U.S. Department of Health & Human Services · National Institutes of Health

National Center for Complementary and Integrative Health

Implementation and De-implementation Methodologies for Complementary Health Approaches

Implementation and De-implementation Methodologies for Complementary Health Approaches Meeting Summary

The National Center for Complementary and Integrative Health (NCCIH) held an expert panel meeting on implementation and de-implementation methodologies for complementary health approaches on December 10, 2019. This panel consisted of a combination of experts in implementation science and/or complementary health interventions. [The complete attendance list follows this summary.]

The purpose of the meeting was to have discussions around implementation science and complementary health interventions.

- What is the level of evidence for various complementary health interventions?
    - When is a complementary health intervention ready to move to implementation?
    - Do complementary health interventions need special considerations before moving to implementation?
- When is a complementary health intervention ready for de-implementation?
- What are the barriers and facilitators specific to implementing or de-implementing complementary health interventions?

The meeting started with welcoming comments from Dr. Dave Clark and Dr. Emmeline Edwards (NCCIH), including the charge to the group.

Keynote Presentation

The Keynote Presentation from Dr. Todd Molfenter (UW-Madison) set the stage for the group discussions. Dr. Molfenter described the NIATx Model (Network for Improvement of Addiction Treatment) as an example of implementing multiple evidence-based interventions at the same time. NIATx was initially developed to improve addiction treatment and has since been applied to other areas of medicine, as well as other settings such as homeless shelters. Dr. Molfenter described two implementation science frameworks: CFIR (Consolidated Framework for Implementation Research) and EPIS (Exploration, Preparation, Implementation & Sustainment).

Dr. Molfenter asked for reactions to these models. Comments included:

- The models are helpful for getting people to think about the wide variety of factors that could affect program implementation. It has been suggested that there are about 100 factors.
- The models are complex and could be intimidating, especially for researchers and clinicians who are new to implementation science.
- The models don't explain how to address the issues.
- It's important to understand where to start, including where you have the most leverage.
- Transdisciplinary teams are needed to address the issues raised in the models.
- Researchers and health care systems look at situations differently and over different time frames. It's important to meet the operational people "where they are."

Dr. Molfenter said that the NIATx model was developed to provide the "how to" not included in the previous models. NIATx has limitations and doesn't work in all settings, but it helps identify areas of focus.

The five key principles of NIATx are:

Fix key problems—those that keep the CEO awake. Leadership support and the involvement of an executive sponsor are essential if implementation science projects are to be executed properly. The executive sponsor's role is to identify challenges and remove barriers, not to lead day-to-day activities. In complex organizations, such as the Department of Veterans Affairs (VA), it may be necessary to work with multiple levels of leaders. It is also important to recognize that leadership changes may occur during a project.

Select the right change leader(s). This should be an individual (or individuals), not a committee, and should not include the executive sponsor. It should be someone influential, who is respected across the organization and who can challenge the status quo tactfully when necessary.

Get ideas from outside the field/organization. Bringing in new ideas, rather than recycling old ones, shifts thinking. Introducing ideas from other fields can be a game changer.

Do rapid-cycle testing before rollout. Rather than attempting to plan a program perfectly before implementing it, use adaptive models. New programs should be tested before they are implemented on a wide scale. People are more willing to try a brief test than to agree to full implementation of a new program.

Understand and involve the customer. This principle is as predictive of success as the other four combined. Customers are anyone you serve in your process. In the health care setting, there are multiple sets of customers, including patients, all the people who interface with them, payers, and policymakers. Involving the customer may require walkthroughs and patient simulations (for example, following the experience of someone who comes in for an initial appointment), as well as customer interviews.

Implementation Discussion

The group discussion on implementation started with a brief description of the evidence for acupuncture as an example of a complementary health intervention. While acupuncture has strong evidence for the treatment of chronic low-back pain, problems encountered in the implementation of acupuncture have included difficulty in translating up-to-date knowledge to make it relevant for stakeholders and decisionmakers. For example, the Centers for Medicare and Medicaid Services (CMS) does not currently have sufficient evidence needed to make coverage decisions about acupuncture for pain as most of the supporting research studies have involved young and middle-aged participants, with few older adults included. (NOTE: Following this meeting, CMS issued a National Coverage Determination on covering acupuncture for chronic low-back pain.)

The discussion moved to the question: How much evidence is required to move an intervention to implementation? The answer to the question of what is "enough" may be contextual. An individual health care provider may be willing to try something in response to a recommendation from a colleague, but Federal agencies require much more extensive evidence. Sometimes concerns are raised about the replicability of efficacy from randomized controlled trials (RCTs). The trials may not have studied an intervention as it is used in clinical settings. Most RCTs have very high internal validity but lack the high external validity found in Pragmatic Clinical Trials (PCTs).

For integrative approaches to pain management, focusing on intervention-specific results may not be the optimal approach. Acupuncture and other complementary interventions are not magic wands, and pain conditions such as chronic low-back pain are not unified conditions. Rather than asking whether acupuncture works, it may be better to ask what role it plays in the management of chronic pain.

It was suggested that there are at least two important dimensions of the effectiveness of implementation efforts: financial vs. nonfinancial incentives and patient side vs. supply side. Considering these factors as a 2x2 matrix can be useful. The literature on social insurance programs illustrates that even if programs are available for free, uptake is not universal because other barriers may be present. For example, some people may not obtain food stamps if they must travel to sign up for them. Effective implementation strategies may need to overcome both factors.

Patients typically engage in complementary health interventions on their own and almost always pay out-of-pocket for these interventions. Currently, there is a push to incorporate complementary health interventions into the U.S. medical system, but integration into "traditional" health care may not be ideal for all complementary health interventions. Complementary health approaches that involve providers, such as

acupuncture and massage, may be a more natural fit with the health care system, but others, such as mindfulness interventions delivered through apps, may not be.

It's important to be clear about whether the goal of implementation is to get the approach(es) into the health care system or to inform the public about what is available and how to get access to complementary health interventions on their own. The U.S. health care model has a long history of working in tandem with outside services such as smoking cessation and weight loss. Physicians routinely counsel patients to stop smoking or lose weight and recommend resources available in the community to help accomplish their goals. Similarly, they could also counsel patients to try community-based yoga, tai chi, or other complementary health programs.

Patient expectations may be barriers to implementing some complementary health approaches. When patients go to physicians, they may expect to receive a prescription or have something done to them. The idea of being told to engage in a complementary health intervention, such as going to an acupuncturist, may often be unexpected. Some patients may feel a complementary health referral is an indication the treating physician doesn't believe their symptoms are real or severe, doesn't take their case seriously, and is offering a lesser level of care.

Underreached populations have special considerations in implementation science approaches. Participants noted that members of these populations are most likely to respond to advice from someone who looks like them, speaks their language, and meets them at their level. Barriers that affect all populations, such as copays, transportation issues, and getting time off from work to see a provider, may be magnified in low-income communities. On the other hand, cultural barriers perceived as difficult may not be; for example, it has been less difficult than anticipated to recruit low-income people for yoga trials.

Lack of a physician recommendation—or the perception that the physician does not support the use of an approach—is another barrier to implementation. A recent paper by Barbara Stussman and colleagues showed that roughly 50 percent of physicians recommend complementary therapies to at least some patients. This suggests an opportunity to reach out to physicians to let them know that there is evidence supporting these therapies.

Intervening at multiple ecological levels is important for successful implementation. Intervening only with the provider or only with the patient is less likely to be effective than getting both patients and providers, as well as facilities and payers, all moving in the same direction.

Workforce issues and training are important in implementation. In some instances, providers already in the system can be given a short training and paired with qualified instructors for interventions such as yoga or mindfulness-based stress reduction. However, this approach is not appropriate for some interventions such as acupuncture. If acupuncture is going to be covered by a health system or insurance,

many decisions need to be made such as who will provide the intervention, how much training is needed for staff, are licensed providers required, where will the intervention be provided, what will the out-of-pocket costs be for the patient, and how many sessions will be covered. A lack of consistency in the delivery of complementary health interventions—for example, how many sessions of mindfulness or yoga are provided—could be a challenge in interpreting implementation science results.

Implementation science has traditionally been thought of as something that happens after efficacy and effectiveness have been demonstrated, but it would be wise to think about implementation earlier in the process (Riddle & Clark 2011). Implementation science isn't just about barriers and facilitators; it's about examining and testing strategies for implementation. It's important to capture how much you're modifying the intervention for a study, as well as fidelity to the implementation strategy. Suitable study designs include sequential multiple assignment randomized (SMART) trials, cluster randomized trials, time series, and stepped wedge designs. Protocol papers are a useful source of information on these designs.

De-Implementation Discussion

The discussion of de-implementation began by talking about interventions that are in widespread use before effectiveness has been proven, or despite evidence that the intervention is no better than placebo, or evidence that the intervention may be harmful. The group was asked to focus on the following questions: What are the implications and limitations of de-implementation? What constitutes enough evidence to justify de-implementation? Is de-implementation applying the principles of implementation in reverse, or are other, special methods needed?

The group talked briefly about whether de-implementation and implementation could be combined in one study, for example by offering mind-body therapies or other types of self-care in place of opioids. De-implementation often requires providing a viable alternative. De-adoption of common practices in health care settings usually takes longer than adoption of new practices. Some of the reasons include confirmation bias (the tendency to interpret new evidence as confirmation of existing beliefs), optimism bias (the belief that they themselves are less likely to experience a negative event from using an intervention), and loss aversion (the pain of losing is psychologically about twice as powerful as the pleasure of gaining). Providers may be afraid of revenue loss or of decreasing the options available to patients.

Systematic reviews, such as the Cochrane Reviews, are often held as one of the highest levels of evidence. The Cochrane Collaboration was founded on the concept of doing meta-analyses to enable faster changes in practice. Despite the rigor and high standards of systematic reviews, they were never designed to make recommendations. Some reviews include implications for practice but rarely say outright that something works. Therefore, the reviews are often used to justify not implementing an intervention. Review language isn't usually well suited for people who make high-level decisions, such as legislators or CEOs. There is a need to move from evidence that's compelling for a research audience to messages that are useful for decisionmakers. A review may label an intervention as having "lower quality evidence." This doesn't necessarily mean that the trials are bad; the situation is more nuanced, and this may not be apparent to decisionmakers. Systematic reviews also do not provide all the information needed for implementation. For example, they may not indicate barriers or facilitators for why some patients/providers/health care systems didn't choose an intervention.

De-implementation of the physical examination was provided as an instructive example. The physical exam was once the primary means of making a diagnosis in hospitals and physician offices, but it has been largely superseded by imaging and laboratory tests. Physical examination is still taught in medical schools but is deemphasized, and today's physicians are not as skilled as their predecessors. It's

not clear whether the physical exam was de-implemented because substitutes became available that required less effort, or whether it was found to be inferior to the newer methods.

A service or intervention can likely be de-implemented more rapidly if a substitute is available. In the example of opioid use for chronic pain, an intervention that stops opioid use without introducing new interventions to manage pain is likely to be unsuccessful. There may still be cases where a practice can be de-implemented without a substitute. For example, taking a chest x-ray as part of an annual physical was found to be expensive, exposed the patient to unnecessary radiation, and had little or no benefit to the patient. These x-rays have decreased without other imaging to replace them.

De-implementation typically focuses on practices that are not evidence based but are part of usual care; however, complementary health interventions are not typically part of usual care. Therefore, de-implementing complementary health approaches is different from de-implementing conventional therapies because the emphasis may need to be patient facing rather than clinician facing. One example of patient-facing de-implementation is the decreased sales of certain botanicals after publication of negative studies or emergence of evidence of harm. In this case, the public seemed to respond quickly to changes in evidence.

The Federal Government also has a role in de-implementation. An example is the de-implementing of paper health records in favor of electronic records. Also, de-implementing brand-name drugs in favor of generic drugs. Decisions about coverage and capacity (such as how many doctors to train) are also de-implementation decisions influenced by the government. The CMS is influential in implementation/de-implementation because other health care systems look to the CMS even though it is not their mandate to play a leadership role. In general, third-party payers play important roles in implementation and de-implementation through coverage and reimbursement.

The evidence on implementation and de-implementation in the complementary health field is not as advanced as in some other fields. The development of strategies for implementation or de-implementation is the same as in any other field; however, complementary health studies should have a stronger emphasis on identification of barriers. Another consideration is the haphazard or inconsistent delivery of care for some conditions, such as low-back pain. This creates challenges for implementing and de-implementing complementary health approaches. It was noted that de-implementation studies could provide opportunities to showcase innovative study designs and suggested that developing a standard way to describe the "implementability" of an intervention would be useful. The CFIR does a good job of outlining numerous characteristics that influence implementation. Many participants mentioned the CFIR website as an excellent resource: https://cfirguide.org/.

Implementation Science and Complementary Health Interventions: Possible Future Directions

NCCIH is interested in building the implementation science portfolio. Implementation and de-implementation projects are aligned with the NCCIH "building blocks" and pipeline of clinical research. NCCIH currently participates in the NIH-wide Dissemination & Implementation Research Funding Opportunity Announcements (FOAs). Presently, NCCIH is signed on to:

- PAR-19-274 "Dissemination and Implementation Research in Health (R01 Clinical Trial Optional)"
- PAR-19-275 "Dissemination and Implementation Research in Health (R21 Clinical Trial Optional)."

These FOAs may or may not be the best choices for implementation science research in complementary health interventions. The best choice depends on the research questions. NCCIH-specific clinical trial funding opportunities might be better in some instances, particularly for hybrid effectiveness-implementation studies. In other instances, funding opportunities from other institutes or centers might be more suitable. Potential applicants are encouraged to contact a program official to discuss the funding opportunities that best match their research goals.

Meeting participants were asked what would help move implementation science forward for complementary health interventions. The following summarizes the discussion of this topic:

Create a framework for levels of evidence for complementary health interventions, similar to or perhaps based on those of the Community Guide or the National Cancer Institute's Research-Tested Intervention Programs (RTIPs). Those frameworks have ways of identifying interventions that are "promising" or "emerging" even if they cannot yet be recommended for use. It might be worthwhile to add to or refine Cochrane reviews to specify levels of evidence in ways that are helpful in identifying the additional research that needs to be done.

Short plain-language communications about implementation of complementary approaches are important to reach stakeholders other than the research community. Identifying and engaging with key stakeholders are also important.

The maximum amount of information relevant to implementation should be squeezed from current evidence. Investigators who are publishing RCTs need to be aware of the need to report about topics such as likely barriers to uptake and adoption. There are already guidelines for reporting on interventions, such as the Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA), but they're not focused

on topics relevant to implementation. Outcome domain frameworks that include feasibility and adoption of the intervention would be helpful.

Making complementary health interventions available to low-income/underreached populations is an important consideration for future implementation studies to address disparities in access.

Evidence-based complementary health services could be included in prospective payment budgets. The CMS Center for Medicare & Medicaid Innovation could be one potential pathway for future research or partnership.

One barrier to conducting implementation studies is the fact that Current Procedures Terminology (CPT) codes do not exist for many complementary health interventions.

Additional resources could be made available for:

- Complementary health researchers who want to learn more about implementation science
- Implementation science researchers who want to learn more about complementary health interventions.

Resources could include sessions on implementation science at scientific meetings, webinars, open access publications, and educational opportunities.

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