DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

January 15, 2015

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 2014 Detailed Accounting Submissions and Performance Summary Report for National Drug Control Activities and Accompanying Required Assertions (A-03-15-00352)

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 2014 Actual Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2014, submitted by NIH's National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA), respectively, and

- Performance Summary Report for National Drug Control Activities and management's assertions for the fiscal year ended September 30, 2014, 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 2014 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 Kay L. Daly, Assistant Inspector General for Audit Services, at (202) 619-1157 or through email at Kay.Daly@oig.hhs.gov. Please refer to report number A-03-15-00352 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
Chief Financial Officer
National Institute on Drug Abuse
Donna M Jones 10/30/14

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 2014 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 more than 85% 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 2014 total of NIDA's budget from the FY 2015 Congressional Justification was $1,015,754,000. There was a comparable transfer in the amount of $1,411,000. There was an Secretary's Transfer in the amount of $2,574,000. Finally, NIH returned $3,370,161 to NIDA for the National Children's Study which brought NIDA's appropriation to $1,017,961,161. NIDA obligated $1,017,956,722 and $4,439 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 2014 are for the same reasons described above for the FY 2014 column of the FY 2015 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. As described above, NIDA had the following adjustments to its appropriation for FY 2014: (1) Secretary's Transfer of $2,574,000 (2) Return of National Children's Study funds of $3,370,161.

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.

NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE ON DRUG ABUSE
FY 2014 Actual Obligations
(Dollars in Thousands)

I. RESOURCE SUMMARY

	FY 2014 Actual
Drug Resources by Decision Unit:	
National Institute on Drug Abuse	1,017,957
Total	1,017,957
Drug Resources by Function:	
Research and Development Prevention	337,438
Research and Development Treatment	680,519
Total	1,017,957

Differences Between (1) Actual Obligations and (2) the FY 14 Column of the FY 15 CJ and the National Drug Control Strategy Budget Summary
(Dollars in Thousands)

Total 2014 Col. of the FY 2015 CJ; National Drug Control Strategy	1,015,754
Comparable Transfers	1,411
NCS Transfer	3,370
Secretary Transfer	-2,574
Lapse of Funds	-4
Total Obligations	1,017,957

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. NIDA had the following adjustments to its appropriation for FY 2014: (1) Secretary's Transfer of $2,574,000 (2) Return of National Children's Study funds of $3,370,161.

(5) **Other Disclosures** - none

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 4, 2014

MEMORANDUM TO: Director Office of National Drug Control Policy

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

FROM: Laura L. Lee
Acting Chief Financial Officer
National Institute on Alcohol Abuse and Alcoholism

Laura L. Lee -S

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 use, abuse and dependence in minors (children under the legal drinking age of 21). It includes all alcohol related research in minors, 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 2014 ACTUAL OBLIGATIONS
(Dollars in Thousands)

	FY 2014 Actual
Drug Resources by Decision Unit:	
National Institute on Alcohol Abuse and Alcoholism	$59,350
Total Drug Resources by Decision Unit	$59,350
Drug Resources by Function:	
Research and Development: Prevention	$54,182
Research and Development: Treatment	$5,168
Total Drug Resources by Function	$59,530

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 21, 2014

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, 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

FY 2014 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 use, abuse, addiction and their consequences in underage populations. (Note: This measure replaces the previous measure which ended in FY 2013. See Appendix on page 23 for details.)

Table 1: NIDA Annual Targets

FY 2014 Target*	FY 2014 Actual	FY 2015 Target*
Develop and assess at least two interventions to prevent drug use, drug use problems, and risk behaviors.	NIH funded research tested multiple interventions to prevent drug use, drug use problems, and drug related risky behaviors including HIV risk behaviors.	Assess the effectiveness of at least two strategies for dissemination and implementation of tested, efficacious interventions to prevent youth and young adult drug use, drug use problems, and risk behaviors.

(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 abuse and addiction (including tobacco, alcohol, illicit, and nonmedical prescription drug use) is leading to 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 underlying propensity to initiate drug use or to escalate from use to substance abuse across different developmental stages. Information about these contributors to substance abuse and addiction and the different ways biological psychosocial and environmental factors operate across individuals is critical to designing more effective prevention messages. **Measure SRO-5.15 focuses on developing, refining, evaluating, and disseminating evidence-based intervention strategies to prevent substance use, abuse,**

addiction 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 abuse or 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. 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. High levels of sensation-seeking, and other traits known to be risk factors for substance abuse, may be identified early using genetic markers.

A number of genetic markers have been identified that influence risk for addiction. This information can be harnessed for improving prevention by personalizing interventions for optimal benefit. Recent research has shown that genetic risk factors can influence the effectiveness of school based prevention interventions. In addition, individual differences seen in response to medications for nicotine and alcohol addiction suggest that genetic predictors of treatment response could lead to more efficacious and cost-effective relapse prevention strategies. Such identification would enable substance abuse 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 abuse 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 abuse 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 abuse in high sensation-seeking youth.

(2) Provide narrative that examines the FY 2014 actual performance results with the FY 2014 target, as well as prior year actuals. If the performance target was not achieved for FY 2014, 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 FY2014. Prevention of the initiation of drug use and prevention of the escalation to addiction in those who have already initiated use continues to be one of NIDA's primary strategic goals (see NIDA's Strategic Plan). NIDA continues to fund a robust theory-based prevention portfolio that builds upon solid

epidemiological findings and insights from genetics and neuroscience and applies this knowledge to development of effective strategies to prevent initiation of drug use and escalation of use to addiction in underage youth.

From FY 2014 to the present (FY 2015), multiple studies have been funded to develop and test interventions to prevent drug use, drug use problems, and risk behaviors. NIDA is currently supporting studies to test culturally and developmentally appropriate strategies to prevent substance use and abuse across the lifespan: for all developmental stages, from birth through adulthood and older age; for diverse racial/ethnic populations, targeted to diverse settings such as family, school, community, and health care settings; and for diverse special populations and/or high risk populations, such LGBT, homeless, child welfare involved, juvenile justice system involved, criminal justice involved, individuals comorbid conditions, populations at risk for HIV/AIDS.

In FY 2014 multiple publications were released related to this target by NIDA-funded researchers who conducted studies that tested interventions to prevent drug use, drug use problems, and risk behaviors. One recent study explored the effect of a Multidimensional Treatment Foster Care (MTFC) in at-risk female youth who had been referred for out-of-home placement due to chronic delinquency.[1] Previous studies have shown that juvenile justice girls have high rates of co-occurring risk behaviors including substance abuse. The current research showed that women with prior juvenile justice involvement who were assigned to the MTFC intervention during adolescence showed greater decreases in drug use than girls assigned to treatment as usual. In addition, women who participated in MTFC were found to be more resilient to partner drug use than women in the treatment as usual condition.

Another recent publication demonstrated that girls who participated in the Middle School Success (MSS) Intervention, a program to promote healthy adjustment in foster girls, showed lower levels of health risk-taking behaviors.[2] The analysis demonstrated that the effect of the intervention on health-risking sexual behavior was mediated through its effect on tobacco and marijuana use. These finding demonstrate that the MSS prevention intervention delivered during adolescence improves young adult drug use trajectories (7-9 years after the study began). These findings add to a growing body of evidence of the longer term impacts of early prevention interventions delivered during adolescence to a high risk population.

Another ongoing study is looking at the feasibility and effectiveness of using web-based tools for screening college students for marijuana use and providing brief interventions.[3] Students who use marijuana have an increased likelihood of poor academic performance, as well as physical health and relationships problems. Despite the availability of efficacious interventions, few students identify their marijuana use as problematic or seek treatment to reduce their use. Recent

[1] Rhoades KA et al. Drug Use Trajectories After a Randomized Controlled Trial of MTFC: Associations with Partner Drug Use. J Res Adolesc. 2014 Mar 1;24(1):40-54. PubMed PMID: 24729667

[2] Kim HK, et al. Intervention Effects on Health-Risking Sexual Behavior Among Girls in Foster Care: The Role of Placement Disruption and Tobacco and Marijuana Use. J Child Adolesc Subst Abuse. 2013 Nov 1;22(5):370-387. PubMed PMID: 24043921

[3] Palfai TP, et al. Web-based screening and brief intervention for student marijuana use in a university health center: pilot study to examine the implementation of eCHECKUP TO GO in different contexts. Addict Behav. 2014 Sep;39(9):1346-52.

developments in health technology have expanded the range of tools available to engage students in screening and to deliver interventions. A pilot study was conducted to explore the efficacy of a web-based screening and brief intervention tool that delivers personalized feedback to students presenting to a university health center about their marijuana use in an easily utilized and confidential manner. The researchers found that while the intervention did not reduce frequency of marijuana use the intervention significantly altered perceived norms regarding marijuana use. The findings demonstrated that it is feasible to screen and identify marijuana users in a college student health center and deliver a web-based intervention and suggest that these types of technology based intervention can be useful for correcting misperceptions of norms and reducing related consequences.

Collectively these findings further support key prevention lessons and principles that have emerged from NIDA funded studies: prevention interventions implemented in early childhood have effects in later developmental stages and into young adulthood; universal interventions can have strong effects in higher risk youth; universal substance use prevention interventions can have effects on other behavioral outcomes, beyond those specifically targeted by the intervention (e.g. , social services utilization).

(3) The agency should describe the performance target for FY 2015 and how the agency plans to meet this target. If the target in FY 2014 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2015.

In FY 2014, NIDA began reporting on a new measure SRO-5.15 – 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 target for FY 2014 was met.

The FY 2015 target is to assess the effectiveness of at least two strategies for dissemination and implementation of tested, efficacious interventions to prevent youth and young adult drug use, drug use problems, and risk behaviors. Prevention of the initiation of drug use and the escalation to addiction 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 genes, environment, 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 prevent people from ever taking drugs and from progressing to addiction if they do. NIDA's Division of Epidemiology, Services, and Prevention Research includes 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. 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. 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 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 (http://grants.nih.gov/grants/policy/nihgps_2013/) 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 principle 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 previous animal data or, if not available, replicated and validated in newly generated animal models more 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 abusers, 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. For example, NIDA relies on the latest findings of biochemical and other (e.g., neuroimaging) experimental evidence suggesting that a particular gene might be involved in the addiction process and on whole genome association scans, an *unbiased* strategy for identifying genetic variations within large experimental populations, to identify genes that may confer substance abuse vulnerability. Genes putatively associated with addiction are subjected to further characterization and validation, typically through animal models. 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-8.7: By 2018, identify three effective system interventions generating the implementation, sustainability and ongoing improvement of research-tested interventions across health care systems.

Table 2: NIDA Annual Targets

FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Target	FY 2014 Actual	FY 2015 Target
Collaborative protocols have been developed to test 2 implementation models in CJ-DATS – MATTICCE and HIV-STIC.	2 studies have been fielded to test 4 implementation strategies for incorporating research-supported treatment interventions in the criminal justice system.	All research centers have either begun or completed the implementation protocols for the 2 studies.	The CJ-DATS research protocols MATICCE and HIV-STIC completed data collection in FY 2013.	Undertake analyses to examine the effects of implementation strategies used in MATICCE and HIV-STIC protocols.	Eight peer-reviewed publications analyzing the effects of implementation of the MATICCE and HIV-STIC protocols have been published. Several more manuscripts are in progress.	Establish cooperative partnership with at least 3 juvenile justice agencies across the United States to participate with NIDA investigators in studies intended to develop and test models that facilitate uptake of evidence based drug abuse prevention and treatment interventions. The level of achievement from this target is conditional on receiving applications of sufficient scientific merit.

(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.

Decades of research have led to today's improved understanding of addiction as a chronic, relapsing brain disease characterized by compulsive behaviors and caused by a combination of genetic, social, environmental, and developmental factors. NIH supports multidisciplinary research addressing the myriad factors that influence the development and progression of substance abuse and addiction, with the goal of informing and improving strategies to treat substance use disorders and prevent relapse.

NIH recognizes that despite major strides in treatment research, only limited improvements have occurred in non-research settings. An unacceptable gap separates scientific discoveries from their implementation into community and other practice 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. NIDA highlights two

approaches the NIH is taking to address the gap in implementing interventions in non-research settings (i.e., improving treatment integration in criminal justice settings).

Criminal Justice Setting

Drug abuse and crime are highly correlated in both the adult criminal justice system and the juvenile justice system. It is estimated that 70–85 percent of State inmates need drug abuse treatment, yet only about 13 percent receive it while incarcerated. About 600,000 inmates per year are released back into the community, often without having received drug abuse treatment in prison or linkage to community-based drug treatment for continuing care. Left untreated, drug-addicted offenders often relapse to drug use and return to criminal behavior. This situation jeopardizes public health and public safety and leads to re-arrest and re-incarceration, which exacerbates already high burdens on the criminal justice system. To better address public health and safety concerns, a prevention and treatment model within the criminal justice system is needed that fits the chronic nature of addictive disorders and ensures a continuity of services in line with the individual's needs. Such an integrated model should be designed not only to incorporate the best criminal justice practices and therapeutic services but also to use the best organizational practices to deliver them.

NIDA funds a broad portfolio of research addressing drug abuse in the context of the criminal justice system. From 2002-2014 NIDA funded the Criminal Justice Drug Abuse Treatment Studies (CJ-DATS) program, a multisite research cooperative. The CJ-DATS program aligned with NIDA's multi-pronged approach to rapidly move more promising science-based addiction treatments into community settings, to improve existing drug treatment for criminal justice populations, and to inform the development of integrated treatment models. The CJ-DATS program included testing of *Medication-Assisted Treatment Implementation in Community Correctional Environments (MATICCE) and HIV Services and Treatment Implementation in Corrections (HIV-STIC)*. The MATICCE protocol tested implementation approaches aimed at improving service coordination between community correctional agencies and local treatment agencies. The HIV-STIC protocol tested an organizational intervention strategy targeting effective implementation of quality improvements in HIV services for preventing, detecting, and treating HIV in offenders under correctional supervision. Through these studies CJ-DATS contributed to a significant body of research describing existing treatment practices in the criminal justice system, developing and testing the effectiveness of specific interventions, and exploring strategies for implementation, quality improvement, and of drug abuse treatment programs for criminal justice populations.

In 2013 NIDA launched the Juvenile Justice Translational Research on Interventions for Adolescents in the Legal System (JJ-TRIALS) program. JJ-TRIALS is a seven-site cooperative research program designed to identify and test strategies for improving the delivery of evidence-based substance abuse and HIV prevention and treatment services for justice-involved youth. Many evidence-based interventions targeting adolescent substance abuse and HIV screening, assessment, prevention, and treatment currently exist. Unfortunately, implementation of these interventions within juvenile justice settings is variable, incomplete, and non-systematic at best. This research program will provide insight into the process by which juvenile justice and other service settings can successfully adopt and adapt existing evidence-based programs and

strategies to improve drug abuse and HIV service delivery for at-risk youth. The cooperative will also conduct a nationally representative survey of the juvenile justice system that will provide information about policies and practices related to substance use assessment and service delivery in these settings across the United States.

NIDA is also currently supporting the Seek, Test, Treat, and Retain (STTR) Initiative to empirically test the STTR paradigm with drug abusers in criminal justice populations. Researchers are developing, implementing, and testing strategies to increase HIV testing and the provision of HAART to HIV positive individuals involved with the criminal justice system, with particular focus on continuity of HAART during and after community re-entry following incarceration.

SRO-8.7 is focused on testing implementation and quality improvement strategies for effective treatment interventions within the criminal justice system. SRO-8.7 represents NIDA's long-term strategy for improving drug abuse treatment nationwide, thereby contributing to the ***National Drug Control Strategy's Goals of: Integrating Treatment for Substance Use Disorders into Healthcare and Expanding Support for Recovery (Chapter 3) by supporting Seek, Test, and Treat HIV in the Criminal Justice System; and Breaking the Cycle of Drug Use, Crime, Delinquency, and Incarceration (Chapter 4) by supporting Innovative Criminal Justice Research Programs.***

(2) Provide narrative that examines the FY 2014 actual performance results with the FY 2014 target, as well as prior year actuals. If the performance target was not achieved for FY 2014, 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 2014 target was met. The CJ-DATS research protocols described in the FY 2010 target completed data collection in FY 2014. Across the two protocols described below, 8 peer-reviewed publications have been published to date[4,5,6,7,8,9,10,11]. More than a dozen additional manuscripts are in progress.

[4] Pearson, F., et al. (2014).Efficacy of a process improvement intervention on delivery of HIV services: A multi-site trial. American Journal of Public Health.
[5] Visher, C., et al. (2014). The effect of a local change team intervention on staff attitudes toward HIV service delivery in correctional settings: A randomized trial. AIDS Education and Prevention, 25:5, 411-428.
[6] Gordon, M., et al. (2014). Buprenorphine treatment for probationers and parolees. Substance Abuse. DOI: 10.1080/08897077.2014.902787
[7] Swan, H., et al. (In press, 2015). Improvements in correctional HIV services: A case study in Delaware. Journal of Correctional Health Care. Special Issue 21(2).
[8] Belenko, S., et al. (2013). Policies and practices in the delivery of HIV services in correctional agencies and facilities: Results from a multi-site survey. Journal of Correctional Health Care, 19(4), 293-310.
[9] Ducharme, L.J., et al. (2013). Implementing drug abuse treatment services in criminal justice settings: Introduction to the CJ-DATS study protocol series. Health & Justice, 1:5.
[10] Friedmann, P.D., et al. (2013). A cluster randomized trial of an organizational linkage intervention for offenders with substance use disorders: Study protocol. Health & Justice, 1:6.
[11] Belenko, S., et al. (2013). A cluster randomized trial of utilizing a local change team approach to improve the delivery of HIV services in correctional settings: Study protocol. Health & Justice, 1:8.

MATICCE (Medication-Assisted Treatment Implementation in Community Correctional Environments)

MATICCE was a collaborative study involving nine academic research centers (RCs), each with two community corrections partner agencies. The MATICCE protocol tested implementation approaches aimed at improving service coordination between community correctional agencies and local treatment agencies. The goals were to increase the number of persons in corrections who are given access to medication-assisted treatment (MAT) and to improve community corrections agents' knowledge and perceptions about MAT and increase their intent to refer individuals to appropriate community-based MAT services. The study randomized correctional agencies to one of two implementation strategies: (1) a KPI (Knowledge, Perception, and Information) intervention where correctional staff received structured training on use of medications in addiction treatment, including the effectiveness of MAT for reducing drug use and crime, for overcoming negative perceptions about MAT, and for providing information about local healthcare providers offering MAT; or (2) the KPI training plus an Organizational Linkage (OL) intervention, which engages key representatives from the corrections and treatment agencies in a strategic planning process designed to facilitate inter-organizational referral relationships, thereby improving the flow of offenders from community corrections to community-based treatment.

One peer-reviewed publication reporting on results of the MATICCE program is currently in press. This publication reports that the KPI staff training coupled with the facilitated OL strategic planning intervention was more effective than staff training alone in improving probation and parole officers' acceptance of MAT and willingness to refer clients to treatment. There are currently two additional publications related to the MATICCE study undergoing peer review and five being prepared for submission.

HIV Services and Treatment Implementation in Corrections (HIV-STIC)

HIV-STIC was a collaborative study involving 9 academic research centers (RCs) and 30 community corrections partner agencies. The HIV-STIC protocol tested an organizational intervention strategy targeting effective implementation of quality improvements in HIV services for preventing, detecting, and treating HIV in offenders under correctional supervision. The study randomized correctional facilities to one of two conditions. A control received basic training on the fundamentals of HIV infection, prevention, testing, and treatment, as well as information about the HIV services continuum. The experimental group implemented a process improvement approach to guide a Local Change Team (LCT) through a structured series of steps to improve HIV services. Such models have been found to improve health services implementation in other settings, but had not previously been tested in correctional settings or with HIV services.

Multiple peer-reviewed publications were released in 2014 demonstrating that the modified NIATx (Network for Improvement of Addiction Treatment) process improvement model used by the HIV-STIC protocol was successful in increasing the likelihood that a correctional facility would successfully deliver HIV services to their inmates as compared to facilities that only

received training on HIV services.[12] The process improvement model also resulted in more positive attitudes toward HIV service delivery among correctional staff.[13] A survey of sites participating in the CJ-DATS HIV-STIC protocol prior to study commencement indicated that there was wide variation in the degree to which these correctional facilities adhered to national guidelines around HIV prevention, detection and care.[14] Gaps in HIV service delivery were primarily attributed to limited resources. Five additional publications related to HIV-STIC are currently in development.

(3) The agency should describe the performance target for FY 2015 and how the agency plans to meet this target. If the target in FY 2014 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2015. The FY 2015 target is to establish cooperative partnerships with at least 3 juvenile justice agencies across the United States to participate with NIDA investigators in studies intended to develop and test models that facilitate uptake of evidence-based drug abuse prevention and treatment interventions. To meet this target, NIDA will continue to support the JJ-TRIALS program and the STTR initiative as they develop and test interventions to improve the implementation of evidence-based programs for prevention and treatment of substance use disorders and HIV.

(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 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.

Additional controls specific for CJ-DATS.
For each study protocol, NIDA's CJ-DATS had an extensive process for ensuring the data were collected, verified, cleaned, analyzed, and reported in a systematic and consistent manner. CJ-DATS had a Data Management Committee (DMC) that included one or more representatives from each Research Center, which developed data collection and processing rules and monitored compliance across all protocols. The CJ-DATS Coordinating Center (CC) implemented these rules and worked in collaboration with the DMC to ensure quality control in the collection, entry,

[12] Pearson, F., et al. (2014). Efficacy of a process improvement intervention on delivery of HIV services: A multi-site trial. American Journal of Public Health.
[13] Visher, C., et al (2014). The effect of a local change team intervention on staff attitudes toward HIV service delivery in correctional settings: A randomized trial. AIDS Education and Prevention, 25:5, 411-428
[14] Belenko, S., et al. (2013). Policies and practices in the delivery of HIV services in correctional agencies and facilities: Results from a multi-site survey. Journal of Correctional Health Care, 19(4), 293-310.

verification, and documentation of data. NIDA staff actively monitored each study protocol and participated in regular meetings of the DMC and CC. Briefly, the process was as follows:

1. The DMC and CC worked collaboratively to establish overall data tracking, collection, and quality control procedures to ensure the collection of accurate data using reliable and valid measures consistently across all protocols. Any deviations from established data collection/entry protocols required approval by the DMC before being implemented.
2. The DMC developed data collection forms recognizable by TeleForm scanners (a commercial Optical Character Recognition software) and created templates for exporting scanned data into the statistical software system. Teleform eliminates the need for most hand-keying of data, thus improving accuracy of data entry.
3. The DMC and CC developed protocols for data quality checks to be followed by each Research Center before scanning data into the TeleForm system. Back-up procedures were developed for forms that could not be successfully scanned for any reason.
4. Research Centers uploaded data on a no-less-than monthly basis to a secure online system monitored by the CC. After receiving data uploads from Research Centers, CC staff complete extensive verification procedures to ensure the data's quality. This process includes reviewing automatic alerts generated by the TeleForm software and manually verifying all data fields.
5. CC staff follows set protocols for communicating with personnel at each Research Center to verify and correct any mistakes identified in their manual review of scanned data.
6. After the CC verified the accuracy of the data and corrected any mistakes, data files were made available to a data analysis subcommittee for each protocol. Each committee was led by an expert in quantitative analysis and included staff from each RC. This committee reviewed each data file in detail and completed a number of sophisticated analyses to check for possible errors (outliers, validation, etc.) that were not identified as part of the manual process described above. Errors, omissions, and other issues were documented for each RC, and corrections were requested within given time parameters.
7. Data files were considered ready for analysis only after the data analysis subcommittee and the CC completed all checks and were confident of the data's integrity. These "locked" files were then uploaded to a secure web-based file system where they were made available for analysis. A separate analytic file request/approval process managed by a lead data analyst for each study protocol ensured documentation of the use of each analytic file—by whom and for what purpose. This process avoided duplication of effort and ensured that only the current version of an analytic file was in use, and that the use was appropriate given the measures in the data file.
8. The CC staff also implemented a comprehensive inventory detailing the status and ultimate disposition of every form distributed to the RCs for data collection. Those data were used to calculate response rates and to ensure that every completed form was included in the analytic files.

In addition to the procedures outlined above, the DMC holds weekly calls to review any problems that emerge as part of this process. Key decisions or changes to procedures are documented and disseminated to the cooperative via the project's secure website. Logs are used to track the transfer of files among analysts.

Methodology Used to Establish Targets/Actuals

The targets were established based on the existing protocols. As discussed above, these protocols underwent a rigorous review process to determine which research areas held the most promise for filling gaps and should therefore be prioritized for testing. The target values were 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 was used to generate the targets for this measure.

Data Sources

Data collection for all CJ-DATS protocols was completed in FY 2013. In FY 2013 and continuing in FY 2014, several structured procedures were developed, refined and implemented to ensure accurate calculation and reporting of response rates, consistent use of syntax and documentation for constructed variables, minimum requirements for computed variables (e.g., scale reliabilities and factor weighting).

Decision Unit 2: NIAAA

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 use, abuse, addiction and their consequences in underage populations. (Note: This measure replaces the previous measure which ended in FY 2013. See Appendix on page 23 for details.)

Table 1: NIAAA Annual Targets

FY 2014 Target	FY 2014 Actual	FY 2015 Target
Develop materials for dissemination to academic officials that help them address underage and harmful drinking and other substance use by their students.	NIAAA developed the College Alcohol Interventions Matrix (College-AIM), 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.	Evaluate the effectiveness of screening and brief intervention for alcohol and other drug use in a variety of 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.

NIH's growing knowledge about substance abuse and addiction (including tobacco, alcohol, illicit, and nonmedical prescription drug use) is leading to prevention strategies that are based not on anecdotal experience but on validated epidemiological, genetic, and neuroscience research. NIH-supported research is building the scientific knowledge base needed to advance our goal of developing effective tailored prevention strategies.

Adolescence is the time of life during which the brain continues to develop, particularly the frontal cortex which mediates executive function. It is also the time of life during which the use of alcohol, tobacco, and marijuana all ramp up significantly, as well as a period of dramatic biological, social, and environmental changes. Alcohol remains the substance of choice among youth, and binge drinking and heavy drinking continue to be public health concerns. Early use of alcohol, tobacco, or illicit substances, as well as polysubstance use, is associated with increased risk of addiction. Alcohol, tobacco, marijuana, and other addictive substances may interfere with the developing brain, and given that the brain continues to develop past adolescence into a person's twenties, these substances may have short- and long-term consequences for brain function and behavior. Substance use increases risk for other adverse outcomes such as cognitive impairment, blackouts, physical and sexual assault, risky behavior, alcohol poisoning, drug overdose, injuries, and death. Given the pervasive use of alcohol,

tobacco, and illicit substances among young people, the potential impact on their developmental trajectories, and the increased risk for addiction and other harmful consequences, effective prevention strategies are needed to preempt the adverse consequences of underage substance use for individual users, their families, their communities, and society-at-large.

SRO-5.15 is focused on developing, evaluating, and promoting evidence-based intervention strategies to prevent substance use, abuse, addiction, 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 focuses on risk assessment and screening, universal and selective prevention, early intervention (before problems escalate and/or become chronic), and timely treatment for all individuals who need it. NIAAA will pursue different levels of interventions, e.g. school/college, family, and community, in support of this goal.

(2) Provide narrative that examines the FY 2014 actual performance results with the FY 2014 target, as well as prior year actuals. If the performance target was not achieved for FY 2014, 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 2014 was met. Working with researchers with expertise in college drinking interventions, NIAAA developed a research-based decision tool to help colleges and universities select appropriate strategies to meet their alcohol intervention goals. The user-friendly decision tool will form the basis of a guide which will allow college presidents and administrators to review the strategies they are currently using as well as explore others that may serve them better. This tool and guide, the NIAAA College Alcohol Interventions Matrix (College-AIM), will allow users to search for strategies according to intervention level (e.g., individual, group, campus-wide, community) and evaluate factors such as effectiveness, cost, and ease of implementation. The NIAAA College-AIM is being finalized and will be released in 2015. An interactive online version of the decision tool is envisioned.

(3) The agency should describe the performance target for FY 2015 and how the agency plans to meet this target. If the target in FY 2014 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2014.

The FY 2015 target is to evaluate the effectiveness of screening and brief intervention for alcohol and other drug use in a variety of settings. Alcohol screening and brief intervention (SBI) has been shown effective in intervening with harmful drinking in adults, and evidence indicates that it can be effective in preventing and intervening with alcohol use and its consequences in children and adolescents. In 2011, NIAAA released an alcohol screening guide for pediatricians and other health care providers to identify children at elevated risk for using alcohol, children and adolescents who have already begun to experiment with alcohol, and those who are more heavily involved with alcohol. While this tool was developed for use in the primary care setting, it may also be useful in other settings. NIAAA-supported research to evaluate the youth guide in a variety of settings 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

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 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 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 (http://grants.nih.gov/grants/policy/nihgps_2013/) 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 principle 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.

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, and they represent the next logical scientific steps for moving a particular field or initiative forward. For example, to promote the use of evidence-based intervention strategies for college drinking, NIAAA engaged a team of premier researchers with expertise in college drinking interventions to assess the state of the science on their effectiveness, cost, and ease of implementation. This process informed the development of the College-AIM, a decision tool designed to help college administrators more easily review and select alcohol interventions that are appropriate 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

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-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 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Target	FY 2014 Actual	FY 2015 Target
Products that promote assessing and managing problem drinking in different media formats were refined and/or pursued.	NIAAA has disseminated new multimedia products that promote implementation of screening and brief intervention in primary care and educate the general public about the health effects of alcohol. NIAAA also continued to support research on the implementation of screening and brief intervention in primary care.	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.	Support research to evaluate the effectiveness of the underage drinking screening guide as a predictor of alcohol risk, alcohol use, and related problems, including alcohol use disorders to improve service and treatment options for at-risk youth.	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.	Penetrate primary care to increase alcohol screening and brief intervention by providing online continuing medical education (CME) for the underage drinking guide and by supporting efforts to enhance medical training curricula.

(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.

Primary Care Settings

NIH 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 primary care. 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 knowledgeable adults about alcohol, and intervene before or after drinking starts, as well as before or after problems develop. NIAAA's youth alcohol screening guide was devised to help health care providers identify alcohol use and alcohol use disorders in children and adolescents, as well as identify risk for alcohol use, especially in younger children. The tools, including a brief two-question screener and support materials about brief intervention and referral to treatment, 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 may also be useful in other settings.

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 alcohol abuse 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 2014 actual performance results with the FY 2014 target, as well as prior year actuals. If the performance target was not achieved for FY 2014, 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 2014 was met. To expand the venues in which at-risk youth can be serviced and referred to treatment when appropriate, NIAAA supported six ongoing five-year studies that are evaluating the youth alcohol screening guide in practice: one in a network of emergency departments, one in a juvenile justice setting, one in a school setting, two in primary care, and one with youth who have a chronic condition (e.g., asthma, diabetes). In addition to evaluating the effectiveness of the screening guide as a predictor of alcohol risk, alcohol use, and related

problems, including alcohol use disorders, these studies are also evaluating the effectiveness of the guide as an initial screen for drug use and other behavioral health problems. These studies will provide feedback to NIAAA that will facilitate refinement of the guide and help identify settings where use of the guide is appropriate and effective, thereby informing strategies for more widespread dissemination. In FY 2014, NIAAA also continued efforts to increase physicians' use of the youth alcohol screening guide in primary care and other health care settings.

(3) The agency should describe the performance target for FY 2015 and how the agency plans to meet this target. If the target in FY 2014 was not achieved, this explanation should detail how the agency plans to overcome prior year challenges to meet targets in FY 2014.

The FY 2015 target is to penetrate primary care to increase alcohol screening and brief intervention by providing online continuing medical education (CME) for the underage drinking guide and by supporting efforts to enhance medical training curricula. The CME course is currently available and NIAAA will continue to provide this training for healthcare providers in FY 2015. Recognizing the importance of training health care providers in preventing, screening and managing alcohol-related problems, NIAAA will also support efforts to enhance medical training curricula.

(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

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.

Appendix: Previous Prevention Measure

SRO-3.5: By 2013, identify and characterize at least 2 human candidate genes that have been shown to influence risk for substance use disorders and risk for psychiatric disorders using high-risk family, twin, and special population studies.

Table 1: NIDA Annual Performance

FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual
Research has identified or verified genetic markers of nicotine dependence vulnerability or outcomes of smoking cessation therapies including: CYP2A6, CHRNB2, SLC6A3, and NR4A2.	Three studies confirmed the association of gene variants in Chrna5, Chrna3, and Chrnb4, on *chr15q25* with smoking frequency. Also, the first polygenic complex genetic score to significantly aid in predicting (in combination with other clinical attributes) success in smoking cessation was developed and tested.	Replicate/validate genetic markers that identify differences in treatment response and/or vulnerability to drug dependence in a minority population	NIH researchers characterized the functional roles of genes previously identified as being associated with addiction to tobacco and other drugs, including those within the CHRNA5/A3/B4 gene cluster and A11G of the human mu opioid receptor gene.	NIH researchers characterized additional gene variants associated with drug dependence and smoking cessation as well as developed new resources to help interpret the functional significance of identified variants.

Table 2: NIAAA Annual Performance

FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual
Functional differences related to alcohol dependence and treatment were validated for the A118G SNP of the OPRM1 gene.	Functional differences were characterized for sequence variations in genes encoding serotonin receptors and transporters, the oxidative stress enzyme SOD2, and nicotinic receptor subunits. (Target Met)	NIH researchers conducted functional studies of gene variants that are associated with increased risk for alcohol dependence through population-based research in European-Americans and African Americans.	NIH researchers replicated and extended the results of previous association studies in East Asian populations to populations of European and African ancestry.	NIH researchers identified genomic variants that were associated with risk for alcohol dependence.