2012

Adoption of NIDA's Evidence-Based Treatments in Real World Settings

---A National Advisory Council on Drug Abuse Workgroup Report

This report is produced in response to a charge by the NIDA Director for the Workgroup to:
1) Determine how effectively the treatment interventions developed, tested, and evaluated through NIDA's extramural programs are being transferred and utilized in real world settings (e.g. community treatment centers, primary care settings, criminal justice settings, etc.);
2) Explore barriers for moving from research findings to adoption as standard practice; and
3) Consider whether and how the organization of NIDA could be best structured to meet these evolving scientific goals.

National Advisory Council on Drug Abuse
National Institute on Drug Abuse
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UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

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July 30, 2012

Nora D. Volkow, M.D., Director
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Dear Dr. Volkow:

I am pleased to transmit the report and recommendations of the National Advisory Council on Drug Abuse Work Group "*Adoption of NIDA's Evidence Based Treatments in Real World Settings*". This Work Group was created at your request in 2011. The report and recommendations reflect the unanimous view of the Work Group members. We take full responsibility for the contents and are available to meet with you and/or members of your staff to discuss our conclusions and recommendations, if needed.

The Work Group was impressed with the dedication and leadership of NIDA's extramural staff. Yet, significant evidence to practice gaps remain for substance use treatments. In light of this, the Work Group recommends creation of new infrastructure and processes within NIDA to bolster Implementation Science in this area. In addition, the Work Group believes that NIDA can partner effectively with other federal agencies and private organizations to create regulatory, financing, or policy decisions that would create markets for, or improve adoption of, its evidence-based treatments.

The members of the Work Group and I would like to thank Meena Hiremath, Ph.D. for her exceptional and vital support throughout the process. She helped the Work Group to consider what types of questions, data, and resources were needed for our evaluation and assisted in writing and editing portions of the report. In addition, Teri Levitin, Ph.D. was extremely helpful in partnering with the Work Group to provide collegial input and assistance on critical issues and Dr. Robert Katt played a key role in preparing meeting notes for us. Thank you for this opportunity to support NIDA's mission.

Sincerely yours,

Caryn Lerman, Ph.D.

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Report of the Adoption of NIDA's Evidence-Based Treatments in Real World Settings Workgroup

National Institute on Drug Abuse

2012

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EXECUTIVE SUMMARY

The National Institute on Drug Abuse (NIDA) is responsible for a broad range of discovery, translational, clinical, and implementation research designed to better understand, prevent, and treat substance use disorders. NIDA, like all other NIH institutes, has the responsibility to ensure that a significant proportion of its research will result in broadly applied interventions with public health value and economic sustainability.

Bringing scientific discoveries into broad application and practice is only partly a research process. Research evidence can be useful in promoting and encouraging change but is rarely by itself sufficiently powerful to change behaviors or systems. The evidence-to-practice gap is particularly significant in the area of implementation of substance use disorder treatments with proven efficacy. The existing "markets" for evidence-based treatments in the substance use disorder field derive largely from regulatory systems, legislative actions, consumer demands, and public and private sector investments. Indeed, regulatory and policy formulation at the state level, as well as government and private sector funding decisions, guide the range of activities adopted in real world treatment settings. Certainly, many of these social, political, and economic determinants of implementation are beyond NIDA's core research mission and are the responsibility of other federal agencies and private organizations. However, NIDA can and should partner effectively with relevant agencies to inform regulatory, financing, or policy decisions that may create markets for, or improve adoption of, its evidence-based treatments.

As described in Section II below, the "Adoption of NIDA's Evidence-Based Treatments in Real World Settings" Workgroup (referred to as "the Workgroup") was created and charged to determine how effectively the treatment interventions developed, tested, and evaluated with NIDA support are being transferred and utilized in diverse practice settings. The Workgroup's team of clinical, research, and administrative members considered the barriers and facilitators of adoption of effective treatments, including NIDA's current organization and programs.

To facilitate the translation of evidence-based treatments to practice, the Workgroup recommends that the following actions be taken. These recommendations reside directly within the domain of NIDA. The rationale for each of these recommendations and proposed action items are described within this report.

1. **Create a new entity for Translation and Implementation Science within NIDA to help bring its scientific findings on treatment efficacy into broad practice.**

2. **Establish NIDA guidelines for funding consideration of treatment development research projects that consider the potential for implementation, adoption, scalability, and sustainability in various practice settings.**

3. **Establish systems-based research networks within naturalistic settings to evaluate intervention effectiveness, adoption, and sustainability in practice.**

4. **Target funding to expand the grant portfolio for implementation science.**

5. **Establish a recurring NIDA-based peer review panel charged with evaluating research applications that focus specifically on advancing rapid adoption of evidence-based interventions.**

I. WORKGROUP CHARGE AND STUDY PROCESS

The Charge

In November 2011, the Director of the National Institute on Drug Abuse (NIDA), Nora D. Volkow, M.D., established the National Advisory Council on Drug Abuse's "*Workgroup on Adoption of NIDA's Evidence-Based Treatments in Real World Settings"* (referred to here as " the Workgroup").[1]

The Workgroup was charged by Dr. Volkow with the following tasks:

1. **Determine how effectively the treatment interventions developed, tested, and evaluated through NIDA's extramural programs are being transferred and utilized in real world settings (e.g., community treatment centers, primary care settings, criminal justice settings, etc.).**

2. **Explore barriers for moving from research findings to adoption as standard practice.**

3. **Consider whether and how the organization of NIDA could be best structured to meet these evolving scientific goals.**

The Workgroup considered "treatments" broadly to include evidence-based quality improvement strategies, best business practices, models of care, screening and assessment instruments, behavioral interventions, and medications. This definition also extends to continuing care, recovery support and monitoring. Although the Workgroup was not charged with evaluating the adoption of NIDA's *prevention* interventions in practice or public health settings, it is noted that many of the treatment-focused recommendations below may also be applicable to prevention interventions. However, the Workgroup concurs that a more detailed analysis of the prevention portfolio would require a subsequent workgroup process and engagement of members with different expertise.

The Workgroup was asked to be mindful of NIDA's mission to lead the Nation in bringing the power of science to bear on drug abuse and addiction. NIDA accomplishes this by: 1) strategically supporting and conducting research across a broad range of disciplines; and 2) striving for the rapid and effective dissemination and use of the results of that research to improve prevention and treatment and to inform policy as it relates to drug abuse and addiction. These goals are in contrast to those of the Substance Abuse and Mental Health Services Administration (SAMHSA). Established in 1992 and directed by Congress, SAMHSA's mission is to effectively target substance abuse and mental health services to the people most in need and to translate research in these areas effectively and rapidly into the general health care system.

Process

At the first in-person Workgroup meeting held on February 13-14, 2012, the Workgroup heard presentations from several NIDA staff members about NIDA's mission, programs, and portfolios related to substance use disorder treatment research [2]. The presentations and discussions occurred in an executive session format in order to facilitate candid dialogue. The presentations, portfolio data, and ensuing discussions provided the foundations for the Workgroup's assessment of how effectively treatment interventions are being adopted and utilized in various treatment settings and of how NIDA's structural organization could be optimized to enhance adoption of evidence-based treatments more broadly in practice.

[1] Appendix A lists the Workgroup members and their affiliations.
[2] The agenda for this formal meeting of the Workgroup is included as Appendix B.

To explore barriers to, and facilitators of, adoption of NIDA's treatments, the Workgroup identified public and private sector key partners in this process and leaders of those entities who could provide insights for adoption and sustainability of NIDA's treatments. Representatives of the following organizations were contacted for further discussion outside of the face-to-face meetings with the full Workgroup: National Cancer Institute (NCI) Division of Cancer Control and Population Sciences, Substance Abuse and Mental Health Services Administration (SAMHSA), National Quality Forum (NQF), Agency for Healthcare Research and Quality (AHRQ), and Aetna (as a representative of the insurance industry).[3]

The Workgroup held its second in-person meeting on May 8-9, 2012. At this meeting, the Workgroup discussed NIDA's legislative authorization and efforts to communicate and disseminate materials about the latest research related to treatment and prevention of substance use disorders with NIDA staff from the Office of Science Policy and Communications. The Workgroup also explored how other National Institutes of Health (NIH) Institutes and Centers utilize systems-level networks to evaluate and assess implementation of treatments in various practice settings. At this meeting, the Workgroup formulated initial drafts of the key recommendations to the NIDA Director.[4]

In addition to the activities described above, Workgroup members participated in telephone conference calls on January 6, 2012, February 2, 2012, March 16, 2012, April 2, 2012, and April 25, 2012 to discuss information needs, assess findings, plan future steps, and ponder implications as the process progressed. Subsequent to the final in-person meeting on May 8-9, 2012, additional teleconference calls were held to discuss, review, and revise sections of the draft report on June 29, 2012 and July 20, 2012. The final report was approved by the Workgroup members on August 10, 2012.

[3] A list of specific contacts participating in these calls is provided as Appendix C.
[4] The agenda for this formal meeting of the Workgroup is included as Appendix D.

II. GENERAL INTRODUCTION TO THE PROBLEM

Evidence-Based Treatments for Substance Use Disorder Are Infrequently Used in Practice

The Institute of Medicine has issued reports challenging the health care system to provide safe, effective, patient-centered, efficient, equitable, and timely services (IOM 2000, 2001, 2006). Over the past 15 years, behavioral health services have undergone scrutiny for quality improvement, with growing recognition that addiction treatment services have lagged behind in quality improvement (Fishbein and McCarty 1997; Young and Magnabosco 2004; Patel et al.2006; McCarty et al. 2009; Quanbeck et al. 2012). Delivery of high quality treatment is challenging for various reasons: without universally acceptable biological markers for the addictive state, its consequences, or a defined state of recovery, the definition and outcome measures of "effective treatment" can vary (Smith and Larson 2003; Miller and Miller 2009; Laudet 2011; Tiffany et al. 2012a; Tiffany et al. 2012b; Donovan et al 2012; Uchtenhagen 2012). Treatment effectiveness outcomes may include short-term or long-term abstinence, reduction in drug use, and associated consequences (e.g., HIV-AIDS, arrests, unemployment, overall health status), completion of a course of treatment, and cost-effectiveness. Ongoing research on substance use disorder interventions and treatment provides new insights, as well as refinements of procedures and strategies that constitute "effective treatment". With appropriate design, interpretation, verification and consensus, research findings evolve into protocols, guidelines, or principles for treatment/ treatment improvement, as issued by Federal agencies (NIDA 2009, 2012; NIAAA 2000, 2004; CSAT 1998, 1999, 2005, 2006).

Validated research protocols and treatment manuals that improve identification and treatment of substance use disorders have impact only if they are scalable, translated, widely implemented in practice, and sustainable. Comparison of the "Principles of Drug Addiction Treatment" (NIDA 2009) with the results from the 2010 SAMHSA-generated survey of treatment centers (SAMHSA 2011) [5] provides substantial evidence that translation of evidence-based treatments and treatment principles have not effectively penetrated the majority of treatment services. The SAMHSA survey demonstrates the presence of many deficiencies in current substance use treatment and monitoring practices. These deficiencies include:

- A full range of treatment options is not available in the majority of treatment centers.
- A significant number of treatment centers do not offer recovery support services.
- Only a small fraction of centers (8-9%) offer medication treatment for substance use.
- Less than 50% of centers offer mental health assessment and an even smaller proportion offer medications for psychiatric conditions.
- Fewer than 35% of facilities test for commonly occurring infectious diseases, such as HIV/AIDS, tuberculosis (TB), Hepatitis B or C, and sexually transmitted diseases (STDs).
- A proportion of facilities offer detoxification services, but it is not possible to determine if these services are integrated with treatment on a facility-by-facility basis.
- A majority of centers have drug testing capabilities, but it is not clear if these facilities routinely monitor for drug use.

These significant deficiencies reflect: 1) poor integration with health care systems that are capable of providing an essential and comprehensive level of care (e.g., medications assistance, infectious disease diagnosis and treatment, mental health assessment, and provision of medications); 2) poor uptake of best practices (e.g., inadequate percentage of centers that provide recovery support services, choices of treatment approaches, seamless integration of detoxification with treatment,

[5] See Appendix E for a comparison of the "Principles of Drug Addiction Treatment" (left side of the table (NIDA 2009)) with the results of the 2010 SAMHSA-generated survey of the majority of treatment centers (right side of the table (SAMHSA 2011)).

adequately licensed and credentialed treatment staff, and incentives for positive treatment outcomes); and 3) inadequate records and reporting systems (e.g., routine drug testing, drop-out rates, relapse rates, follow-up care and length of follow-up care, seamless entry into treatment, continual assessment and modification of an individual's treatment plan, adequate duration in treatment, and voluntary versus involuntary treatment entry). Other reports also document deficiencies in current substance use disorder treatment services and offer strategies for improvement (McKay et al. 2009; Humphreys and McLellan 2011).

There has been some progress in incorporating substance use Screening, Brief Intervention, and Referral to Treatment (SBIRT) procedures into healthcare services (Madras et al. 2009; Madras 2010), and the availability of medications is key to accelerate the medicalization of SBIRT procedures. However, this potential is tempered by the minimal use of medications assistance (8-9%) in community-based treatment programs and by poor integration of SBIRT services in healthcare systems with a seamless referral system for those in need of specialty treatment[6]. This statistic underscores the importance of strategic planning for adoption of future approved medications and innovative behavioral treatments within treatment services, as well as integration of these practices into community-based settings.

There are several unique barriers to adoption of substance use disorder *medication* treatments and *behavioral* treatments. Some of these challenges are more significant for medication studies, others are more acute in behavioral studies, and all are potentially important in trials examining combined medication and behavioral interventions. Barriers include:

- Few community-based treatment centers have full-time and on-site medical staff to prescribe medications.
- For specific medications (agonists, partial agonists), prescribing practices may be highly regulated by federal or state law, requiring training, or impose restrictions on take-home medications.
- There may be reluctance by counselors to treat addiction with medications.
- Privacy concerns embedded in regulations (e.g. 42CFR Part 2 (*eCFR* 2009)) conceivably create reporting, coding, and billing challenges for medical professionals.
- The "individual-based" approach of most evidence-based behavioral treatments is an obstacle for most public and private treatment services which are "group-based". Even as substance use services become integrated in primary care, it is likely that these services will continue to be group-based treatments by primary care teams, as is the case for behavioral treatments for other health conditions.
- There is a lack of infrastructure or significant industry that is positioned to market, sell, service, and inform users about behavioral interventions and social services. This seriously diminishes the potential for broad utilization and disincentivizes research and development of behavioral and social services interventions.
- For the past 45 years, the vast majority of treatment for substance use disorders has been located in specialty treatment programs (~13,000) and largely detached from an academic research foundation. Thus, many of the clinical researchers in the substance use disorder field do not actually deliver care, and, therefore, may be less in tune with implementation issues that affect adoption in real world settings.
- Counselors have little economic power or regulatory oversight, and thus there is no "industry" pressure to create better counseling protocols.

Lessons from Theory and Research on Adoption of Evidence-based Treatments

[6] See Appendix F for a discussion about SBIRT and NIDA's role in expanding these services within healthcare systems.

The longstanding problem of moving research results into policy and practice is well documented. While it is beyond the scope of this report to summarize the field, we provide some key insights below and refer the reader to some comprehensive sources (Wolfe 1994; Lamb et al. 1998; Langley 1999; Schoenwald and Hoagwood 2001; Gotham 2004; Glisson and Schoenwald 2005; Aarons 2004; Aarons 2005; Gotham 2006; Wirsam and Muller 2006; Walker and Koroloff 2007; Garner 2008; Bond et al. 2009).

The development of treatments that are implementable requires an interaction between the stakeholders of the treatment and the researchers. Thus, the decisions about what is required in order to be implementable when an evidence-based practice is developed requires "buy-in" at multiple levels – from insurers or other purchasers, to individuals (e.g., patients, family, providers) to groups (e.g., care teams), to establishing "standards of care and accreditation", to organizations (e.g., clinic or Health Maintenance Organization (HMO)), and to professional association/political entities (e.g., states, policy makers) (Schoenwald and Hoagwood 2001; Birkel et al. 2003; Gotham 2004; Nelson et al. 2006; Gotham 2006; Sterling and Weisner 2006; Humphreys and McLellan 2011). Intermediaries such as 'opinion leaders' and 'change agents' can influence adoption, even though they are not directly adopting the treatment themselves (Dopson et al. 2002; Doumit et al. 2007; Majumdar et al. 2007; Flodgrem et al. 2011). In the stakeholder/research relationship, using health care systems as an example, the stakeholders include health plan administrators, clinicians, consumers, and purchasers of services (in the private sector, given how health insurance is financed in the U.S., this primarily refers to employers). All of these groups play key roles both in the development of research questions and in the resulting implementation of interventions. Taking stock of all possible key stakeholders who can be levers of change for implementation is of paramount importance to translating research findings to practice (Bogenschneider and Corbett 2010).

Numerous factors can influence the rate and likelihood of adoption: attributes of the treatment; tendencies to adopt new approaches; policy and power relationships; peer group influences; level of contact change agents have with potential adopters; and the degree of local control and adaptation allowed (Stocking 1985; Nutley et al. 2002; Dopson et al. 2002; Nutley et al. 2007). Adoption is influenced also by individual practitioner attitudes about the effectiveness of treatments (Nelson et al. 2006; Lundgren et al 2011; Amodeo et al. 2011); implementation concerns (e.g., competence, increased workload, uncertainty, change fatigue); the nature of evidence (e.g., size and complexity of the evidence base; experience as evidence, habit)(Gonzales et al. 2002); risk (Panzano and Roth 2006); social class and hierarchy (Lindbladh et al. 1997); availability of data on the use of treatments in special populations (Castro et al 2010; Larios et al. 2011; Novins et al. 2011); and incentives and true institutional support for implementation (Kanter et al. 1992, Dawson 1996 ; Haynes and Haines 1998).

Measuring the critical outcomes of implementation of evidence-based treatments is of paramount importance and is challenging (Proctor et al. 2009; Proctor et al. 2011). Indeed, eight conceptually distinct implementation outcomes have been proposed: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability (Proctor et al. 2011).

Other Agencies and Barriers to Adoption

Partnering with other agencies may be an effective strategy for NIDA to address some of the barriers to adoption described above. Beyond the recommendations provided below, NIDA could engage in the following activities:

- Partner with the Centers for Medicare and Medicare Services (CMS), Health Resources and Services Administration (HRSA) and possibly private insurers to conduct research designed to

determine the general health effects and cost savings from various types of substance use disorder medications and behavioral treatments.

- Join the Office of National Drug Control Policy (ONDCP) and CMS to initiate dialogue with third party health care insurance companies about coverage for substance use disorders. CMS provides modest insurance coverage for substance use disorders; yet, CMS accounts for about 39% of all healthcare expenditures (2010) in the US (CMS 2011). CMS standards usually become the standards for the rest of the insurance industry.
- Interact more extensively with HRSA, a potential key federal agency partner in a position to bring evidence-based practices to scale within healthcare services. HRSA now contains coverage for substance use and mental illness within their block grant, an important opportunity for integration of healthcare and substance use disorder care. Further integration of services is likely with healthcare reform (Buck 2011), which provides insurance coverage and training for primary care physicians and nurses and pharmacists. Thus, the large population of private practice and office-based therapists (social workers, psychologists, psychiatrists) will be paid to manage substance use disorders in these settings.
- Engage strategically with AHRQ and its networks (Practice-Based Research Network (PBRN) and Accelerating Change and Transformation in Organizations and Networks (ACTION)) to improve implementation, adoption, and diffusion of treatments for substance use disorders.
- Partner with the Food and Drug Administration (FDA) to develop drug testing and development criteria that reflect a chronic care perspective on the use of specific medications.
- Strengthen interactions with SAMHSA and co-develop strategies to improve the delivery and quality of substance use disorder treatments available to the public. Because federal reimbursement for substance use disorder services has largely been through block grant dollars administered by SAMHSA, they are a critical partner in translating and disseminating NIDA findings. To date, NIDA and SAMHSA have not produced a consistent, strong, and effective alliance which could lead to uniform translation of NIDA-based treatment research principles into SAMHSA-funded treatment centers.
- Encourage the Office of Personnel Management (OPM) to issue, within their annual "call letter", adherence to principles of effective treatment.

A Major Legal Barrier: 42 CFR Part 2

Although not part of its charge, the Workgroup notes that a critical factor affecting the implementation of NIDA interventions is 42 CFR Part 2, which poses substantial barriers both to integration of substance use treatment programs to other healthcare and to integration among institutions providing medical care (*e-CFR* 2009). The 42 CFR regulations prevent physicians from accessing information about a patient's substance use history when providing healthcare, including medications, without having strong "due cause and by reporting in triplicate that this disclosure has been made." This rarely occurs in the process of providing health care. These barriers for exchanging critical information have resulted in medical error, as well as public safety problems.

Workgroup recommendations will be less effective without modification of 42 CFR Part 2 so that disclosure of any alcohol or drug use treatment or diagnosis made by a treatment program could be more readily accessed by healthcare providers. This federal regulation, originally introduced in the early 1970s in response to federal drug enforcement raids of methadone maintenance clinics to access data for criminal prosecutions (Lewis 1976), predates current research that provides clear evidence for the benefits of integrating health care information. Further, many of the protections (e.g., removal of pre-existing conditions) that have come with the Affordable Care Act (DHHS 2012) are responsive to the concerns about having substance use disorder diagnoses in medical records. Resolving the barriers imposed by 42 CFR Part 2 could significantly facilitate the implementation of substance use treatment interventions into practice.

III. ASSESSMENT OF NIDA'S CURRENT RESEARCH PROGRAMS

Division of Epidemiology, Services and Prevention Research (DESPR)

The DESPR materials and presentations offer lessons learned and reflect strategic and innovative thinking and "real world" examples that can be significant contributors to the end products Dr. Volkow sought in framing the Workgroup's charge. A small segment of DESPR's portfolio is dedicated to implementation-related work: 26 out of 328 grants in the past seven years have focused specifically on dissemination and implementation (with some studying dissemination rather than implementation). DESPR is the locus of the Criminal Justice-Drug Abuse Treatment Studies (CJ-DATS) program, which has been innovative with regard to approaches to implementation. The Division also has made some strategic collaborative efforts toward integrating its research and evaluation efforts with other federal agencies.

DESPR's approach of encouraging researchers not only to identify specific facilitators and barriers for implementation but also to explore approaches to integrate facilitators and circumvent barriers as intermediate outcomes is notable. For example, DESPR promotes research that addresses if and how various business practices, service delivery models, coordination and integration of care, and screening and referral processes can improve treatment delivery and retention. Evaluation and assessment of these approaches will inform the process as NIDA establishes guidelines and standards for treatment development that consider the implementation potential of an intervention (Recommendation 2). With the exception of CJ-DATS and some co-funding of research with SAMHSA, on the whole, DESPR's portfolio has not included many studies that involve "systems" in implementation or dissemination. DESPR's experiences will inform the proposed entity in the Director's office (Recommendation 1), and there is also expectation that DESPR's mission-related efforts and portfolio will benefit from that same entity.

It appears that DESPR's mission, and generally the missions of other NIDA units, are detrimentally impacted by organizational boundaries within NIDA. For example, research supporting treatment development and efficacy testing is organizationally separated from health services research. Organizational barriers may curb developing integrated lines of research and constrain researchers to narrow borders, thus increasing the probability of a delay in the development, implementation, and dissemination of the overall product, in this case a treatment for substance use disorders. The proposed entity in Recommendation 1 should also alleviate these organizational barriers.

Criminal Justice-Drug Abuse Treatment Studies (CJ-DATS)

The CJ-DATS program is an example of cross-federal agency funding with SAMHSA's Center for Substance Abuse Treatment (CSAT), National Institute on Alcohol Abuse and Alcoholism (NIAAA), Department of Justice (DJ), and CDC contributing to the CJ-DATS 1 (2002-2008) and CSAT and DJ contributing to CJ-DATS 2 (2008-2013). The overall focus of this program is to access and utilize sectors of the criminal justice system, whose clients represent a significant proportion of the overall population of persons with substance use disorders, to provide treatment that not only improves public health but also benefits public safety through reduced recidivism. CJ-DATS 2 is attempting to explore systems-level interventions and implementation strategies which will undoubtedly inform the emerging field of implementation science. The CJ-DATS approach presents a paradigm shift in its efforts to organizationally facilitate the coordination of treatment interventions and services between the criminal justice and the treatment service systems, especially considering the significant challenge of their seemingly conflicting missions and cultures. Results from CJ-DATS 2 have the potential to inform both implementation strategies and improved services and treatments for client outcomes. The CJ-DATS program is commended on all of these bases.

In CJ-DATS 2, the requirement to recruit at least one criminal justice agency partner as a co-investigator is especially noteworthy. Through this effort, nine organizational criminal justice partners share authority and decision processes. This partnership enabled the criminal justice expert to "coach" the academic expert and others about the realities of the respective justice system cultures so that improvements in interventions and implementation strategies could be achieved. This type of organizational partnership may serve to promote both acceptance of evidence-based interventions/practices as the desired product and establishment of that intervention/practice as a funding standard, so that evidence-based interventions are sustained despite the changes in organizational leadership that occur over time.

Division of Clinical Neuroscience and Behavioral Research (DCNBR)

DCNBR supports research on clinical neuroscience, brain and behavioral development and behavioral and integrative treatment. A major focus of the Division is on translational science, specifically translation of basic and clinical neuroscience research to develop and test novel substance use disorder treatments in a clinical research setting. Within this Division, the Behavioral and Integrative Treatment Branch supports research on all phases of development of behavioral treatments, from development and pilot testing to efficacy and effectiveness evaluation. The potential to link clinical neuroscience research on the brain substrates of substance use disorder core components (e.g., cue reactivity, response inhibition) with intervention development within the same Division is viewed as an organizational strength. Efficacious substance use disorder treatments for adolescents supported by DCNBR include multi-systemic therapy and multi-dimensional family therapy as well as several additional behavioral, cognitive-behavioral, and contingency management approaches. For adults, contingency management approaches and various cognitive-behavioral therapies have been shown to be efficacious.

The Division has developed a stage model framework for behavioral intervention development which has been adopted by some NIDA treatment researchers. However, some of these behavioral treatment interventions can be costly and are labor intensive for clinicians. While the work in this Division is commendable, the Workgroup emphasizes the need to develop an increased focus within the Behavioral and Integrative Treatment Branch on interventions that have greater potential portability to varied health care settings. Moreover, careful consideration of implementability of proposed interventions should be a consideration in funding, regardless of the priority score of an application (Recommendations 2 and 4). This shift in emphasis is crucial for NIDA-funded behavioral treatment research to be more widely adopted in a sustainable manner in real world treatment settings.

Division of Pharmacotherapies and Medical Consequences of Drug Abuse (DPMCDA)

DPMCDA includes a successful Medication Development Program. The grants and contracts portfolio for DPMCDA includes multiple therapeutic strategies for a variety of substance use disorders. The process begins with the identification of novel molecular targets and molecular entities. It proceeds from *in vitro* testing, through preclinical *in vivo* testing, to clinical trials in pursuit of FDA approval, with sound "go-no go" decision trees. Studies at all stages of the pipeline are supported, and the process is not always linear. Within the past seven fiscal years, eleven new grants and/or contracts have supported the testing of new molecular entities. However, because the length of the typical drug development cycle exceeds ten years, none of these new molecular entities has yet entered Phase III trials. Between fiscal years 2005 and 2011, DPMCDA funded 156 research grants and six contracts to support Phase II and Phase III trials for medications for substance use disorders.

To date, NIDA has been involved in the development of buprenorphine (and various formulations), levacetylmethadol (LAAM), naloxone, and naltrexone for opiate use disorders. Currently, the Division is also interested in the repurposing of existing "de-risked" medications that either failed for other indications or have been parked due to funding or programmatic considerations. This year, it is expected that two supplemental new drug applications (sNDA) will be filed with the FDA. These supplements are filed to change a label (to include a new patient population), market a new dosage or strength of a drug, or change the way a medication is manufactured. If a new patient population (e.g. a substance using population) is added to a FDA label of an already marketed medication, it validates the treatment such that it qualifies for reimbursement by insurance companies and other third party payers. DPMCDA also supports safety and efficacy studies of approved medications in a variety of populations, such as adolescents, HIV/AIDS-positive individuals, and other groups with medical or psychiatric co-morbidity.

The Workgroup recognizes the many challenges in developing medications: 1) Few pharmaceutical firms are interested in engaging in research and development in this area. In order for a firm to develop medications for this population, it needs to mitigate the risk that illegal drug use may potentially increase the number of adverse effects reported and thus "contaminate" the medication label. 2) Clinical trials with addicted individuals and individuals with psychiatric co-morbidity can be particularly challenging due to retention, safety and other practical issues. 3) Drug-drug interaction studies during clinical trials may require administration of illicit drugs to a population vulnerable to relapse. 4) The FDA standards for approving a substance use disorder medication often require new medications to produce sustained abstinence, often following cessation of the medication, at a 6-month follow-up. Many pharmaceutical companies consider this criterion onerous and a reason to avoid research and development for this class of drugs. 5) The required initial investment for research and development by a pharmaceutical firm can be a barrier, particularly for conditions with a small market (e.g. heroin addiction). Requirements for provision of services for substance use disorders, through the Affordable Care Act and the Mental Health Parity and Addiction Equity Act, may greatly expand markets for substance use medications and interventions.

Notwithstanding these obstacles, the Workgroup is encouraged by two important new initiatives: 1) studies to assess the beneficial health outcomes associated with reductions in drug use; and 2) studies to develop and validate markers of medication compliance. The Workgroup also learned that DPMCDA is working with the FDA to have NIDA become a holder of sNDAs. The Workgroup commends DPMCDA for building a robust scientific program with significant clinical and public health impact and for explicitly endorsing real-world adoption as a central metric by which DPMCDA's efforts should be evaluated. Given the need to increase approved substance use disorder medications, several members of the Workgroup commented that the Division's budget may be too small. Efficacious medications for substance use disorders are crucial for translating evidence-based treatments to medical practice settings.

The Workgroup notes that DPMCDA does not routinely use the CTN for clinical trials with medications, despite the CTN programs being designed to specifically engage and facilitate medications testing. While it is beyond the scope of this report, the reasons for this disengagement are not clear and require further scrutiny.

Clinical Trials Network (CTN) and Blending Initiative

The CTN is a cooperative network of treatment researchers and community-based service providers created to validate, refine and deliver new treatment options to patients in community treatment programs. This partnership between academic leaders and community treatment providers is designed to study behavioral and/or pharmacological treatments in community settings. The CTN has undergone a series of significant changes since it was created. The CTN has increased the representativeness of subjects and providers. It is positioned to study efficacy and

effectiveness of medications and psychosocial interventions within individual programs. A perusal of completed and pending studies reflects both CTN's achievable goals for efficacy/effectiveness research and CTN's limitations for advancing implementation of evidence-based practices.

Although CTN partnerships between academic leaders and community treatment providers are designed to develop studies that can be transferred into practice, the CTN's structure, consisting of discrete programs, is not able to investigate the full spectrum of barriers to "real-world" implementation and dissemination that are related to systems (see Recommendation 2). Implementation and services research extend well beyond effectiveness research, because decisions about adopting interventions are typically made at the level of the system of which they are a part, and are also made with feasibility in mind. In a healthcare system, the stakeholders may include health plan administrators, clinicians, consumers, and purchasers of services (primarily employers), and the factors that can influence the rate and likelihood of adoption (attributes of the treatment, training, implementation costs, availability of and acceptance by change agents, assessment of practitioner attitudes, competence, workload, incentives, fidelity, and sustainability) are not readily measurable in the CTN infrastructure.

Specialized knowledge and skills are required to investigate system level barriers, potential facilitators and mechanisms to position an intervention within widely varied clinics or specialty programs. Such research must consider multiple factors, beyond patient response, for usefulness and adoptability. These factors include type of staffing, scheduling, individual versus group, "fit" with the resources available in the clinic, training requirements, time involved, acceptability to purchasers of the service, cost and coordination of care and investigation of reasons for resistance to change and mechanisms to surmount resistance to change. Thus, reconstituting the CTN to include public or private primary care clinics within its network is not an adequate solution for developing a structure to investigate implementation research. Underscoring this, most of the treatments shown effective by the CTN have not been adopted in the health care system; indeed many have not even been adopted in the very CTN specialty treatment programs that helped evaluate them.

The Blending Initiative, now a CTN responsibility, brings NIDA staff and researchers together with clinicians to disseminate information on evidence-based practice. Despite funding limitations, a number of large, well-attended conferences have been organized under this initiative. The initiative also produces educational products (e.g., publications, ATTC trainings) that facilitate the use of science in clinical practice. The initiative also partners with state-level organizations for the purposes of improving practice. All of these activities have some intuitive appeal, but the Workgroup notes that none has been rigorously evaluated for impact on practices or expansion of implementation.

Overall, the CTN may be succeeding in its original goals, in efficacy and effectiveness research, but in the view of the Workgroup, it was not positioned to conduct system-level implementation research nor can it be repositioned or reorganized to do so, given its history, structure and personnel.

Office of Science Policy and Communications (OSPC)

One of NIDA's missions is to ensure rapid and effective dissemination of NIDA research results, and the Office of Science Policy and Communications (OSPC) supports this effort by generating and disseminating publications, such as reports and communications about treatment, to targeted audiences, such as teenagers, the healthcare industry, and the criminal justice system. OSPC is increasingly using targeted websites, such as the easy-to-read website for those with low scientific literacy, and social media (e.g. FaceBook, Twitter, and YouTube) to increase its outreach. OSPC has also helped NIDA develop its newly revamped main website, www.drugabuse.gov.

OSPC coordinates the development of NIDAMED, a web-based outreach to clinicians and other healthcare professionals, which incorporates NM-ASSIST, an interactive screening tool for screening and brief intervention (SBI) techniques. Since its 2009 launch, innovations such as inclusion of a quick-screen option, in addition to the full NM-ASSIST, have increased the number of SBI sessions completed. NIDAMED also is part of the Addiction Performance Project, a continuing medical education (CME) program aimed at overcoming common biases physicians have about drug abuse. There are currently six NIDA-developed CME curricula available on AAMC's MedEd portal. There are plans in place to develop CME modules, in conjunction with Medscape, on safe prescribing for pain and on managing patients who abuse prescription drugs, developing a mobile application (app) version of NM-ASSIST for use on smart phones and notebooks, and creating an application programming interface so that existing apps can access and use NIDAMED resources.

While OSPC products and efforts are scientifically grounded and informative, there are some major challenges. It appears that much of the public is not sufficiently aware of the resources available from NIDA. It would be worthwhile to assess which of NIDA's informational resources (including their website) are being effectively utilized and by which communities. Further, much of the information developed by NIDA is targeted for physicians, physician assistants, or nurses. However, in order to implement change in policies, procedures, or practice, those who need to be targeted are administrators, insurers (medical malpractice insurers), and decision makers. NIDA may benefit from a plan for dissemination of materials to these key players.

In efforts to inform and facilitate the medical community in identifying, treating, and referring patients with substance use disorders, OSPC only has anecdotal information about the adoption of the NIDAMED SBI tools and no web-based feed-back provisions for users. Also, the NM-ASSIST does not include information on where to get specialty treatment and on criteria for effective treatment (although the accompanying resource booklet for clinicians who use the screening tool provides information including links to treatment sources). Thus even if a physician identifies a patient needing treatment, it is still a tremendous challenge for that physician to easily discern what type of treatment might be most beneficial for that patient and where he/she might obtain that treatment. This problem is not limited to the NIDAMED website; navigation of the general NIDA websites by physicians is challenging and few in the healthcare community, other than substance use disorder professionals, are aware of NIDA's products. There needs to be a thorough and independent evaluation about the utility of the NIDAMED website with ample opportunities for customer feedback and marketing for the application to be effective and user friendly. Again, as with the Blending conference, these activities have some intuitive appeal, but the Workgroup notes that none has been rigorously evaluated for impact. Further, there is concern that NIDAMED will not be implemented in health care settings because it is simply too lengthy. This is a problem that will greatly limit the value of NIDAMED.

It also seems that differences in philosophies and approach to treatment between SAMHSA and NIDA prevent NIDA and SAMHSA from working together effectively to achieve goals that are in the interest of both agencies. SAMHSA approaches treatment with a more consensus basis while NIDA takes a stronger scientific approach. Given SAMHSA's visibility within the substance use disorder and mental health community, it would be optimal for NIDA to more effectively collaborate with SAMHSA to prepare shared documents and dissemination plans to promote effective implementation of substance use treatment strategies among their shared community.

IV. RECOMMENDATIONS

The review and analysis of the relevant scientific literature and of NIDA's units that house relevant research formed the basis of the Workgroup's recommendations. As per the charge, the Workgroup focused on the adoption of NIDA's evidence-based treatments. Five key Workgroup recommendations are presented below, and the following description and definition of the term "implementation science" was used by the Workgroup in developing those recommendations:

*"Biomedical, social science, organizational and managerial research constantly produce new findings – but often these are not routinely translated into health care practice. Implementation research [science] is the study of methods to promote the systematic uptake of proven clinical treatments, practices, organizational and management interventions into routine practice, and hence to improve health. In this context, it includes the study of influences on patient, healthcare professional, and organisational behaviour in either healthcare or population settings.The lack of routine uptake is strategically important for the development of healthcare as it clearly places an invisible ceiling on the potential for research to enhance health" (*Implementation Science™ 2012).

Recommendation 1: Create a New Entity for Translation and Implementation Science Within NIDA to Help Bring Its Scientific Findings on Treatment Efficacy Into Broad Practice

Rationale: Translating scientific findings into broadly applied treatments and services will require expertise beyond the skills needed to develop and test clinical, behavioral and pharmacological interventions. Recognizing the importance of factors other than the basic research and clinical trials currently supported by NIDA in determining which interventions are ultimately adoptable in practice settings, the Workgroup notes that it is critical to create a new entity within NIDA which will lead translation and implementation science. This is essential in order to create pharmacologic and behavioral interventions which are widely adopted and sustained. The specific goals and action items listed below apply not only to existing "implementable" interventions, but also to evidence-based interventions that may be "rescued" and adapted to increase portability and to interventions that are developed in the future.

The specific goals and functions of this new organizational entity should include the ability to:

1. Engage NIDA staff, other government agencies, policy-makers and other stakeholders (e.g., treatment providers, insurers, and businesses) to assist NIDA in bringing its findings into broad practice, including development of a strategic plan for implementation science.
2. Oversee the development of criteria for the evaluation of addiction treatments at very early stages of development to ensure adoption and sustainability in practice (see Recommendation 2).
3. Design a funding opportunity announcement (FOA) for systems-based implementation science networks (see Recommendation 3).
4. Advise the NIDA Director and train relevant NIDA staff on ways to incorporate implementation considerations into funding and internal policy decisions.
5. Oversee NIDA's outreach and education functions, materials development and dissemination (functions currently within OSPC), and the Blending Initiative.
6. Establish a panel to identify factors that interfere with expansion of screening, brief interventions, brief treatment and referral to treatment services in healthcare systems and to recommend strategies to fill these voids.
7. Leverage existing partnerships and cultivate new partners for co-development, co-branding and co-funding of addiction treatment interventions which are more likely to be implemented. Relevant federal agencies include CDC, HRSA, CMS, Veterans Affairs (VA), and the

Department of Defense (DoD). Other relevant partners could include state healthcare and health insurance agencies; as well as private insurers, self-insured companies and Human Resources departments, as well as performance measurement and accreditation organizations, such as the NQF, the Commission on Accreditation of Rehabilitation Facilities (CARF) and the Joint Commission. Consider also the involvement of private foundations that focus on health care and behavioral health issues, such as the Commonwealth Fund, Kaiser Family Foundation, Pew Charitable Trusts, and the Milbank Memorial Fund.

8. Serve as a resource for investigators to facilitate design of addiction treatment interventions that are scalable and sustainable.

Action Items:

- Recruit a new Implementation Science leader for this entity from outside of NIDA who will report directly to the NIDA Director.
- Establish a taskforce of researchers and other stakeholders and charge them to guide, monitor, and evaluate the functions of this new entity.
- Allocate adequate resources for this activity.
- Ensure that implementation is understood by, and is an incentivized part of performance for, leaders across the institute.
- Establish an ongoing Council subcommittee to provide oversight and monitor progress of this entity.
- Ensure the sustainability of the new entity within the new NIH Institute for substance use research, should a new Institute be created. This could be encouraged by NIDA leadership educating NIH leadership involved with the restructuring efforts about the importance of this new entity for addressing the unique systems of, and approaches to, care of persons with substance use disorders versus those with other chronic medical conditions.
- Continue to manage the portfolios for most implementation science grants through NIDA's current divisions, particularly DESPR, and establish an internal process for evaluation of this new entity through the Office of Extramural Affairs.

Recommendation 2: Establish NIDA Guidelines for Funding Consideration of Treatment Development Research Projects that Consider the Potential for Implementation, Adoption, Scalability, and Sustainability in Various Practice Settings

Rationale: NIDA has supported world-class research on treatment development and efficacy testing. However, some interventions that have strong scientific support have little or no chance of being adopted in the real world, in part because there has been insufficient consideration of implementation potential. If any intervention costs many times more than what any purchaser will pay, it does not matter if it has been supported in clinical trials. Likewise, if it requires extremely costly and elaborate training to deliver a treatment coupled with extensive and enduring monitoring of the provider, the treatment will rarely be adopted, regardless of its efficacy. There is a need to move beyond incremental science in treatment development to innovations that ensure that NIDA's treatment portfolio can be utilized broadly by practitioners and health systems.

Toward that end, the workgroup proposes that operational standards be established for NIDA to increase the likelihood of adoption and sustainability. For example, specific standards for treatment development may include expertise in cost-benefit analyses for procedures in various health-care settings and expertise in commercial large-scale behavioral change such as advertising, marketing and human engineering. Specific evaluation metrics to be applied within a research application may include the number of sites or practices implementing targeted behavioral treatments or medications, number of physician-hours or behaviorist-hours, costs of training required for

implementation, and feedback from "front-line" providers as to the ease and feasibility of incorporating the practice into routine care.

This recommendation is especially germane to complex or intensive non-pharmacological interventions that may have limited reproducibility in, or portability to, clinical practice settings. It is relevant across NIDA's Division of Clinical Neuroscience and Behavioral Research (DCNBR) program, as well as in the CTN's program of research.

Action Items:

- Establish a NIDA Task Force to create a white paper outlining specific standards and evaluation criteria for substance use disorder treatment development and efficacy testing, with a focus on adoption, scalability, cost-effectiveness, and sustainability in diverse practice settings. Include outside business experts, implementation science experts, purchasers, regulatory agencies such as NQF and the National Committee for Quality Assurance (NCQA), primary care providers, and other stakeholders.
- Consider including representatives and findings of the National Business Group on Health (http://www.businessgrouphealth.org/) whose members are primarily Fortune 500 companies and large public sector employers, including the nation's most innovative health care purchasers) who provide health coverage for more than 50 million workers, retirees and their families. Among their initiatives is an Institute on Health Care Costs and Solutions, a National Committee on Evidence-based Benefit Design, and a Pharmaceutical Council.
- Provide a comprehensive, integrated analysis of each NIDA unit involved in treatment research to serve as background for the Task Force in its development of a white paper.
- To ensure transparency and to impact on NIDA's treatment research, disseminate this white paper to staff and the scientific community, including potential applicants and reviewers.
- Give funding priority to those applications which most strongly provide evidence that they will succeed in implementation, adoption and/or sustainability of treatment.
- Incorporate links to this white paper for each applicable funding opportunity.

Recommendation 3: Establish Systems-Based Research Networks within Naturalistic Settings to Evaluate Intervention Effectiveness, Adoption and Sustainability in Practice

Rationale: The NIDA Clinical Trials Network (CTN) has been highly effective for efficacy and effectiveness testing in addiction treatment programs, with a significant impact on the substance use disorder field. However, with the passage of the Affordable Care Act, there will be fundamental changes in primary care settings for the delivery of substance use disorder screening, referral, and treatment. As addressed above, the structure and staffing of the CTN are not consistent with what is required to evaluate the implementation and sustainability of treatments in healthcare and related systems.

It is critical that systems-based research networks be established to evaluate adoption, scalability, sustainability and cost-impact of substance use disorder treatments. Settings include public and private health systems (e.g. primary care, emergency rooms, and disease management/chronic care programs), mental health systems, and county, state and other government structured addiction treatment program systems with and without significant academic linkages. The Workgroup envisions a range of research networks which would be made up of systems. This is consistent with the approach being used by other NIH institutes, including the National Heart, Lung and Blood Institute (NHLBI), NCI, and National Institute of Mental Health (NIMH). The new network platforms should be accessible to "non-network members" for implementation science research, with a transparent process for application and funding of concepts.

Research conducted through the proposed infrastructure should include the following: studies of dissemination of evidence-based interventions; rigorous evaluation of medication and behaviorally-oriented treatment effectiveness, scalability, adoption, sustainability, and cost-impact; assessment of short- and long-term treatment outcomes, such as medical and psychosocial consequences, and societal impacts (e.g., education, work force, public safety, and cost impact); evaluation of generalizability to diverse settings and populations; and identification of individual patient differences in treatment benefit and risk.

To ensure the sustainability of treatment delivery in these settings, the Workgroup proposes that NIDA funds support infrastructure for training, data collection and analyses, as other NIH institutes have done.

Action Items:

- Support extant networks that shift their emphasis from traditional addiction treatment programs to include other systems and networks, such as Federally Qualified Health Centers (FQHCs), the HMO Research Network, employee assistance programs (EAPs), Accountable Care Organizations, and/or HRSA sites, Indian Health Services.
- Consider states with impressive service networks and overall health initiatives, such as North Carolina with its legislatively supported Institute of Medicine ties (NCIOM 2009) and CMS-approved structures (see http://www.ncdhhs.gov/mhddsas/providers/CABHA/index.htm) and Vermont with its "Blueprint for Health". In order to identify new ideas and practices, for nine years now, Vermont is among the most innovative health efforts in the country, and it involves community health teams working with primary care providers to improve patient access to behavioral health, chronic care management, and social services support (Bielaszka-DuVernay 2011).
- Include novel underutilized resources/settings such as health plans' pediatrics and adolescent medicine or departments, college campuses, and EAPs.
- Encourage and support the development and testing of novel, but practical and implementable, web-based and telephone-based interactive screening approaches, referral strategies, reminder systems, and treatment and booster interventions, including recovery-oriented practices.
- Ensure that networks address effectiveness, adoption, scalability and sustainability of substance use disorder treatments.
- Ensure that networks are formed as needed for a limited period of time by creating a plan to evaluate the networks for renewal or phasing out.

Recommendation 4: Target Funding to Expand the Grant Portfolio for Implementation Science

Rationale: As noted previously, only a fraction of NIDA's evidence-based treatments are currently being utilized in practice settings. To bridge the significant gap between treatment-related science and implementation in practice, it is essential to establish a knowledge base about the ways evidence-based substance use disorder treatments are being utilized in practice settings and systems as well as about the optimal methods to promote adoption into healthcare policy and practice – this is essentially the operational definition of Implementation Science. Toward this end, the Workgroup proposes that NIDA encourage and increase support for empirical studies to evaluate methods to implement substance abuse treatments to ensure broad-based use and sustainability in practice.

This recommendation refers to research projects, rather than infrastructure, with the proposal that this portfolio of implementation science grants continue to be managed through NIDA's current divisions, particularly DESPR.

Action Items:

- Establish an ongoing forum for researchers and stakeholders to identify important topics for additional FOAs. These could include evaluating clinical decision support tools, understanding health care systems factors in adoption, implementation science trials to evaluate best practices to translate effective interventions, research to evaluate intervention impact on long-term outcomes, and cost-impact of substance use disorder treatments.
- Ensure that NIDA Council has an oversight role in reviewing concepts prior to FOA publication and in monitoring progress with these efforts.
- Ensure transparency of specific criteria that applicants, reviewers, and NIDA staff will utilize in the submission, review, and funding process.
- Develop a plan to seek co-funding by other NIH institutes (NIMH, NCI, etc.), federal agencies (e.g., VA, SAMHSA, CDC), and non-federal partners.

Recommendation 5: Establish a Recurring NIDA-Based Peer Review Panel Charged with Evaluating Research Applications that Focus Specifically on Advancing Rapid Adoption of Evidence-Based Interventions

Rationale: Most research applications submitted to NIH are reviewed by the Center for Scientific Review (CSR), the appropriate venue for reviewing standard applications of interest to the various Institutes from basic science to clinical research. However, the Workgroup is proposing the development of a specific science of rapid translation and adoption of evidence-based findings for drug use disorders. Appropriate review for this type of science will necessitate a critical mass of reviewer expertise in the complexity and unique challenges of the substance use disorder treatment system. Reviewers will need to appreciate that the substance use disorder treatment system is more complex than the treatment systems for most other chronic diseases. Further, reviewers will need expertise different from what is typically needed to assess more standard treatments and interventions. How is it possible to best to identify, orient and bring reviewers into this new program? The Workgroup believes that the best way to develop an implementation science portfolio (Recommendation 4) and reviewers with the expertise to review applications submitted for this portfolio will be to house the review within NIDA itself. The challenge is to ensure that program, review and grants management staff work in concert to develop this program so that there is, from the inception, a shared understanding of the goals of the program and the optimal ways to reach those goals, including obtaining appropriate review expertise. Housing the review within NIDA will permit this essential joint conceptualization, planning, and development of the Program. All professional staff within the Institute are involved in the Institute's strategic and scientific planning. Thus, Institute-based review staff are uniquely poised to function in alignment with the Institute's goals, more knowledgeable about nuances in the field than would be expected of review staff at CSR who review applications from many different Institutes, and therefore better able to ensure that reviewers with appropriate expertise are identified, recruited, oriented and able to provide the rigorous reviews needed to ensure that this new portfolio contains the most innovative and rigorous approaches to adoption/implementation science.

Action Items:

- Identify the stakeholders who must be involved in successful portfolio development (e.g., potential applicants, potential reviewers, various constituency groups, program, review and grants management staff at NIDA, other federal agencies/staff) and ensure that there is consistency and transparency for all concerning program development.
- Convene workshops of representatives from various scientific communities, constituency groups and agencies to gather further input into the development of new funding opportunity announcements that promote broad adoption of interventions, improve sustainability and

scalability. Ensure that program and review staff are involved in developing and evaluating these activities.

- Ensure that program, review and grants management staff work together to conceptualize, plan, and develop funding opportunity announcements that promote implementation science. NIDA must speak with a single voice as to the purposes, development, review and support of this portfolio.
- Ensure that the new funding opportunity announcements are compliant with NIH guidelines, policies, and practices while also adopting and adding review and other criteria consistent with programmatic needs.
- Develop application review criteria to include implementability. Include reviewers on grant review panels who understand the world of practice and can evaluate implementation science.
- Given that these applications will focus on new paradigms and new science, employ as needed a wide range of grant proposal evaluation strategies, such as applicant interviews and/or site visits.

V. CONCLUSION

NIDA's continued support for the development of new behavioral and medication treatments for substance use disorders is essential and laudatory. Based on the charge of the Workgroup, it is clear that NIDA comprehends the importance of supporting quality treatment research that can be adopted, implemented, scaled and sustained in mainstream treatment settings. Objective data indicate that evidence-based principles of effective treatments have had limited acceptance and adoption by treatment providers on a national scale. NIDA has begun to support research on how evidence-based substance use disorder treatments are being used in practice settings and systems. Fundamental changes in the substance use disorder treatment delivery system brought about by the passage of the Affordable Care Act and other legislative actions reinforce the critical need to engage systems-based research networks in studies to evaluate the potential for adoption, scalability, acceptability, sustainability and cost-impact of substance use disorder interventions. As a research institute, NIDA is uniquely positioned to support treatment research that considers and incorporates analyses of the multiple factors that enable utilization beyond the constraints of clinical trials. This report encourages NIDA to develop a systems approach, based on its research mission, which can facilitate surmounting the barriers to adoption of effective treatments in practice settings. It summarizes our recommendations to advance these goals by developing new initiatives within the structure of NIDA and by engaging appropriate stakeholders (e.g. end-users, policy-makers, third party payers, etc.) and partners to identify elements of interventions that increase acceptability and utilization. The formations of this research framework and of an Institute-based peer review panel to provide review of this evolving science are deemed essential. In conclusion, it is the view of the Workgroup that, if implemented, the recommendations in this report will expedite and advance NIDA's efforts to increase the utilization of NIDA-supported treatments within the variety of settings and systems of care that provide treatment for substance use disorders.

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APPENDIX A: ADOPTION OF NIDA'S EVIDENCE-BASED TREATMENTS IN REAL WORLD SETTINGS WORKGROUP MEMBERS

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APPENDIX B:
ADOPTION OF NIDA'S EVIDENCE-BASED TREATMENTS IN REAL WORLD SETTINGS COUNCIL REVIEW WORKGROUP MEETING,
FEBRUARY 13-14, 2012

National Institute on Drug Abuse
Adoption of NIDA's Evidence-Based Treatments in Real World Settings Workgroup

Forest Glen Room
Bethesda North Marriott
Bethesda, Maryland
February 13 - 14, 2012

AGENDA

Monday, February 13, 2012

9:30 – 10:00 a.m.	**Registration**
10:00 – 10:15 a.m.	**Welcome, Introductions, Purpose of Meeting** *Caryn Lerman, Ph.D. (Workgroup Chair)* *Mary W. Calkins Professor of Psychiatry* *University of Pennsylvania*
10:15 – 10:45 a.m.	**Workgroup Charge** *Nora D. Volkow, M.D.* *Director* *National Institute on Drug Abuse (NIDA)*
10:45 a.m. – 12:30 p.m.	**Overview of NIDA, NIDA's mission, and NIDA's Evidence-Based Treatments** *David Shurtleff, Ph.D.* *Acting Deputy Director* *National Institute on Drug Abuse (NIDA)*
12:30 – 1:30 p.m.	***Working Lunch/Workgroup Discussion*** **Workgroup Discussion** • Review Key Issues • Identify Additional Information Needs from NIDA • Identify Additional Information Needs from outside NIDA
1:30- 2:30 p.m.	**NIDA's Evidence-Based Behavioral Treatments** *Joseph Frascella, Ph.D.* *Director, Division of Clinical Neuroscience and Behavioral Research*

NIDA

2:30- 3:30 p.m. **NIDA's Pharmacotherapies Research Program**
Phil Skolnick, Ph.D., D.Sc. (hon.)
Director, Division of Pharmacotherapies and Medical Consequences of Drug Abuse
NIDA

3:30-3:45 p.m. **Break**

3:45- 4:45 p.m. **NIDA's Criminal Justice-Drug Abuse Treatment Studies (CJ-DATS) Program**
Redonna Chandler, Ph.D.
Chief, Services Research Branch, Division of Epidemiology, Services and Prevention Research
NIDA

4:45- 6:00 p.m. **Workgroup Discussion**
- Review Key Issues
- Identify Additional Information Needs from NIDA
- Identify Additional Information Needs from outside NIDA

6:00 p.m. **Adjourn for Day 1**

Tuesday, February 14, 2012
8:00 a.m. – 12:00 p.m.

8:15 – 9:00 a.m. **NIDA's Blending Initiative/Conferences**
Betty Tai, Ph.D.
Director, Center for the Clinical Trials Network
NIDA

9:00 – 10:00 a.m. **NIDA's Clinical Trial Network as a Platform for Disseminating and Implementing Evidence-Based Treatments**
Betty Tai, Ph.D.

10:00-10:15 a.m. **Break**

10:15-11:15 a.m. **Dissemination, Implementation, and Adoption of Evidence-Based Treatments and Barriers**
Wilson Compton, M.D., M.P.E.
Director, Division of Epidemiology, Services and Prevention Research
NIDA

11:15 a.m. – 12:00 p.m. **Workgroup Discussion**
- Review Key Issues
- Identify Additional Information Needs from NIDA
- Identify Additional Information Needs from outside NIDA

12:00 p.m. **Adjournment**

APPENDIX C:
ADOPTION OF NIDA'S EVIDENCE-BASED TREATMENTS IN REAL WORLD SETTINGS COUNCIL REVIEW WORKGROUP MEETING, WORKGROUP SUBCOMMITTEES' CALLS

Call Date/Time	Agency	Agency Contact(s)	Workgroup Members	NIDA's Designated Federal Official(s)
March 27, 2012/ 1:00 PM ET	National Quality Forum (NQF)	Heidi Bossley Angela Franklin	Connie Weisner Caryn Lerman	Meena Hiremath
March 30, 2012/ 3:30 PM ET	National Cancer Institute (NCI)	Russell Glasgow	Caryn Lerman Bertha Madras	Meena Hiremath
April 5, 2012/ 3:00 PM ET	Aetna (HMO)	Hyong Un	Tom McLellan Connie Weisner	Meena Hiremath
April 20, 2012/ 2:30 PM ET	AHRQ	Carolyn Clancy	Junius Gonzales Bertha Madras	Meena Hiremath Teri Levitin
May 2, 2012/ 1:00 PM ET	SAMHSA	Pamela Hyde Peter Delany Michael Etzinger Kevin Hennessy Anne Herron Sharon Larson Charles Reynolds	Keith Humphreys	Meena Hiremath Teri Levitin

APPENDIX D:
ADOPTION OF NIDA'S EVIDENCE-BASED TREATMENTS IN REAL WORLD SETTINGS COUNCIL REVIEW WORKGROUP MEETING,
MAY 8-9, 2012

National Institute on Drug Abuse (NIDA)
Adoption of NIDA's Evidence-Based Treatments in Real World Settings Workgroup

Linden Oak Room
Bethesda North Marriott
Bethesda, Maryland
May 8 – 9, 2012

AGENDA

Tuesday, May 8, 2012

9:30 – 10:00 a.m.	**Registration**
10:00 – 10:15 a.m.	**Welcome, Introductions, Purpose of Meeting** *Caryn Lerman, Ph.D. (Workgroup Chair)* *Mary W. Calkins Professor of Psychiatry* *University of Pennsylvania*
10:15 – 11:00 a.m.	**NIDA's Office of Science Policy & Communications** *Gaya Dowling, Ph.D.* *Acting Branch Chief, Science Policy Branch, Office of Science Policy & Communications* *NIDA*
11:00 a.m. – 12:00 p.m.	**National Institutes of Health HMO Networks** *David Chambers, Ph.D.* *Associate Director, Dissemination and Implementation Research and Chief, Services Research and Clinical Epidemiology Branch*
12:00 – 12:15 p.m.	***Break***
12:15 – 1:00 p.m.	***Working Lunch: Discussion of Morning Presentation***
1:00 – 3:30 p.m.	**NIDA Workgroup: Refine Set of Recommendations**

3:30 – 3:45 p.m.	***Break***
3:45 – 6:00 p.m.	**NIDA Workgroup: Action Items for Recommendations**
6:00 p.m.	***Adjourn for Day 1***

Wednesday, May 9, 2012
8:15 a.m. – 12:00 p.m.

8:15 a.m. – 12:00 p.m.	**Workgroup: Additional Report Components and Future Plans**
12:00 p.m.	***Adjournment***

APPENDIX E: PRINCIPLES OF SUBSTANCE USE TREATMENT VERSUS PRACTICE

Table 1. Principles and Practices

PRINCIPLE	PRACTICE*
Addiction is a complex but treatable disease that affects brain function and behavior. Treatment must be readily available.	Addiction treatment centers are available. However, there is no reporting system that readily reports the availability or accessibility of treatment centers based on immediate specific needs.
No single treatment is appropriate for everyone.	Use of the following was reported always or often: counseling (95%); relapse prevention (85%); cognitive-behavioral therapy (64%); motivational interviewing (54%); 12-step facilitation (53%); brief intervention (34%); contingency management (25%); trauma-related counseling (21%); rational emotive behavior therapy (16%); community reinforcement plus vouchers (4.4%).
Effective treatment attends to multiple needs of the individual, not just his or her drug abuse.	Services include: substance abuse education (95%), case management (77%), social skills development (69%), mental health services (57%), HIV or AIDS education/counseling (56%), other health education (50%), mentoring/peer support (47%), self-help groups (46%), assistance locating housing (45%), hepatitis education/counseling (39%), transportation (38%), domestic violence services (36%), employment counseling (34%), early HIV intervention (25%), smoking cessation (25%), childcare (7.5%), residential beds for clients' children (3.7%).
Treatment programs should assess for infectious diseases.	20-34% Testing for TB, HIV, hepatitis B and C, STDs
Counseling (individual and/or group) and other behavioral therapies are the most commonly used forms of drug abuse treatment.	95% of facilities offer substance use counseling
Medications are important for treatment for many patients, especially combined with counseling and other behavioral therapies.	Only 8-9% of all facilities offer pharmacotherapy**.** Of those offering, these include: nicotine replacement (20%), Buprenorphine (18%), Campral (17%), Naltrexone (16%), Antabuse (16%), smoking cessation medications (15%), methadone (11%).
Many drug-addicted individuals also have other mental disorders. Treatment should address both (or all).	43% of clients had a diagnosed co-occurring substance abuse and mental health disorder; in Federal government-operated facilities, it is 62%. • 63% offer screening mental health disorders • 43% offer comprehensive mental health assessment • 57% offer mental health services • 35% offer medications for psychiatric disorders
Medically assisted detoxification is only the first stage of addiction treatment and by itself does little to change long-term drug abuse.	The proportion of facilities providing detoxification from specific substances were: opiates (84%); alcohol (68%); benzodiazepines (60%), cocaine (55%), methamphetamine (54%), other (13%). There are no reporting system requirements of seamless entry into treatment from detoxification.
Drug use during treatment must be monitored continuously, as lapses during treatment do occur.	60% of sites use breathalyzer tests; 84% perform urine drug screening.

* The 2010 N-SSATS survey (http://wwwdasis.samhsa.gov/10nssats/nssats2010web.pdf) provides the latest results from an annual census of facilities providing substance abuse treatment. In this survey, 14,060 facilities completed the survey at a 91.1% response rate. The percentages for addiction categories were: 43-46% alcohol + drugs; 35-29% drugs; 18% alcohol only. Of the facilities that responded, types and percentage of facilities included were: Private non-profit: 58%; private for-profit: 30%; Local gov: 6%; State gov: 3%; Fed gov: 3%; Tribal gov: 1%. The primary focus of these facilities was reported as: substance abuse treatment: 61%; mental health and substance abuse treatment: 31%; mental health alone: 6%; general health care: 1%. Types of care provided by these facilities were: outpatient: 81%; residential: 26%; hospital inpatient: 6%.

APPENDIX F: SCREENING, BRIEF INTERVENTION AND REFERRAL TO TREATMENT (SBIRT) AND NIDA

Although not formally part of the Workgroup's charge, and therefore not rising to the level of an independent recommendation, the Workgroup sees a strong rationale for NIDA to take the lead in developing and standardizing SBIRT protocols for illicit drug use so that they can be more readily adopted in various treatment settings.

Background: SBIRT is a comprehensive, integrated, public health approach for assessment of intensity of substance use and delivery of early intervention and treatment services for persons with substance use disorders or those at risk of developing these disorders (Madras et al. 2009; Madras 2010). Screening is an evidence-based brief questionnaire that identifies the spectrum of substance use (tobacco, alcohol, illicit drugs, and prescription drugs misuse) and severity of the problem, including adverse consequences, by proving a numerical score that guides the needed level of intervention. A brief intervention is useful for mild symptoms of substance use, as it provides feedback of the score, raises awareness of risks, and motivates and establishes goals and strategies to reduce use and related risks. Brief treatment, for individuals whose screening score indicates moderate use, is provided over several counseling sessions in general medical settings. Referral to specialty treatment centers is provided for severe symptoms or for patients with complicated psychiatric symptoms. There is evidence to support that each step within the SBIRT protocol is beneficial for reducing substance use and/or preventing progression of substance use to an increased level of severity.

Rationale: In order to successfully treat substance use disorders, it is first imperative to identify patients and populations in need of treatment. Approximately, 23.5 million people aged 12 or older have a substance use disorder, based on DSM IV criteria, and need treatment for alcohol and/or illicit drug use. Yet, almost 95% of people with substance use disorders (over 21 million people) do not realize they have a problem, and therefore do not seek treatment, and most of those that recognize their problem make no recorded effort to seek treatment. Also, the latest NSDUH survey demonstrates that past month users of illicit drugs (~ 20 million) and heavy alcohol users (~40 million) exceed the number of people (~21 million) harboring a DSM-IV diagnosis of substance abuse/addiction. Early detection and treatment of substance use is critical; data shows that the prevalence of addiction among adults who initiated drug use during early adolescence is much higher than those who initiated later than age 18 and that treatment is more challenging for those who initiated use early and have been exposed for a long period of time. Effectively integrating substance use SBIRT protocols into healthcare treatment settings can result both in earlier identification and treatment of risky substance use and substance use disorders and in quality of life improvement in these individuals through reductions in co-occurring medical and psychiatric conditions, adverse drug interactions, and improved wellbeing of patients' family members and caregivers. Societal benefits for effective implementation of SBIRT for substance use potentially include reduced healthcare costs and reduced criminal justice involvement (Smith and Larson 2003; Madras et al. 2009; Miller and Miller 2009; Madras 2010; Laudet 2011; Donovan et al. 2012; Tiffany et al. 2012a; Tiffany et al. 2012b; Uchtenhagen 2012). A lack of sufficient information and evidence related to the adequacy and effectiveness of SBIRT protocols for illicit drug use is a major impediment to mainstreaming the protocol into standard of medical care. NIDA can- and should-lead efforts to direct and support research that can satisfy this information void.

Action Items:

- Effectively partner with the United States Preventive Services Task Force (USPSTF), American Medical Association (AMA), Joint Commission, National Committee for Quality Assurance (NCQA), National Quality Forum (NQF), Joint Commission, CMS, and other relevant stakeholders (consumers, purchasers, emergency room and primary care doctors, policy

makers, representatives from health plans, etc.) to determine what data already exist that could support SBIRT measures for illicit drug use and what data/evidence still needs to be gathered so that it may be endorsed by USPSTF and/or recommended as a measure to NQF for its endorsement. Especially noteworthy are limited data on SBIRT effectiveness for populations at high risk, e.g. consumers of prescription drugs for non-medical purposes, adolescents, pregnant women, college students, and the unemployed. Challenges to implementation may also surround standardized questions and delivery time and complexity.

- Identify challenges that need to be effectively addressed to adequately promote SBIRT in healthcare settings, such as quick and efficient ways to seamlessly identify appropriate levels of treatment and treatment center locations that effectively offer needed care/treatment. Additional challenges include level of evidence to support the protocol, the reliability and validity of the protocol, utility of the protocol/measure for public reporting purposes, feasibility to perform the measure (it must be brief and easily utilized in busy primary care clinics), cost of the measure, and ability to capture it on the electronic health record (EHR). Further, in order for SBIRT to be endorsed for illicit drug use measure, there need to be clearer defined and endorsed effective treatments.
- Publish findings about the status of SBIRT for substance use, areas where there are still research needs to endorse SRIRT, and challenges for promoting SBIRT in healthcare settings in a white paper so that the public is fully aware of the research needs and limitations.
- Explore means to develop or promote medications or medication assisted treatments for substance use disorders that can be delivered in general medical office settings in order to accelerate delivery of SBIRT services within healthcare systems.
- Decipher methods or approaches to more effectively and efficiently integrate SBIRT services into community-based settings.
- Devise creative funding opportunities, with appropriate federal partners, to quickly and effectively gather information to fill the research voids for proper development and endorsement of SBIRT for illicit drugs so that it is quickly implemented and adopted in healthcare systems. Incorporate links in these funding opportunities to the white paper describing the status of the field, additionally needed research, and current challenges.
- Advance and promote the implementation and adoption of SBIRT by promoting presentations about SBIRT by NIDA staff at professional meetings and other venues so that there is increased awareness about the research needs and NIDA's priority for furthering this effort and/or increased utilization and dissemination of SBIRT in various treatment settings.