuse	1,048,971
Total	1,048,971
Drug Resources by Function:	
Research and Development Prevention	357,161
Research and Development Treatment	691,810
Total	1,048,971

Differences Between (1) Actual Obligations and (2) the FY 16 Column of the FY 17 CJ and the National Drug Control Strategy Budget Summary
(Dollars in Thousands)

Total 2016 Col. of the FY 2017 CJ; National Drug Control Strategy	1,050,550
Secretary Transfer	-1,491
Lapse of Funds	-88
Total Obligations	1,048,971

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute on Alcohol
Abuse and Alcoholism 5635
Fishers Lane
Bethesda, MD 20892-9304

December 29, 2016

MEMORANDUM TO: Director Office of National Drug Control Policy

THROUGH: Sheila Conley
Deputy Assistant Secretary of Finance
Department of Health and Human Services

FROM: Judit O'Connor
Chief, Financial Management Branch
National Institute on Alcohol Abuse and Alcoholism

Judit O'connor -S

Digitally signed by Judit O'connor -S
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, cn=Judit O'connor -S, 0.9.2342.19200300.100.1.1=0013363641
Date: 2016.12.29 15:41:48 -05'00'

SUBJECT: Assertions Concerning Drug Control Accounting

In accordance with the requirements of the Office of National Drug Control Policy Circular "Accounting of Drug Control Funding and Performance Summary," I make the following assertions regarding the attached annual accounting of drug control funds:

Obligations by Budget Decision Unit

I assert that obligations reported by budget decision unit are the actual obligations from the National Institutes of Health (NIH) financial accounting system for this budget decision unit after using the National Institute on Alcohol Abuse and Alcoholism's (NIAAA) internal system to reconcile the NIH accounting system during the year.

Methodology

I assert that the methodology used to calculate obligations of prior year budgetary resources by function for the institute was reasonable and accurate in accordance with the criteria listed in Section 6b(2) of the Circular. Obligations of prior year underage drinking control budgetary resources are calculated as follows:

The NIAAA prevention and treatment components of its underage drinking research are included in the ONDCP drug control budget. Underage drinking research is defined as research that focuses on alcohol misuse and alcohol use disorder in minors (youth under the legal drinking age of 21). It includes all alcohol related research involving youth, including behavioral research, screening and intervention studies, and longitudinal studies, with the exception of research on

fetal alcohol spectrum disorders resulting from alcohol use by the mother during pregnancy. Beginning with the reporting of FY 2010 actual obligations, NIAAA's methodology for developing budget numbers uses the NIH research categorization and disease coding (RCDC) fingerprint for underage drinking that allows for an automated categorization process based on electronic text mining to make this determination. Once all underage drinking projects and associated amounts are determined using this methodology, NIAAA conducts a manual review and identifies just those projects and amounts relating to prevention and treatment. Contract expenditures supporting underage prevention activities are also included. This subset makes up the NIAAA ONDCP drug control budget. Prior to FY 2010, there was no validated fingerprint for underage drinking, and the NIAAA methodology was completely dependent upon a manual review by program officers.

Application of Methodology

I assert that the drug methodology described in this section was the actual methodology used to generate the table required by Section 6a of the Circular.

Reprogramming or Transfers

I assert that NIAAA did not reprogram or transfer any funds included in its drug control budget.

Fund Control Notices

I assert that the obligation data presented are associated against a financial plan that complied fully with all Fund Control Notices issued by the Director under 21 U.S.C. 1703(f) and with ONDCP Circular *Budget Execution,* dated January 18, 2013.

NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM FY 2016 ACTUAL OBLIGATIONS
(Dollars in Thousands)

	FY 2016 Actual
Drug Resources by Decision Unit:	
National Institute on Alcohol Abuse and Alcoholism	$55.177
Total Drug Resources by Decision Unit	$55.177
Drug Resources by Function:	
Research and Development: Prevention	$48,783
Research and Development: Treatment	$6,394
Total Drug Resources by Function	$55.177

ATTACHMENT

Exhibit A

(1) **Drug Methodology** – Actual obligations of prior year drug control budgetary resources are derived from the NIH research categorization and disease coding (RCDC) fingerprint for underage drinking and a manual review to identify projects related to prevention and treatment.

(a) **Obligations by Budget Decision Unit** – NIAAA's budget decision units have been defined by ONDCP Circular, Budget Formulation, dated January 18th, 2013. NIAAA reports only a portion of the budget dedicated to treatment and prevention to ONDCP. This unit is referred to as:

- National Institute on Alcohol Abuse and Alcoholism

(b) **Obligations by Drug Control Function** – NIAAA distributes drug control funding into two functions, prevention and treatment:

- Research and Development Prevention
- Research and Development Treatment

(2) **Methodology Modifications** – none

(3) **Material Weaknesses or Other Findings** – none

(4) **Reprogrammings or Transfers** - none

(5) **Other Disclosures** - none

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: November 9, 2016

MEMORANDUM TO: Director
Office of National Drug Control Policy

THROUGH: Norris Cochran
Deputy Assistant Secretary, Budget, DHHS

FROM: Director, Division of Program Coordination,
Planning, and Strategic Initiatives (DPCPSI), NIH

SUBJECT: Assertions Concerning Performance Summary Report

In accordance with the requirements of the Office of National Drug Control Policy circular "Accounting of Drug Control Funding and Performance Summary," I make the following assertions regarding the attached Performance Summary Report for National Drug Control Activities:

Performance Reporting System

I assert that NIH has a system to capture performance information accurately and that this system was properly applied to generate the performance data presented in the attached report.

Explanations for Not Meeting Performance Targets

I assert that the explanations offered in the attached report for failing to meet a performance target are reasonable and that any recommendations concerning plans and schedules for meeting future targets or for revising or eliminating performance targets are reasonable.

Methodology to Establish Performance Targets

I assert that the methodology used to establish performance targets presented in the attached report is reasonable given past performance and available resources.

Performance Measures Exist for All Significant Drug Control Activities

I assert that adequate performance measures exist for all significant drug control activities.

James. M. Anderson, MD, PhD
Director, DPCPSI

FY 2016 Performance Summary Report for National Drug Control Activities

Decision Unit 1: NIDA

Prevention

Measure SRO-5.15 (started in FY 2014)**:** By 2018, develop, refine, and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations[1].

Table 1: NIDA Annual Targets

FY 2014 Actual	FY 2015 Actual	FY 2016 Target	FY 2016 Actual	FY 2017 Target
NIH-funded research tested multiple interventions to prevent drug use, drug use problems, and drug-related risky behaviors including HIV risk behaviors.	NIH-funded research tested over twenty strategies for improving the dissemination and implementation of evidence-based interventions to prevent drug use, drug use problems, and drug-related risky behaviors including HIV risk behaviors.	Assess the efficacy/ effectiveness of brief interventions to prevent substance use and other risk behaviors in a variety of settings.	41 research articles were published examining the efficacy of a variety of prevention interventions to protect youths from initiation or escalation of substance use and associated negative health outcomes.	Assess the efficacy or effectiveness of at least two indicated/selective interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations.

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

NIH's growing knowledge about substance use and addiction (including tobacco, alcohol, illicit, and nonmedical prescription drug use) is helping to inform the development of prevention strategies that are evidence-based and rooted in a growing understanding of the biological (e.g., genetics, neurobiology), psychosocial (e.g., support systems, stress resilience), and environmental (e.g., socioeconomic, cultural) factors that influence risk for substance use and related disorders. NIH-supported research is building the scientific knowledge base needed to advance our goal of developing effective tailored prevention strategies for youth.

NIH's prevention portfolio encompasses a broad range of research to increase our understanding of factors that enhance or mitigate an individual's propensity to initiate drug use or to escalate from use to substance use disorders across different developmental stages. Information about these contributors to substance use and addiction and the different ways biological, psychosocial, and environmental factors operate across individuals is critical to designing more effective

[1] SRO-5.15 was recently revised in response to https://www.whitehouse.gov/ondcp/changing-the-language-draft. The measure's original wording was "By 2018, develop, refine, and evaluate evidence-based intervention strategies and promote their use to prevent substance use, abuse, addiction and their consequences in underage populations." The revision will be reported to HHS as part of the performance reporting for the upcoming FY 2018 Congressional Justification.

prevention messages. **Measure SRO-5.15 focuses on developing, refining, evaluating, and disseminating evidence-based intervention strategies to prevent substance misuse and substance use disorders and their consequences in underage populations and contributes to the *National Drug Control Strategy Goal of Strengthening Efforts to Prevent Drug Use in Our Communities (Chapter 1)*.**

The efficacy and cost-effectiveness of primary prevention programs—designed to prevent substance use before it starts, or prevent escalation to substance use disorders—including their severest form, addiction—can be enhanced by targeting prevention efforts toward populations with specific vulnerabilities (genetic, psychosocial, or environmental) that affect their likelihood of taking drugs or becoming addicted[i,ii,iii]. For example, prevention programs designed for sensation-seeking youth are effective for these youth, but not for their peers who do not demonstrate a high level of sensation seeking[iv]. High levels of sensation-seeking, and other traits known to be risk factors for substance misuse, may be identified early using genetic markers.

A number of genetic markers have been identified that influence risk for addiction and recent research has shown that genetic risk factors can influence the effectiveness of school-based prevention interventions[v]. In addition, individual differences seen in response to medications for nicotine[vi] and alcohol use disorders[vii] suggest that genetic predictors of treatment response could lead to more efficacious and cost-effective relapse prevention strategies. This information can be harnessed for improving prevention by personalizing interventions for optimal benefit. Such strategies would enable substance use prevention programs to target programs more precisely based on individual or group vulnerability markers, ultimately increasing their impact and cost-effectiveness. Combined with improved educational efforts to increase an individual's awareness of his or her personal risk, this preemptive prevention approach can empower people to make decisions that ultimately prevent substance use from starting or escalating.

The information gained from research on the factors that influence risk and resilience to substance use disorders will lay the foundation for improved and tailored prevention efforts in the future. As personalized risk factors for substance use and addiction vulnerability (or protection) are identified, NIH will encourage researchers to use that information to better understand how biological factors, combined with environmental ones, contribute to substance use disorder vulnerability, thereby enhancing its prevention portfolio. NIH will also encourage the scientific community to use this knowledge to develop and test targeted prevention interventions for populations with differing vulnerabilities to improve our Nation's intervention efforts, similar to the strategy now being used to prevent substance use in high sensation-seeking youth.

(2) Provide narrative that examines the FY 2016 actual performance results with the FY 2016 target, as well as prior year actuals. If the performance target was not achieved for FY 2016, the agency should explain why this is the case. If the agency has concluded it is not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The performance target for SRO-5.15 was met for FY 2016. Prevention of the initiation of drug use and escalation to addiction continues to be one of NIDA's primary strategic goals (see

NIDA's Strategic Plan). NIDA continues to fund a robust prevention portfolio that builds upon solid epidemiological findings and insights from genetics and neuroscience and applies this knowledge to develop effective strategies to prevent initiation of drug use and escalation of use to addiction in underage youth.

From FY 2016 to the present (FY 2017), multiple studies have been funded to develop and test interventions to prevent drug use, drug use problems, and risk behaviors and to improve the implementation of these evidence-based interventions. NIDA is supporting research to test culturally and developmentally appropriate strategies to prevent drug use and addiction across the lifespan: for all developmental stages, from birth through adulthood and older age; for diverse racial/ethnic populations, targeted to various settings such as family, school, community, and health care settings; and for high risk populations, such as LGBT, homeless, child welfare involved, juvenile justice system involved, criminal justice involved, individuals with comorbid conditions, and populations at risk for HIV/AIDS.

In FY 2016, 41 studies examining the efficacy of prevention interventions within adolescent populations were published. One recent study examined the efficacy of the Family Check-Up (FCU) intervention on conduct problems (CPs) and antisocial behavior (AB) in children living in high risk, deprived neighborhoods—characterized by poverty, violence, deviant peers and adults, toxic air, and lack of community resources—that are associated with increased risk for poor health outcomes including substance use disorders[viii]. FCU is an annual, three-session, family-centered intervention that motivates parents to promote positive child adjustment and to participate in parent management training that is adapted for their specific needs. CPs and AB were identified from school-based teacher reports. The study found that for most families eligible for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) that were not seeking help for CP with their children, FCU resulted in significant reductions in CP; however, these results did not extend to children living in the most deprived neighborhoods. It was observed, however, that caregivers and children living in extremely deprived neighborhoods that developed particularly positive relationships during early childhood (toddler years) received fewer reports of CP from teachers. Researchers suggested that one reason why FCU may not have provided more long-term efficacy for families living in extremely deprived neighborhoods could be linked to their inability to access mental health services. These findings demonstrate that there is hope for delivering effective preventive interventions to children and families living in the most vulnerable environments by using innovative methods to reach families isolated by their economic status.

Implementation of effective prevention interventions within community settings is very low due to a variety of factors including community readiness or resistance to change, lack of infrastructure and technical support, as well as, poor fidelity to evidence-based prevention interventions (EBPIs)[ix,x,xi,xii]. A recent study examined the implementation of PROmoting School-community-university Partnerships to Enhance Resilience (PROSPER)—a delivery model designed to support dissemination and sustained implementation of evidence-based practices that prevent substance misuse and promote healthy adolescent development through the creation of partnerships between a land-grant university's Cooperative Extension System (CES) and local community organizations. The PROSPER model has demonstrated multiple positive

impacts on youth and their families which include reduced rates of substance use[xiii] and problem behaviors[xiv], as well as improved family bonding and parenting quality[xv].

This current study compared implementation of PROSPER in two states eight years after the discontinuation of grant funding[xvi] and examined the methods used by 14 community teams in two different states (Iowa and Pennsylvania, seven teams per state) to effectively implement and disseminate EBPIs using the PROSPER model as well as to achieve sustained financial independence for their programs. While successful implementation of EBPIs can be achieved by a variety of methods, this study demonstrated that the sustainability of PROSPER was significantly tied to streamlined fundraising efforts that built long-term partnerships with school districts, social service agencies and other partners, and increasing state-level financial resources over time. A striking difference between the diffusion of EBPIs in Iowa and Pennsylvania can be attributed to the Pennsylvania Commission on Crime and Delinquency (PCCD). The PCCD provides grants and implementation support to promote successful community-based dissemination of EBPIs, and consequently PROSPER teams in Pennsylvania were able to achieve sustained, state-based funding and Pennsylvania communities were able to more successfully implement EBPIs.

In addition, the infrastructure provided by the PCCD altered PROSPER team dynamics: Iowa team leaders were much more focused on securing funding than were Pennsylvania team leaders. Ongoing technical assistance in the form of access to expertise in marketing, communications, grant writing, program evaluation, and dissemination skills was also critical for enabling communities to transition from seed funding to sustained financial independence. Overall this study demonstrates that effective dissemination and implementation of EBPIs can be achieved with high quality if community teams actively plan for it, community and state-level resources are available to support it, and teams receive ongoing technical assistance.

Universal prevention programs, while effective, do not work for everyone. NIDA funded researchers investigated whether particular gene variations associated with nicotine sensitivity influenced the efficacy of universal prevention programs delivered using the PROSPER model to prevent smoking in high school students[xvii]. Nicotine produces its addictive effects by binding to nicotinic acetylcholine receptors in the brain. Individuals with specific genetic variants in the nicotine receptor allele (rs16969968) exhibit a heightened sensitivity to nicotine, and are at increased risk of becoming daily smokers. This study analyzed 424 DNA samples from a subset of adolescents participating in school-delivered and in-home prevention interventions to determine if their genotype influenced their smoking behavior or the efficacy of universal prevention interventions to prevent smoking. Students with the risk allele smoked more than students that lacked this allele, but surprisingly, the universal prevention programs were equally effective at preventing smoking regardless of the presence of the risk allele. These results suggest that the effect of this prevention intervention lies in reducing smoking initiation rather than smoking escalation because those who possess the risk allele would experience enhanced nicotine sensitivity and would be predicted to be more likely to continue smoking.

Collectively these findings demonstrate strategies for effective dissemination and implementation of evidence-based substance use prevention programs and further support key prevention lessons and principles that have emerged from NIDA-funded studies: prevention

interventions implemented in early childhood can have positive effects into young adulthood; universal interventions can protect higher risk, vulnerable youth; and universal substance use prevention interventions are effective in individuals with high-risk genotypes.

(3) The agency should describe the performance target for FY 2017 and how the agency plans to meet this target. If the target in FY 2016 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2017.

The FY 2017 target is to assess the efficacy or effectiveness of at least two indicated/selective interventions to prevent substance use and other risk behaviors in "high risk" youth and young adult populations. Prevention of the initiation of drug use and the escalation to substance use disorders in those who have already initiated use is one of NIDA's primary strategic goals (see NIDA's Strategic Plan). To address this goal NIDA funds a robust prevention portfolio to identify the characteristics and patterns of drug use; understand how biology, environment, behavior, and development influence the risk and protective factors for drug use; and to apply this knowledge towards the development and dissemination of more effective strategies to identify populations at "high risk" and prevent them from initiating drug use and from progressing to substance use disorders if they do. NIDA's Division of Epidemiology, Services, and Prevention Research also makes a significant investment in implementation science research to better understand the factors that influence successful dissemination and implementation of tested, effective interventions in real world settings. This implementation science research will be used to achieve this target.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness and Unbiased Presentation

The research field is guided by standard scientific methodologies, policies, and protocols. Any variation from these proven methodologies generates criticism that negates findings. The scientific process also has several benchmarks within it to ensure scientific integrity. For instance, research designs, such as qualitative, quantitative, and mixed methods, have each been tested, with evidence-based strategies established to guide the implementation of all scientific research studies. In these processes, data collection, security, management, and structures are clearly defined to ensure optimum analyses.

Data analyses are guided by statistical methodologies, a mathematical science used to test assumptions. In addition, NIH has incorporated standardized policies and procedures for making funding announcements, assessing meritorious science, monitoring progress of grantees and scientists in achieving the expected outcomes, and assessing performance at the project's conclusion. Researchers are also expected to publish findings in peer-reviewed journals, which offer another layer of assessment and validation of the findings. In addition, all studies involving human subjects must receive Institutional Review Board (IRB) clearance, yet another form of assessment that ensures the relevance of the study and the safety of the subjects. NIH's research

activities implement and practice all scientifically relevant procedures to ensure data quality and to substantiate findings.

In implementing scientific research, NIH uses established tools to develop and oversee programs and improve their performance, proactively monitoring grants, contracts, and cooperative agreements and assessing their performance. The following briefly describes the NIH scientific process, which has been assessed by outside entities and is regarded as premier.

Assessment to fund meritorious science (peer review). NIH uses state-of-the-art assessment to determine scientific merit and make funding decisions based on the best science. In general, project plans presented in competing grant applications and contract proposals are subject to three levels of review focused on the strength and innovation of the proposed research, the qualifications of the investigator(s), and the adequacy of the applicant's resources:

- The first level of review, called peer review, ensures that the most meritorious science, as determined by the scientific field's experts, is identified for funding. NIH has over 11,000 external experts participating in peer review panels, each of whom is nationally recognized for his or her area of expertise. The applications are systematically reviewed and scored to inform funding decisions. NIH is one of the few Federal agencies with a legislative requirement for peer review.
- The second level of review is by the Institute's National Advisory Council, which is comprised of eminent scientists along with members of the general public. The Council serves as a useful resource to keep each Institute abreast of emerging research needs and opportunities, and to advise the Institute on the overall merit and priority of grant applications in advancing the research. All members of Council are appointed by the HHS Secretary.
- The third level of review is by the Institute Director, with input from Institute staff who have relevant expertise. The Director makes the final decision on whether an application will receive funding.

These layers of expert review assessing scientific methodologies and relevance to the field enable funding of the most promising research to advance the field. Consequently, funding decisions made at the agency level are conducted in a consistent, merit-based fashion, guided by scientific methodologies and relevance.

Performance monitoring of grants and contracts. Once an award is made, additional NIH policies and guidelines are implemented to ensure oversight of the proposed project aims and program goals. The NIH Grants Policy Statement (https://grants.nih.gov/policy/nihgps/index.htm) provides the standardized protocols for monitoring performance-based grants and contracts. Although there are many procedures, a few significant items include the timely submission of progress and final reports. These are assessed by NIH project officers and grants management staff to determine adherence to the approved scientific research plan and to appropriate cost principles and legislative compliance. Project officers may work closely with principal investigators to facilitate adherence, address barriers, and ensure quality programmatic achievements.

As a standard performance-based practice, the approved scientific aims and objectives formulate the terms and conditions of each grant award and become the focus of scientific monitoring. The NIH Grants Policy Statement, referenced as a term of every award, states the specific administrative requirements for project monitoring and enforcement actions when a grantee fails to comply with the terms and conditions of the award. NIH staff monitor scientific progress against the approved aims and scope of the project, as well as administrative and fiscal compliance through review of periodic progress reports, publications, correspondence, conference calls, site visits, expenditure data, audit reports (both annual institutional financial reports and project-specific reports), and conference proceedings. When a grantee fails to comply with the terms and conditions of an award, enforcement actions are applied. These may include modification to the terms of award, suspension, withholding support, and termination.

A further checkpoint for programmatic assessment occurs when the applicant requests renewal support of continuation research. A peer review group again assesses the merits of future research plans in light of the progress made during the previous project period, and any problems in grantee performance are addressed and resolved prior to further funding. This process further demonstrates use of assessments to improve performance.

Review of manuscripts. Ultimately, the outcomes of any scientific research are judged based on published results in a peer-reviewed journal. The peer-review publication process is another point in which the quality and innovation of the science undergoes a rigorous evaluation. For most scientific journals, submitted manuscripts are assigned to a staff editor with knowledge of the field discussed in the manuscript. The editor or an editorial board will determine whether the manuscript is of sufficient quality to disseminate for external review and whether it would be of interest to their readership. Research papers that are selected for in-depth review are evaluated by at least two outside referees with knowledge in the relevant field. Papers generally cannot be resubmitted over a disagreement on novelty, interest, or relative merit. If a paper is rejected on the basis of serious reviewer error, the journal may consider a resubmission.

Additional controls specific for genetics projects. For all genetics projects (i.e., both contracts and grants), a three-tier system ensures data accuracy. This system is based on sound, proven scientific methodology internally governed by the larger scientific research community (as described above). First, gene expression levels are validated using highly quantitative methods to measure ribonucleic acid (RNA) levels. Second, each study builds in a replication design using subsets of the study population or, sometimes, different study populations. Third, the information gleaned from these studies is compared against previously collected data or, if not available, replicated and validated in models suited to evaluate the implications of the genetic findings.

Every effort is made to acquire complete data sets; however, several factors conspire against doing so. These factors are either intrinsic to the type of data being collected (inability to collect from all drug users, all ethnic minorities, every developmental stage, every comorbid association, etc.) or linked to the incompleteness of genetic information databases (considerable gaps in SNP collections, many genes yet unidentified or without known function, etc.). Some level of data incompleteness mires all human genomic programs in which population sampling, limited by cost considerations, must be used. These obstacles, however, do not necessarily jeopardize data

quality, since many powerful post-hoc standard protocols are available and being deployed to clean the data sets and ensure accuracy and replicability.

Methodology Used to Establish Targets/Actuals

The targets are established based on the state of the science in a particular field and knowledge of the scientific process by which advances are made. NIDA supports a robust portfolio on implementation science research to better understand the factors that influence successful dissemination and implementation of tested and efficacious interventions in real world settings. The targets are established based on where the field stands in this process and on the next logical scientific step for moving the field forward

Data Sources

As described above, each grantee provides an annual progress report that outlines past-year project accomplishments, including information on patients recruited, providers trained, patents filed, manuscripts published, and other supporting documentation, depending on the goals of the study. This information allows NIH to evaluate progress achieved or to make course corrections as needed.

Treatment

Measure SRO-7.3: By 2020, develop and/or evaluate two treatment interventions using health information technology (HIT) to improve patient identification, treatment delivery and adherence for substance use disorders and related health consequences[2]. (Note: This measure, which started in FY 2014, is replacing SRO-8.7, for which NIDA's contribution ended in FY 2015.)

Table 2: NIDA Annual Targets

FY 2014 Actual	FY 2015 Actual	FY 2016 Target	FY 2016 Actual	FY 2017 Target
Research tested feasibility and efficacy of technology-based treatments, and measurement of real-time contextual feedback, and mobile-technology-based interactions in drug addiction; development of other approaches in the use of mobile technology continues.	Studies examined the efficacy of mobile technology-based treatments to enhance treatment for patients with mental illness, and for interactive treatment of patients with drug addiction; and the feasibility of improving HIV antiretroviral treatment adherence with cell phone reminders, counseling, and two-way personalized text messaging.	Identify next steps for testing or deployment of 2-4 substance abuse treatment or medication adherence interventions using mobile technology.	Five interventions utilizing HIT, including mobile health technology, addressing five research priority areas were developed. All interventions were found to be feasible and will undergo additional revision and efficacy testing in preparation for broad dissemination and implementation.	Continue to test and/or deploy technology-enabled strategies to improve substance use disorder treatment or medication adherence interventions; implement substance use disorder treatment or medication adherence interventions using mobile technology at 1-2 service delivery settings.

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

Addiction is a complex but treatable disorder that affects brain function and behavior. Unfortunately, we have a significant and ongoing treatment gap in our Nation. Among those who need treatment for a substance use disorder (SUD), few receive it. In 2015, 21.7 million Americans needed treatment for a SUD, but less than 11% received specialty treatment[xviii]. Further, many treatment programs do not deliver current evidence-based practices—for example, less than fifty percent provide access to medication assisted treatment for opioid use disorders[xix], and they typically do not coordinate care with the patient's general health care providers. In addition, patients receiving treatment for SUD or related health conditions—such as HIV or mental health disorders—often do not fully adhere to the treatment plan recommended by their doctor. NIDA is committed to supporting health services and implementation research to develop and test technologies that aim to reduce these gaps.

[2] SRO-7.3 was revised in the spring of 2016. The measure's original wording was "By 2016, develop and/or evaluate one to four interventions using mobile technology to improve treatment delivery and adherence for addiction and related health consequences." The revision was provided to HHS as part of performance reporting for the Current Services Budget Justification in the summer of 2016.

An unacceptable gap also separates scientific discoveries from their implementation into community health care settings. A scientific approach must be brought to bear on effectively testing and disseminating research-based treatments and understanding how health service systems and settings influence treatment implementation. Ultimately, NIH strives to make research-based treatments user friendly, cost effective, and available to a broad range of practitioners and their patients. Health information technology (HIT) tools, including mobile technologies, represent one promising mechanism to achieve this goal.

The last few years have seen tremendous advances in the development and implementation of HIT tools that have great promise for improving the efficiency and quality of health care delivery for substance use disorders – ranging from electronic health records, telehealth, wearable sensors, and mobile health technologies[xx]. These advances are revolutionizing health services research and presenting new opportunities to deliver innovative treatment and recovery interventions. HIT has the power to drive new treatment delivery models by supporting more effective integration of care, extending the reach of the SUD treatment workforce, enabling real-time patient monitoring and support, and engaging patients who are hesitant to participate in traditional behavioral health treatment systems. NIH-supported research is exploring how technology can best be leveraged to increase access to and quality of care to improve patient outcomes.

SRO-7.3 is focused on developing and testing treatment interventions using HIT tools to improve patient identification, treatment delivery, or adherence to treatment for substance use disorders and related health problems. This goal contributes to NIDA's long-term strategy for improving drug use disorder treatment nationwide, thereby contributing to the ***National Drug Control Strategy's Goals of: Seeking Early Intervention Opportunities in Health Care (Chapter 2)*** by supporting screening for substance use and substance use disorders in healthcare settings using mobile technologies***; and Increasing Access to Treatment and Supporting Long Term Recovery (Chapter 3)*** *by supporting innovative research to develop and test mobile technologies to support the delivery of treatment and recovery services.*

NIH's health services research portfolio encompasses a broad array of studies exploring the use of HIT tools to deliver evidence-based treatments, support coordination of care, improve the organization and delivery of treatment services, educate patients to prevent common comorbidities such as HIV or Hepatitis C, improve adherence to treatment for both substance use disorders and comorbid health conditions, increase treatment engagement, and provide recovery support. Research in this area will lay the foundation for leveraging technology to improve health outcomes related to substance use and substance use disorders. As these technologies advance, NIH will continue to encourage innovative research to determine how they can best be applied to address gaps in access to and quality of care as well as treatment engagement to improve public health.

(2) Provide narrative that examines the FY 2016 actual performance results with the FY 2016 target, as well as prior year actuals. If the performance target was not achieved for FY 2016, the agency should explain why this is the case. If the agency has concluded it is

not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The FY 2016 target was met. NIDA funds a broad portfolio of research on the potential of HIT tools to improve health care delivery and health outcomes related to SUDs as described in over 12 publications released in fiscal year 2016. Research findings leveraging HIT to address five NIDA research priority areas are reported below:

Improving medication adherence using mHealth technologies – A recent NIDA-funded study examined the efficacy of a bidirectional text messaging intervention (TEXT) to improve antiretroviral therapy (ART) adherence, improve attendance at health care visits, and reduce substance use among people living with HIV[xxi]. Text messaging is an ideal platform to collect and deliver real time health information because it can reach patients living in remote areas even when cellular service is weak. The automated TEXT intervention can send daily queries to patients checking on medication dosing, mood, and substance use, and is able to generate appropriate intervention messages based on patient responses. The pilot randomized clinical trial demonstrated that TEXT improved ART adherence and reduced missed HIV care visits; however, TEXT did not significantly improve substance use behaviors as compared to individuals receiving treatment as usual. Study authors are now considering utilizing mobile applications instead of text messages to provide enhanced privacy.

Integration of SUD treatment within broader health care management using health IT – Individuals with SUDs have high rates of medical and psychiatric comorbidities and exhibit poor uptake of health services, resulting in poor treatment compliance. Integration of SUD treatment within general health care not only improves overall health outcomes, including SUD outcomes, but also lowers overall health care costs. The NIDA-supported LINKAGE Clinical Trial examined the feasibility and efficacy of a linkage intervention that utilizes patient portals to facilitate SUD patients' engagement with specialized health care providers to treat comorbid health conditions[xxii]. The LINKAGE intervention educates patients receiving SUD treatment how to proactively engage in their own health care management by using patient portals, accessing online treatment programs (e.g. coping with pain), obtaining medical information, and scheduling appointments. Although there were no significant differences at six months regarding SUD and depression outcomes between patients receiving the LINKAGE intervention compared to those receiving treatment as usual, it is expected that the LINKAGE intervention will demonstrate superior health benefits at later time points allowing patients more time to fully benefit from the intervention.

Preventing substance use using health IT – RealTeen is a gender-specific, web-based substance use prevention intervention tailored to meet the specific concerns of 13-14 year old adolescent girls to delay onset and reduce overall rates of substance use[xxiii]. The intervention consists of nine sessions that address body image, decision making, peer pressure, drug knowledge, communication, and assertiveness. The intervention has undergone an initial evaluation and is currently being revised to include hypothetical scenarios to allow users to practice skills acquisition in addition to improving enhanced content delivery for the web. Once complete, the intervention will be tested for acceptability with the target audience, feasibility, and efficacy for SUD prevention in adolescent girls.

Utilizing mHealth to improve smoking cessation interventions – My Mobile Advice Program (MyMAP) is a mobile optimized website accessed via smartphone, but designed to be accessible on a variety of mobile platforms to improve medication adherence and provide tailored advice to manage symptoms to help users quit smoking[xxiv]. An initial pilot study determined that MyMAP is a feasible, acceptable, and potentially effective means to support varenicline use to quit smoking. Future studies are planned to determine the efficacy of this intervention for smoking cessation.

Improving health outcomes in people living with HIV using mHealth – African-American adolescent girls are disproportionately at risk for HIV infection. While HIV prevention interventions exist, dissemination and effective implementation remain limited and are often inaccessible to this high risk population. SiHLE*Web* is an internet version of the evidence-based, culturally informed HIV prevention program traditionally delivered to female African-American adolescents in an in-person group format that has been adapted for the web to overcome accessibility barriers. A recent pilot study determined that SiHLE*Web* improved knowledge, was easy to use, and generally attractive; however, users reported some difficulties with website navigation[xxv]. Further work is underway to improve this prevention intervention and determine the efficacy in preventing HIV infection within this vulnerable population.

(3) The agency should describe the performance target for FY 2017 and how the agency plans to meet this target. If the target in FY 2016 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2017.

The FY 2017 target is to "continue to test and/or deploy technology-enabled strategies to improve substance use disorder treatment or medication adherence interventions; implement substance use disorder treatment or medication adherence interventions using mobile technology at 1-2 service delivery settings". HIT is a rapidly advancing field that is poised to significantly improve the efficiency and efficacy of healthcare delivery. Based on the research on SRO-7.3, along with other advances in HIT, NIDA recognizes the potential of an array of technologies to transform patient care through the secure sharing and use of health information. SRO-7.3 will assess NIDA's effort to develop and evaluate treatment interventions using HIT (e.g., mobile health tools, web applications, telehealth, and electronic health records) to improve patient identification, treatment delivery, or adherence for substance use disorders and related health consequences.

To address this target, NIDA funds a significant research portfolio to examine the feasibility and efficacy of technology-based treatments for patients with SUDs. Currently, ongoing studies include the development of text messaging interventions to improve smoking cessation in pregnant women; mHealth interventions to improve access and adherence to HIV and HCV treatment; health IT to improve care coordination, diagnosis and treatment of SUD and HIV; and development of a cloud-based patient information exchange framework for health care providers to improve accessibility of coordination of general and behavioral health care services and improve service quality. NIDA's ongoing efforts related to HIT will be used to achieve the FY 2017 target.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness, and Unbiased Presentation

As described above, the research field (including health services research) is guided by standard scientific methodologies, policies, and protocols to ensure the validity of its research results. NIH uses these established tools for program development; for actively monitoring grants, contracts, and cooperative agreements; and for assessing performance of grants and contracts in order to oversee the program and improve performance. These tools have been described in response to question 4 above.

For the SRO-7.3 FY 2016 target, NIDA relied on annual progress reports provided by each grantee that outline past-year project accomplishments, including information on patients recruited, providers trained, patents filed, manuscripts published, and other supporting documentation. This information allows NIH to evaluate progress achieved and to make course corrections as needed.

Decision Unit 2: NIAAA

Prevention

Measure SRO-5.15: By 2018, develop, refine and evaluate evidence-based intervention strategies and promote their use to prevent substance misuse and substance use disorders and their consequences in underage populations.

Table 1: NIAAA Annual Targets

FY 2014 Actual	FY 2015 Actual	FY 2016 Target	FY 2016 Actual	FY 2017 Target
NIAAA developed the College Alcohol Intervention Matrix (*CollegeAIM*), a decision tool to help colleges and universities select appropriate strategies to meet their alcohol intervention goals. *College-AIM* is being finalized and will be released in 2015.	NIAAA supported six studies to evaluate the effectiveness of the youth guide for alcohol screening and brief intervention in a variety of settings.	Disseminate the newly released College Alcohol Intervention Matrix (*CollegeAIM*) and continue to disseminate the youth screening guide.	NIAAA promoted and disseminated the College Alcohol Intervention Matrix (*CollegeAIM*), and disseminated the youth screening guide through print and electronic media.	Continue to promote the College Alcohol Intervention Matrix (*CollegeAIM*).

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

Adolescence is the stage of life during which most people begin drinking, and it is also a time of considerable social, psychological, and physiological change. The brain, particularly the frontal cortex, continues to develop throughout adolescence and does not fully mature until early adulthood. Adolescents are particularly vulnerable to the adverse consequences of alcohol misuse. Adolescent alcohol exposure can affect normal brain development, compromise short- and long-term cognitive functioning, and increase the likelihood of developing alcohol-related problems during adolescence and later in life. Adolescent alcohol misuse also increases the risk for other adverse outcomes such as blackouts, physical and sexual assault, risky sexual behavior, alcohol overdose, injuries, and death. Given the pervasive use of alcohol among young people, the potential impact on their developmental trajectories, and the increased risk for alcohol use disorder (AUD) and other harmful consequences, effective strategies are needed to prevent the initiation and escalation of youth alcohol use and the associated adverse outcomes.

SRO-5.15 is focused on developing, evaluating, and promoting evidence-based intervention strategies to prevent substance misuse and substance use disorders and their consequences in underage populations, thereby contributing to the ***National Drug Control Strategy Goal of Strengthening Efforts to Prevent Drug Use in Our Communities (Chapter 1)***. NIAAA supports research on preventing and reducing alcohol misuse, including underage alcohol use, as well as preventing and treating AUD and other alcohol-related problems with a focus on risk

assessment and screening, universal and selective prevention, early intervention (before problems escalate and/or become chronic), and timely treatment as appropriate. NIAAA will pursue a range of interventions designed to act at multiple levels (e.g., individual, school/college, family, and community) in support of this goal.

(2) Provide narrative that examines the FY 2016 actual performance results with the FY 2016 target, as well as prior year actuals. If the performance target was not achieved for FY 2016, the agency should explain why this is the case. If the agency has concluded it is not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The target for FY 2016 was met. In September 2015, NIAAA released the College Alcohol Intervention Matrix (*CollegeAIM*) guide and website, important new resources to help colleges address harmful and underage student drinking. Developed with input from researchers and college staff, *CollegeAIM* is an easy-to-use and comprehensive tool to help colleges and universities identify evidence-based alcohol interventions. *CollegeAIM* rates nearly 60 alcohol interventions in terms of effectiveness, costs, and other factors, and presents the information in a user-friendly and accessible way. With this tool, school officials can use research-based information to choose wisely among the many potential interventions to address student drinking.

With the release of *CollegeAIM*, NIAAA embarked on a multifaceted promotion and dissemination effort throughout FY 2016. To introduce *CollegeAIM* to college and university officials, NIAAA senior staff and selected researchers from the *CollegeAIM* development team made numerous presentations, including at meetings of: the National Prevention Network; the Student Affairs Administrators in Higher Education, the American College Health Association; Community Anti-Drug Coalitions of America; Higher Education Center for Alcohol and Drug Misuse, Prevention, and Recovery; and the Campus Safety National Forum. NIAAA also collaborated with the NIAAA College Presidents Working Group to Address Harmful and Underage Drinking to organize two regional workshops which introduced *CollegeAIM* to college staff and offered step by step instructions on using the guide and website. In FY 2016, the *CollegeAIM* website received 32,137 visitors, 10,711 print copies of the *CollegeAIM* booklet were distributed, and the booklet was downloaded 4,027 times.

In FY 2016, NIAAA continued to promote and disseminate the youth alcohol screening guide, *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide.* The guide is designed to help primary care providers identify 9 to 18-year-olds who are at risk for alcohol use, are using alcohol, or have AUD, and to help providers intervene as appropriate. It introduces a two-question screening tool and an innovative youth alcohol risk estimator to help clinicians overcome time constraints and other common barriers to alcohol screening and brief interventions. This tool was developed for use in primary care settings; however, it may also be useful, and is being evaluated, in other settings. If adopted in those settings, youth access to alcohol prevention and intervention services could be expanded. NIAAA distributed 8,829 print copies of the youth screening guide in FY 2016. The guide continues to be accessible online at the NIAAA website.

(3) The agency should describe the performance target for FY 2017 and how the agency plans to meet this target. If the target in FY 2016 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2017.

The FY 2017 target is to continue to promote *College AIM*. NIAAA is planning additional regional workshops, webinars, and meeting presentations for college and university officials and other relevant audiences during FY 2017.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness and Unbiased Presentation

Data analyses are guided by statistical methodologies, a mathematical science used to test assumptions. In addition, NIH has incorporated standardized policies and procedures for making funding announcements, identifying meritorious science, monitoring progress of grantees and scientists in achieving the expected outcomes, and assessing performance at the project's conclusion. Researchers are also expected to publish findings in peer-reviewed journals, which offer another layer of assessment and validation of the findings. In addition, all studies involving human subjects must receive Institutional Review Board (IRB) clearance, yet another form of assessment that ensures the relevance of the study and the safety of the subjects. NIH's research activities implement and practice all scientifically relevant procedures to ensure data quality and to substantiate findings.

In implementing scientific research, NIH uses established tools to develop and oversee programs and improve their performance, proactively monitoring grants, contracts, and cooperative agreements and assessing their individual performance. The following briefly describes the NIH scientific process, which has been assessed by outside entities and is regarded as premier.

Assessment to fund meritorious science (peer review). NIH uses state-of-the-art assessment to determine scientific merit and make funding decisions based on the best science. In general, project plans presented in competing grant applications and contract proposals are subject to three levels of review focused on the strength and innovation of the proposed research, the qualifications of the investigator(s), and the adequacy of the applicant's resources:

- The first level of review, called peer review, ensures that the most meritorious science, as determined by the scientific field's experts, is identified for funding. The NIH has over 11,000 external experts participating in peer review panels, each of whom is nationally recognized for his or her area of expertise. The applications are systematically reviewed and scored to inform funding decisions. The NIH is one of the few Federal agencies with a legislative requirement for peer review.
- The second level of review is by the Institute's National Advisory Council, which comprises eminent scientists along with members of the general public. The Council serves as a useful resource to keep each Institute abreast of emerging research needs and

opportunities, and to advise the Institute on the overall merit and priority of grant applications in advancing the research. All members of Council are appointed by the HHS Secretary.

- The third level of review is by the Institute Director, with input from Institute staff who have relevant expertise. The Director makes the final decision on whether an application will receive funding.

These layers of expert review assessing scientific methodologies and relevance to the field enable funding of the most promising research to advance the field. Consequently, funding decisions made at the agency level are conducted in a consistent, merit-based fashion, guided by scientific methodologies and relevance.

Performance monitoring of grants and contracts. Once an award is made, additional NIH policies and guidelines are implemented to ensure oversight of the proposed project aims and program goals. The NIH Grants Policy Statement (https://grants.nih.gov/policy/nihgps/index.htm) provides the standardized protocols for monitoring performance-based grants and contracts. Although there are many procedures, a few significant items include the timely submission of progress and final reports. These are assessed by NIH program officials and grants management staff to determine adherence to the approved scientific research plan, appropriate cost principles, and legislative requirements. Program officials may work closely with principal investigators to facilitate adherence, address barriers, and ensure quality programmatic progress.

As a standard performance-based practice, the approved scientific aims and objectives formulate the terms and conditions of each grant award and become the focus of scientific monitoring. The NIH Grants Policy Statement, referenced as a term of every award, states the specific administrative requirements for project monitoring and enforcement actions when a grantee fails to comply with the terms and conditions of the award. NIH staff monitor scientific progress against the approved aims and scope of the project, as well as administrative and fiscal compliance through review of periodic progress reports, publications, correspondence, conference calls, site visits, expenditure data, audit reports (both annual institutional financial reports and project specific reports), and conference proceedings. When a grantee fails to comply with the terms and conditions of an award, enforcement actions are applied. These may include modification to the terms of award, suspension, withholding of support, and termination.

A further checkpoint for programmatic assessment occurs when the applicant requests renewal support to continue a project. A peer review group again assesses the merits of future research plans in light of the progress made during the previous project period, and any problems in grantee performance are addressed and resolved prior to further funding. This process further demonstrates use of assessments to improve performance.

Review of manuscripts. Ultimately, the outcomes of any scientific research are judged based on published results in a peer-reviewed journal. The peer-review publication process is another point in which the quality and innovation of the science undergoes a rigorous evaluation. For most scientific journals, submitted manuscripts are assigned to a staff editor with knowledge of the field discussed in the manuscript. The editor or an editorial board will determine whether the

manuscript is of sufficient quality to disseminate for external review and whether it would be of interest to their readership. Research papers that are selected for in-depth review are evaluated by at least two outside referees with knowledge in the relevant field.

Methodology Used to Establish Targets/Actuals

The targets are established based on the state of the science in a particular field and knowledge of the scientific process by which research advances are made. As a result, a target may represent the next logical step for advancing a particular scientific field or initiative, or fulfilling a public health or research need. For example, to promote the use of evidence-based intervention strategies for harmful and underage college student drinking, NIAAA engaged a team of premier researchers with expertise in college drinking interventions to assess the state of the science on the effectiveness, cost, and barriers to implementation of existing interventions. This process informed the development of *CollegeAIM*, a decision tool designed to help college and university administrators more easily navigate and select alcohol interventions for their campuses. An additional group of prominent college drinking researchers served as peer reviewers for the data analysis underlying the decision tool.

Data Sources

Progress reports that outline project accomplishments allow NIH to evaluate progress achieved and/or to make course corrections as needed.

Treatment

Measure SRO-8.7: By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health systems.

Table 2: NIAAA Annual Targets

FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Actual	FY 2016 Target	FY 2016 Actual	FY 2017 Target
NIAAA developed strategies for dissemination of the underage drinking screening guide and began dissemination for use in primary care settings.	NIAAA supported two additional studies to evaluate its youth alcohol screening guide and developed continuing medical education (CME) training through Medscape for physicians, nurses and physicians' assistants.	NIAAA continued to support research to evaluate the underage drinking screening guide in emergency department, juvenile justice, school, and primary care settings, and for youth with chronic conditions.	NIAAA promoted alcohol screening and brief intervention in primary care by offering online continuing medical education (CME) on the underage guide to primary care providers, and by collaborating with federal and non-federal stakeholders to facilitate integration of prevention and early intervention of alcohol misuse in primary care training and practice.	Continue to encourage alcohol screening for all youth, and referral to treatment for those who need it, by disseminating the youth screening guide. Continue to support online training on the use of the guide that allows healthcare providers to earn continuing medical education credits.	NIAAA encouraged youth alcohol screening and referral to treatment by supporting and promoting continuing medical education training on the use of the guide, organizing or participating in symposia addressing youth alcohol screening, and supporting studies to evaluate the youth screening guide in various settings and populations.	Continue to support studies evaluating screening and brief alcohol interventions in underage or young adult populations

(1) Describe the measure. In doing so, provide an explanation of how the measure (1) reflects the purpose of the program, (2) contributes to the *National Drug Control Strategy*, and (3) is used by management of the program. This description should include sufficient detail to permit non-experts to understand what is being measured and why it is relevant to the agency's drug control activities.

NIAAA has a strong focus on preventing and reducing underage drinking, recognizing the pervasive use of alcohol among young people and the association between early initiation of alcohol use and future alcohol problems. A major focus is to integrate screening and brief intervention for youth into healthcare practice. Research shows that while many youth are willing to discuss alcohol use with their doctors when assured of confidentiality, too few clinicians follow professional guidelines to screen their young patients. Clinicians often cite insufficient time, unfamiliarity with screening tools, the need to triage competing problems, and uncertainty about how to manage a positive screen, as barriers to alcohol screening. They, therefore, miss the opportunity to express concern about early alcohol use, allow their young

patients to ask questions about alcohol use, and intervene before or after drinking starts or problems develop. NIAAA's *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide,* was devised to help health care providers identify alcohol use and alcohol use disorder (AUD) in children and adolescents, as well as identify risk for alcohol use, especially in younger children. It includes a brief two-question screener and support materials about brief intervention and referral to treatment that are designed to help surmount common obstacles to youth alcohol screening in primary care. This tool was developed for use in the primary care setting, and NIAAA is supporting research to evaluate its use in primary care and other settings. Recognizing the importance of training health care providers in identifying, preventing and addressing youth alcohol misuse and the associated consequences, NIAAA partnered with Medscape to develop an online training course based on the guide to familiarize clinicians with the screening and brief intervention process and increase their skill and comfort level with it.

SRO-8.7 is focused on identifying the key factors influencing the scaling up of research-tested interventions across large networks of services systems such as primary care, specialty care and community practice. SRO-8.7 represents NIAAA's long-term strategy for improving AUD treatment nationwide, thereby contributing to the ***National Drug Control Strategy's Goal of: Seek Early Intervention Opportunities in Health Care (Chapter 2)*** **by** ***Evaluating Screening for Substance Use in Healthcare Settings*** **and** ***Enhancing Healthcare Providers' Skills in Screening and Brief Intervention.***

(2) Provide narrative that examines the FY 2016 actual performance results with the FY 2016 target, as well as prior year actuals. If the performance target was not achieved for FY 2016, the agency should explain why this is the case. If the agency has concluded it is not possible to achieve the established target with available resources, the agency should include recommendations on revising or eliminating the target.

The target for FY 2016 was met. NIAAA continued to encourage alcohol screening for all youth and referral to treatment for those who need it. In FY 2016, NIAAA disseminated the *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide* in print and electronic media formats to help health care and other professionals identify alcohol use in children and adolescents. NIAAA also continued to offer its Continuing Medical Education (CME) course based on the guide and partnered with the National Association of Pediatric Nurse Practitioners, the Centers for Disease Control and Prevention's Learning Connection, and the Interagency Coordinating Committee for the Prevention of Underage Drinking to promote training on use of the guide. Over three thousand CME certificates were awarded to healthcare providers for completing the CME course in FY 2016, and over 37,700 certificates have been awarded since the course's inception. NIAAA has also continued to raise awareness about the importance of youth alcohol screening by organizing and/or chairing symposia at national conferences, including the American Society of Addiction Medicine Annual Conference, the Society for Prevention Research Annual Meeting, and the American Psychological Association Annual Meeting.

NIAAA is currently supporting studies to evaluate the youth screening guide in primary care settings, emergency departments, a juvenile justice setting, a school setting, and with youth who

have a chronic health condition. In one recent study, investigators compared the use of NIAAA's two-question youth screening tool with a standard 53-question instrument for assessing alcohol use and substance use disorders—the Diagnostic Interview Schedule for Children (DISC)—with children aged 9-18 who were being treated for Type 1 diabetes, asthma, cystic fibrosis, inflammatory bowel disease, or juvenile idiopathic arthritis at a large children's hospital. They found that NIAAA's youth alcohol screening tool is highly efficient for detecting alcohol use and AUD among these populations.

A second study used a computer-administered assessment to examine alcohol involvement, including patterns of alcohol consumption and presence of AUD in a large sample of adolescents seen in rural primary care settings. The study found that 10 percent of these youth over age 14 years have past-year AUD. When they examined various alcohol use patterns in this population as a screen for AUD, the researchers found that a single question on past year drinking frequency as recommended in NIAAA's *Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide*, performed very well in identifying youth at moderate risk for AUD and those at the highest risk. These and other studies demonstrating the utility of the youth screening guide are expected to encourage further adoption of youth alcohol screening in healthcare and other appropriate settings.

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(3) The agency should describe the performance target for FY 2017 and how the agency plans to meet this target. If the target in FY 2016 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2017.

The FY 2017 target is continue to support studies evaluating screening and brief alcohol interventions in underage or young adult populations. NIAAA will continue to support ongoing studies to evaluate its youth alcohol screening guide as a predictor of alcohol risk, alcohol use, and AUD, and as an initial screen for other behavioral health problems in youth ages 9-18 in various settings. In addition, in FY 2015 NIAAA issued a funding opportunity announcement (FOA) to encourage research on screening and brief interventions to prevent and/or reduce alcohol use and alcohol-related harms among underage and young adult populations. No awards have yet been made under this FOA, but a number of applications are under consideration for funding in FY 2017.

(4) The agency should describe the procedures used to ensure performance data for this measure are accurate, complete, and unbiased in presentation and substance. The agency should also describe the methodology used to establish targets and actuals, as well as the data source(s) used to collect information.

Data Accuracy, Completeness, and Unbiased Presentation

As described above, the research field (including health services research) is guided by standard scientific methodologies, policies, and protocols to ensure the validity of its research results. NIH uses established tools for program development; for actively monitoring grants, contracts, and cooperative agreements; and for assessing performance of grants and contracts in order to oversee the program and improve performance. These tools have been described in response to question 4 above.

Methodology Used to Establish Targets/Actuals

The targets have been established based on the existing protocols. As discussed above, these protocols undergo a rigorous review process to determine which research areas hold the most promise for filling gaps and should therefore be prioritized for testing. The target values are based on sound methodological procedures and related timelines set for each protocol. While these methodologies cannot precisely predict the course of a study, the likely path of implementation and timing is based on knowledge gained from earlier research and will be used to generate the targets for this measure.

Data Sources

Progress reports that outline project accomplishments allow NIH to evaluate progress achieved and/or to make course corrections as needed.

Endnotes Related to Decision Unit 1: NIDA

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