



Substance Use, Abuse, and Addiction Working Group Report and Recommendations September 15, 2010

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"... to recommend whether organizational change within NIH could further optimize research into substance use, abuse, and addiction and maximize human health and/or patient well being."



Working Group Membership

Non-Federal

William Roper, MD, MPH (Chair)

Deborah Powell, MD

Eugene Washington, MD, MSC

Huda Zoghbi, MD

Norman Augustine (ad hoc)

Federal

Josephine Briggs, MD

Richard Hodes, MD

Griffin Rodgers, MD, MACP

Lawrence Tabak, DDS, PhD

Francis Collins, MD, PhD (ex officio)



- Since April 2009, the working group has held 12 teleconferences and 3 in-person meetings and has heard from:
 - Current and former NIAAA & NIDA Directors
 - Prevention and treatment specialists
 - Patient advocates
 - Policy specialists
 - Scientists with diverse areas of expertise
 - Leaders of academia
 - Industry representatives
 - Judicial system representatives
 - NIAAA and NIDA Advisory Councils

• Emerging scientific research indicates:

- Similar reward pathways underlie compulsive behavior
- Many substances that pose the potential for abuse may have similar effects on the brain
- Common genetic sites associated with risk for disorders related to abuse
- Addiction is a developmental disease, often beginning in adolescence with common early risk factors across substances
- Many substance abusers suffer from multiple drug dependencies and/or co-morbid conditions

Research/Public Health Needs Not Currently Addressed – NIAAA Perspectives

- A compendium of the pharmacokinetic and pharmacodynamic interactions between alcohol and the therapeutics used to treat general medical and psychiatric conditions (e.g., hypertension, diabetes, epilepsy, depression, etc.)
- Research on the generation of novel metabolites resulting from the in situ interaction of alcohol with opiates, stimulants, hallucinogens, or inhalants (e.g., the production of coco-ethylene) and their pharmacokinetic and pharmacodynamic properties and toxicity
- Mechanisms by which alcohol increases risk for certain cancers
- Encouraging the hesitant patient to seek treatment

Research/Public Health Needs Not Currently Addressed – NIDA Perspectives

- Lack of pharmaceutical industry interest in developing medications to treat addiction/alcoholism
- Insufficient involvement of the medical community in preventing and treating drug addiction and alcoholism
- Although treatments for substance abuse are available, they are not being widely used by those who need them
- There is a bottleneck in translating treatments for substance abuse from bench to bedside to the community

Summary of Findings: Stakeholder Perspectives

- Arguments in favor of structural reorganization
 - Scientific synergies
 - Underserved patient populations
 - Impediments to collaboration and integration

- Arguments in favor of nonstructural reorganization
 - Potential loss of research
 - Establishment of a research dogma
 - Examples of current, successful collaborations
 - Licit vs. illicit substances

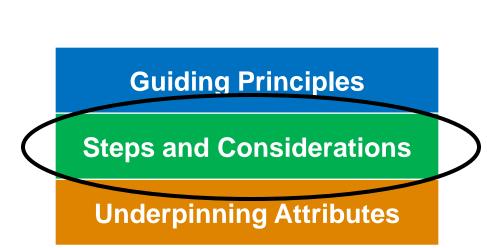
Deliberative Process: Framework

(DOCE Process for Considering Change)

• **STEP 1**:

Assess the need for change

- STEP 2: Evaluate options for change
- STEP 3: Implement and navigate the change



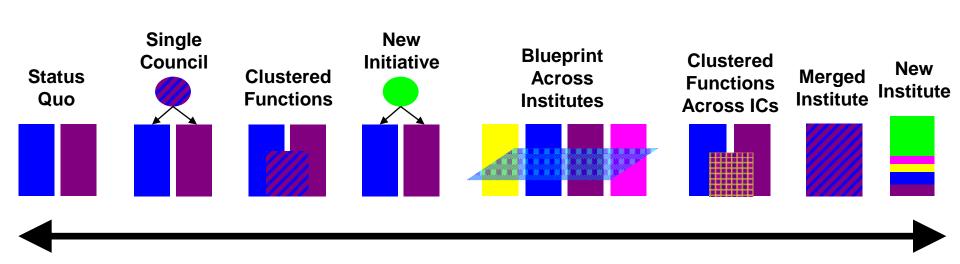
NIH Scientific Management

(DOCE Process for Considering Change)

- Criteria for Assessing the Need for Change:
 - Immediate Crisis
 - Unaddressed Scientific Opportunities
 - Changes in Scientific Landscape
 - Evolving or Emergent Public Health Needs
 - Need for Improvements in Quality and/or Efficiency of Research



Deliberative Process: Spectrum of Potential Options



CONCLUSIONS & RECOMMENDATIONS



Working Group Conclusions

 <u>Status quo is not ideal</u> for fulfilling NIH mission and optimizing research into substance use, abuse and addiction

 <u>Reorganization is needed</u> for NIH to optimize science and best serve public health



Identified Needs for Change

- Unaddressed scientific opportunities, including:
 - Preventing adolescent use, abuse, and addiction
 - Promote an understanding of both alcohol and drug abuse as diseases
 - Understanding drug-drug interactions
- Changes in the scientific landscape, including:
 - Advances in systems-level understanding that warrant a joint approach for many aspects of SUAA research
- Emergent public health needs, including:
 - Populations suffering from co-morbid conditions associated with substance use, abuse, and addiction
 - Rises in other forms of addiction (e.g. gambling, food, sex, etc.)
- Needs for improvement in the quality and/or efficiency of research:
 - Development of an integrated discipline of addiction research
 - Cross-training tracks need to be developed across fields



Key Features of Reorganization

- Integration of addiction research portfolios across NIH
 - Scope of reorganization focused on addiction-related research
 - Broader than drug and alcohol research
 - Include other substances (e.g., tobacco) and behaviors (e.g., gambling)
 - Mission statement should promote
 - Unified vision for addiction research
 - Interdisciplinary approach
 - Flexibility for new areas of study
 - Multidisciplinary approach to training



Key Features of Reorganization (cont.)

- Commitment by all participants to success of reorganization
 - Strong leadership from NIH Director & IC Directors
 - Participation and contribution from NIH staff, community of affected researchers, and other stakeholders
- Functional integration
 - Shared goals
 - Enhanced communication and collaboration
 - Engagement and participation from all relevant parties
 - Identification, creation, and sustention of synergies
 - Cultural shifts
 - Cannot be a change "in name only"



Reorganization Option 1:

SUAA

- Create a New Addiction Institute

Reorganization Option 2:

Form a Trans-NIH Initiative on Addiction



Option 1: A New Addiction Institute

- Integrate all relevant addiction portfolios from NIAAA, NIDA, and other ICs. Include, for example:
 - Drug addiction research from NIDA

- Alcohol addiction research from NIAAA
- Tobacco addiction research from NCI
- Gambling addiction research from NIDA and NIMH
- Transfer non-addiction research portfolios at NIAAA and NIDA to other ICs, as appropriate. For example:
 - Research on alcohol liver disease reassigned to NIDDK
 - Research on Fetal Alcohol Spectrum Disorders reassigned to NICHD



Option 1: A New Addiction Institute (cont)

Funding

- Addiction research funding relocated from existing ICs to the new institute
- Funding for non-addiction and end-organ research programs relocated, as appropriate
- No net change in level of funding for addiction research
- Recruit new director
- Reassign current staff
- Develop a new strategic plan to advance addictionrelated research



- Establish a transition committee
 - Implement reorganization
 - Outline process for development of new mission statement
 - Perform NIH-wide portfolio analysis to identify relevant programs for inclusion
 - Develop organizational structure
 - Establish timelines

Option 2: A New Trans-NIH Initiative on Addiction

- Modeled after the NIH Blueprint for Neuroscience Research or the Basic Behavioral and Social Science Opportunity Network (OppNet)
- Participation by NIAAA, NIDA, and all other ICs with relevant addiction portfolios. Include, for example:
 - NIDA (drug addiction)

- NIAAA (alcohol addiction)
- NCI (tobacco addiction)
- NIMH (compulsive behaviors, gambling addiction)
- NICHD (adolescent use)

Option 2: A New Trans-NIH Initiative on Addiction (cont)

Stable, dedicated funding

- May require a majority of each IC's addiction funds
- Contributions from Office of the Director
- Larger investment than, for example, Neuroscience
 Blueprint
- Dedicated staff support provided by NIAAA and NIDA
- Evaluation to monitor initiative progress and success

Option 2: A New Trans-NIH Initiative on Addiction (cont)

• Organization

- Steering committee to lead the initiative:
 - Include IC directors from respective Institutes
 - Co-chaired by 4-5 IC Directors, including NIDA and NIAAA
- Working groups or coordinating committees carry out main work of initiative. For example:
 - Strategic planning activities
 - Identification of scientific and public health priority areas
 - Development of an evaluation plan



Arguments in Favor of a New Institute

- Changes in the scientific landscape, research opportunities, public health needs, and the potential for more efficient interdisciplinary research provide the rationale for change
 - These goals cannot be met through a trans-NIH initiative on addiction
- Divergence in scientific communities doing alcohol and drug research can only be remedied by establishing a new institute
- Provides a highly visible home for addiction research at NIH
- Enables effective promotion of research on polysubstance abuse, greater understanding of adolescent use, and development of a cohesive public health message that alcohol and illicit drugs can have similar effects on the brain and body

- Changes in scientific landscape, research opportunities, public health needs, and the potential for more efficient research provide the rationale for change
 - These goals could be met through the trans-NIH initiative
- Functional strategies have worked in the past, in other scientific areas, with varying degrees of success
- Establishing a new Institute could create research gaps in understanding alcohol's ubiquitous effects on the body and unique factors contributing to its abuse
- Establishing a new institute constitutes a significant undertaking that will demand considerable effort and cause considerable disruption in the research community
- Trans-NIH initiative would maintain an inherently interdisciplinary component

DISCUSSION