

**NIH Workshop on
Accelerating the Pathway from Ideas to Efficacy: Developing More Effective Interventions for
Lifestyle Behaviors related to Chronic Diseases**

September 28 - 29, 2016
6701 Rockledge Drive (Rockledge 2), Room 9112/9116
Bethesda, MD

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Meeting Summary

Unhealthy lifestyle behaviors (adverse diet, sedentary lifestyles, tobacco use, low rates of adherence to preventive and therapeutic regimens) are major contributors to cancer, diabetes, cardiovascular and other chronic diseases. A promising avenue for improving these behavioral risk factors is to accelerate the translation of findings from basic behavioral and social science research to develop new and potentially more effective behavior change interventions. Basic behavioral science findings in many areas such as memory and learning, executive function, stress, and decision-making are ripe for translation into interventions, yet few avenues are available to support this type of early-phase translational behavioral research on an ongoing, sustainable basis.

The purpose of this Workshop was to (1) highlight exemplars of early-phase translational behavioral research studies aimed at improving behavioral risk factors for chronic diseases such as cancer, cardiopulmonary diseases, and diabetes, using these examples to showcase successes, challenges, and “lessons learned,” and (2) identify avenues for building early-phase translational research capacity, establishing a viable and sustainable “pipeline” for basic-to-clinical behavioral research, and promoting institutional and structural changes to support early-phase behavioral intervention research.

The Workshop took place on September 28 and 29, 2016 in Rockledge 2, Bethesda, MD. It was co-sponsored by NCI, NHLBI, and OBSSR, and participants included extramural scientists as well as NIH staff interested in exploring ways to promote a more sustainable pathway for basic-to-clinical behavioral research. The meeting agenda, participant roster and speaker bios are attached.

Guiding questions. A series of “guiding questions” developed for the Workshop included the following:

1. If one were setting up a new system to fund health-related behavioral research (i.e., starting from “scratch”), how would one construct the system to encourage basic-to-clinical behavioral research?
 - a. How would one create a pipeline for translating basic behavioral science into early-stage interventions?
 - i. How might relevant institutions (e.g., academic/medical institutions, funding agencies, industry & non-governmental partners) be structured to facilitate such research?
 - ii. What funding mechanisms and review structures are appropriate for ensuring this kind of innovative, high-risk/high-reward research?
 - iii. How could one encourage partnerships among the entities most likely to fund this type of research?
 1. Industry

2. Government agencies
 3. NGO's and other private entities (foundations)
- b. How would one build capacity among researchers?
 - i. What would be the role of graduate & post-graduate training in creating this pipeline?
 - ii. How can cross-disciplinary collaboration, especially between basic behavioral/social science & applied/clinical researchers, be promoted?
 - c. What other entities or organizations are needed to facilitate recognition and promotion of early-phase behavioral translation as an important area of research? How can they do so?
 - i. Associations and Professional Organizations
 - ii. Journals
 - iii. Potential end-users of behavioral interventions – e.g., clinicians, patient advocacy groups
 - iv. Clinical guidelines groups (e.g., USPTF)
 - v. Insurance companies and third-party payers

Day 1. On Day 1 a series of speakers highlighted exemplars of early-phase translational research findings in an opening session that was open widely, either in person or via webcast, to NIH staff and the extramural community. The intent of these talks was to examine projects that involved successful translation of basic behavioral science research into health behavior interventions to better understand the processes that occurred, participant roles, and contributions from the institutions and funding agencies involved. Teams of speakers from each of three projects discussed features of the projects, characteristics or actions by the researchers, and/or contextual or environmental factors that contributed most to the success of this program of research, attempting to identify underlying “principles” characterizing successful translational efforts and “lessons learned” to inform future efforts.

Day 1 also involved a series of small discussion groups, organized as “World Café groups,” in which participants discussed five aspects of translational behavioral science. Below are the five groups and guiding questions addressed by each group:

Group #1: Missed Opportunities: How do we identify basic behavioral science research that is ripe for translation? Relevant questions:

--Is there basic behavioral research being conducted that has potential for translation to clinical arena that is not being translated?

--What are some examples of such research?

--What are the barriers to the translation of such research from the basic behavioral science perspective? From the clinical science perspective?

--What might facilitate the translation of such research from the basic behavioral science perspective? From the clinical science perspective?

--If there is a dearth of such research, what can be done to generate basic behavioral research with potential for health-related/clinical translation?

Group #2: Can we increase support for early-phase behavioral translation by promoting interdisciplinary graduate & post-graduate training models? Relevant questions:

- Are interdisciplinary training models an effective approach to improving the integration of and interaction between basic and applied (clinical, population health) research areas?
- Are these models viable within current academic & medical structures?
- What are successful examples of such models?
- If viable, how can they be successfully promoted/disseminated?
- If not currently viable, can academic infrastructures or programs be modified to enable the success of such programs? How?
- Are there other kinds of training models that are useful for promoting greater interaction of researchers & integration of research across basic behavioral & clinical/population health research areas?

Group #3: How can we break down disciplinary silos in academia to enhance basic-clinical integration? Relevant questions:

- What are the institutional/structural features (including physical features) of academic and medical institutions that hinder cross-disciplinary interactions? Which features impede early-phase translational research?
- What cultural factors reinforce our unidisciplinary "siloes" approaches to research? What are the cultural and attitudinal barriers to greater basic-clinical integration and how can they be addressed?
- Are there specific cultural, attitudinal & structural factors that are unique to the behavioral sciences?
- What if anything can we learn from biomedical research programs, the natural sciences, the arts and humanities, that can inform our efforts to improve cross-disciplinary integration?
- What are the roles of hiring, tenure and promotion policies in creating and reinforcing institutional "silos" and impeding greater cross-disciplinary interaction?
- What is the role of academic leaders in breaking down research "silos" and improving collaboration across basic & clinical disciplines?
- How can we design institutional structures, policies and practices to foster cross-cutting basic – clinical translational research? What is required to transform academic institutions so that such interdisciplinary research is supported as a viable and sustainable part of the research enterprise?
- Can funding agencies help encourage policies and practices that increase cross-disciplinary behavioral science? If so, how can this be done?

Group #4: What role can non-academic institutions play in fostering early-phase behavioral translation research? Relevant questions:

- How do journal editors & editorial policies help or hinder promotion of basic-clinical behavioral translational research? How can we improve current policies to promote publication of such research?
- What role can scientific organizations play? Which organizations – both behavioral & non-behavioral – might be most productively engaged?
- Are there government/funding agency policies, mechanisms & practices (e.g., funding & review) that could improve basic-clinical translational behavioral science? What are they?
- Can clinical guidelines and the panels that create them play a role? If so, how?

--How can other science-related organizations and policies – e.g., open-science platforms, reproducibility initiatives, “citizen science” efforts – help promote awareness and implementation of early-phase behavioral translational research?

Group #5: The problem of “market failure:” If our interventions work, why aren’t they in demand?

Relevant questions:

--What role does our ability to translate behavioral interventions into clinical and community care play in promoting early-phase translational research?

--Can we increase support for basic & early-phase behavioral translation research by improving integration of behavioral interventions into practice settings?

-- Can health care systems as currently configured help promote “demand” for behavioral and preventive interventions? If not, how can they be reconfigured to promote such “demand?”

--How can we promote greater recognition and use of behavioral interventions for chronic disease by clinical and community practitioners?

-- What is “designing for dissemination” and is it feasible and desirable to incorporate aspects of later-phase translation into account in early-phase behavioral translation research?

--Are there models of financial reimbursement for effective behavioral interventions that can be promoted and could increase “demand” for behavioral interventions in practice settings?

--What are the roles of health care systems and leaders, 3rd party payers, HMO’s, NGO’s and other partners in promoting use of behavioral treatments in clinical practice? Can these partners/partnerships aid in the recognition, support & promotion of basic-to-clinical behavioral translational research efforts?

Day 2. The second day of the Workshop involved a “think thank” with more limited attendance (e.g., speakers, moderators and NIH staff). Participants formed small groups to discuss and make recommendations for building capacity, improving recognition and facilitating long-term support for early-phase behavioral intervention research. The following are areas recommended by Workshop participants for additional attention and/or follow-up activities:

(1) “Missed opportunities” in basic-to-clinical translation: Discussions and recommendations focused on how to increase new ideas in the pipeline of behavioral change interventions. Ideas included potentially using computerized methods to sift through the basic behavioral science literature and creating opportunities for basic and clinically-oriented behavioral researchers to interact to facilitate the translation of new ideas from the basic behavioral sciences into clinical studies.

(2) Interdisciplinary/translational science training: One challenge identified is how to train scientists to think more expansively and across basic-clinical silos to facilitate engagement in inter- and cross-disciplinary translational work later in their careers. Participants discussed the types of training needed to help junior faculty seek/build interdisciplinary teams, and how “integrated” (cross-disciplinary) research projects could be made a component of graduate training for behavioral scientists. There was support for enhancing intervention development and RCT methods training in behavioral medicine programs and for adding basic behavioral science training supplements to many large-scale (e.g., PPG and Center) behavioral science grants.

(3) How do we reward/incentivize/encourage interdisciplinary team science? Ideas included modifications of the grant application and/or review process to better reward team science, as well as creating metrics and policies that reward team science as part of the academic review (e.g., tenure) process. A particular challenge is how best to encourage and reward junior faculty to develop high-risk

novel approaches/ideas: what are the incentives for junior investigators to work in team science/interdisciplinary collaborations since academia rewards individual rather than team-based work? The importance of senior/credible advocates to “protect” junior investigators who engage in novel, translational and transdisciplinary science was discussed and endorsed. Participants also favored the addition of basic science supplements to ongoing research projects, and suggested several ideas for encouraging team science and inter- and cross-disciplinary research:

- Internal sabbaticals in which investigators work for a time in another department (basic-clinical or clinical-basic)
- Provision of short courses to learn other’s discipline-specific constructs, jargon and methods
- “Grand Challenge” grants that encourage team science and translational science approaches
- Encourage and incentivize cross-disciplinary colloquia attendance
- Incentivize basic researchers to seek out opportunities to sit on dissertation committees in departments other than their own – preferably a very different area where their ideas/insights may be revolutionary
- Experiment with concepts like “team tenure” (i.e., a team rather than an individual receives tenure)
- Develop additional incentives for teamwork – experiment with incentives focused on mentors, trainees, and both

(4) How do we facilitate/support creativity? Since early-phase translational and cross-disciplinary work often transcends boundaries and is high-risk, discussions centered on how to incentivize the submission & consideration of merit for highly risky research projects. How can we encourage a fail early-fail often culture, normalizing failure as a “seed-bed” for innovation? It was agreed that providing freedom and time to researchers is necessary for encouraging the kind of “serendipity” from which new and creative ideas emerge. One idea mentioned was formation of “Agility Teams” -- transdisciplinary groups that meet regularly to generate innovative ideas. Several ideas for reinforcing the emergence and pursuit of serendipitous findings included the creation of an interdisciplinary/multidisciplinary creativity & innovation fund, as well as grant mechanisms that facilitate pursuing great ideas within a grant rather than following a specific research plan. Participants also discussed how to train people to withstand social/peer pressure when they pursue a new idea or technique, to create behavior that is robust & insensitive to pressures/forces that constrain creativity.

(5) Funding, Review, and Journal Publications. Participants discussed the challenges to bridging across the translational spectrum (e.g., combining pre-clinical or animal research and early-phase human trials) within the grant and journal review processes. Suggested changes to review processes included facilitating a knowledge base in the combination of preclinical and clinical studies, since reviewers are often not amenable to combining across these levels. Recommendations also included providing guidelines and resources regarding translational processes and models to educate reviewers, as well as providing training to reviewers in basic & translational behavioral science. Additional focus on “developmental” funding opportunities was encouraged, and potentially starting a Translational Research Journal with focus on early-phase behavioral translation research as well as a new Journal of Negative Trials (or section(s) for these in existing journals). It was decided that the long-term significance of early-phase translational studies needs to be highlighted in a credible way in articles about early-phase studies, with perhaps a special section of journals focused on early-phase translational research that is part of larger, progressive research programs. Additional suggestions were to set up “expert panels” of successful translational scientists to consult on translational grants and increasing the cap on R21s to allow more in-depth exploratory/developmental research.

(6) Networks/CTSAs/Partnerships. Discussions centered around potential NIH funding of Networks of Translational Science – basic & clinical researchers, iterative & bidirectional work – and

potential partnering with agencies such as the National Science Foundation to develop more creative research funding opportunities as well as with NIH Institutes such as NCATS and the CTSA programs. Additional suggestions were to develop partnerships with Industry (e.g., technology companies) to fund early-phase trials, and to explore topics such as psychological “phenotypes” within large-scale trials (such as those funded by NIDDK, NHLBI, NCI).

(7) When & how to move to later translational phases & out to practice? Participants discussed the fact that recognition and advancement of early-phase behavioral research is itself dependent upon such research producing products (interventions) that can be integrated into medical care. However, there are many challenges in disseminating behavioral science evidence and evidence-based treatments, both within clinical and community venues as well as to the public. The inclusion of stakeholders at all levels from the beginning of intervention development, and the concept of “designing for dissemination” (including consideration of later phase translation early in the T1 translational process) were discussed and endorsed as a possible remedy for this problem. In addition, determining the role of medical professionals in administering behavioral health (BH) care and the need for studies to evaluate the effects of funding behavioral health specialists in primary care/medical settings were cited as important directions for improving later-stage, and by implication early-phase, translational efforts. Partnering with marketing groups to market effective behavioral interventions in similar fashion to pharmaceutical companies was also mentioned as an important avenue for exploration. What is an evidence-based intervention? Need clearer definition of evidence-based intervention (Quality of evidence)

Future Directions. Follow-up activities are underway based on Workshop discussions and recommendations to increase capacity in the basic-to-clinical behavioral translation arena and to develop institutional structures and programs that can support early-phase translational research. One such effort – “**Ideas to Interventions**” (I2I) – involves development of a suite of activities aimed at developing, nurturing and growing the community of early-phase translational behavioral scientists. Discussions and input received from a core group of participants from the September Workshop have identified several potential methods for such capacity-building, including use of social media (website, newsletters, webinars) and an “ambassador” program in which early-phase translational behavioral scientists develop programs, work with leadership, influence policy, and reach out to fellow researchers at their institutions to develop structures that can sustain and grow early-phase behavioral translational efforts.

Additional work is underway, spearheaded by a recently formed NIH Behavioral and Social Sciences Research Coordinating Committee (BSSR CC) Workgroup co-chaired by William Elwood of OBSSR and Susan Czajkowski of NCI, to review and advance activities at the NIH level to support basic (T0) and early-phase translational (T1) behavioral and social sciences research. This Workgroup, called “**Zero-to-One**” is tasked with developing and implementing funding opportunities, workshops and other programs and activities within the basic behavioral research arena (via the NIH Opportunity Network for Basic Behavioral and Social Sciences Research or OppNet) and the area of basic-to-clinical behavioral translation research. The Workgroup will be responsible for organizing specific funding opportunity announcements within the T0 to T1 phases of the translational spectrum, as well as focusing on the following areas:

- **Building Capacity/Outreach** via synergies with other similar efforts (I2I, SOBC) and through development of journal and news articles, webinars, workshops, workshop series and meetings to advance bBSSR and T1 research
- Addressing **funding and review issues** specific to T0-T1 research
- Organizing T0-T1 **methods development and training** activities