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The current state of lifestyle intervention implementation research: where do we go next?

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In the USA, the prevalence of obesity is 33.8% [1] and type 2 diabetes is 27% [2]. The landmark Diabetes Prevention Program (DPP) showed that a lifestyle intervention facilitating a 7% weight loss had a significantly greater impact on diabetes risk than placebo or metformin with a risk reduction of 58% over 3 years [3]. Similar findings were reported in diabetes prevention studies in Finland and China [4, 5]. The impact of lifestyle interventions appears to be long term [3, 4]. In the 10-year follow-up of the DPP, the incidence of diabetes in the placebo and metformin groups (who had been offered the lifestyle intervention following the initial intervention period) fell to equal that of the lifestyle group; however, the cumulative incidence of diabetes remained lowest in the lifestyle group [6]. The China Da Qing Study revealed reduced incidence of diabetes from a lifestyle intervention at 20-year follow-up [5]. Widespread availability of lifestyle interventions could have a tremendous impact on public health.

In 2003, the United States Preventive Services Task Force assigned intensive lifestyle weight loss interventions, a B grade based on a review of the literature, with fair to good evidence for modest, sustained weight loss [7]. In spite of the evidence, intensive lifestyle interventions have not become a part of standard health care practice and are not a third party reimbursable service, with only a few exceptions. A significant barrier to large-scale adoption is the feasibility of translating intensive lifestyle intervention into real world settings. The DPP lifestyle intervention cost US $2,780 per person over 3 years and required 135 visit hours [8]. Although the cost was not significantly higher than the metformin group, visit time was 3.5 times higher. The amount of visit time is high relative to most services available in the current health care environment. To impact public health, research is needed to inform the process of translation and implementation of intensive lifestyle interventions into affordable, feasible, and sustainable programs not just in healthcare settings but also in community settings such as community centers, worksites, schools, and churches. To catalyze translational research efforts, in 2006, the National Institute for Diabetes and Digestive and Kidney Diseases sponsored a funding initiative for translational research in diabetes prevention and management. Since then, translational work across myriad settings has been forthcoming. In 2009, a systematic review was performed of the seven studies testing translation into community settings of lifestyle interventions specifically based on the DPP [9]. All reported significant weight loss; however, weight loss achieved (2.6–6%) was typically less than that in the DPP (6.9%). Only three examined 1-year outcomes, but all three had significant weight loss at 1 year. I recently surveyed the authors of these seven programs and found that only two were confirmed to be ongoing, one in a hospital setting [10] and the other in the Young Men's Christian Association (YMCA) [11]. That weight loss was typically much less than that produced in the DPP and the lack of sustainability of these programs present significant challenges. Factors that may contribute to these challenges include reduced

Implications

Practice: Lifestyle interventions can be successfully implemented in a variety of settings, with clinical settings reporting the best outcomes and rates of adoption. However, community setting implementations reach more diverse populations. Training resources are now widely available.

Policy: Cost is a significant barrier to both the implementation and adoption of interventions. Third party reimbursement for lifestyle interventions would catalyze adoption and sustainability.

Research: Cost, staff turnover, institutional commitment, staff commitment and self-efficacy, and lack of a plan to transition from research funded resources to institutional funded resources are barriers that should all be taken into account in future implementation studies.

treatment intensity [9], high prevalence of comorbid conditions associated with poor adherence [12], less motivated samples, and unknown treatment fidelity [9]. Greater insight into the implementation process, including the facilitators and barriers, is needed to inform translational research on lifestyle interventions for obesity and type 2 diabetes.

The purpose of this paper is to provide an overview of the collective experiences of researchers who have implemented interventions targeting obesity and/or type 2 diabetes in clinical and community settings. Each of these studies is published in the *Implementation Research in Obesity and Diabetes* Special Section of *Translational Behavioral Medicine*. The special section includes case studies demonstrating implementation of lifestyle interventions in various settings including community organizations serving low-income minorities [13], primary care settings serving low-income minorities [14], community mental health clinics serving adults with severe mental illness [15], and outpatient clinic settings targeting couples [16]. Authors were specifically asked to discuss challenges, facilitators, and barriers to implementation and to report whether the program was adopted by the target site and if so, what facilitated the adoption, or if not, what prevented it from happening. These case studies describe the process of relationship building between community and academic partners, the balance between scientific and community priorities, and the challenges of implementing interventions which are carefully modified to meet the unique needs of a target community. This special issue also includes effectiveness and cost-effectiveness studies in a range of settings including Women, Infant and Children's (WIC) Centers [17], schools [18], Latino family health centers [19, 20], and community mental health settings [21]. Also included is a systematic review by Whittemore of 16 translational studies of the DPP lifestyle intervention using the RE-AIM model [22] as an organizing framework [23]. The systematic review includes studies performed in hospital, primary care, community, worksite, and church settings and concludes with a discussion of the most promising settings in the context of RE-AIM model. The special issue has two policy-related pieces as well. In one piece, Millstein and Sallis discuss a novel model for engaging youth in obesity prevention advocacy efforts targeting environment and policy changes to improve nutrition and physical activity [24]. The other piece discusses efforts by the Society of Behavioral Medicine to more actively and systematically engage the society and its membership in becoming aware of, contributing to, and reacting to public policy relating to health, including obesity and diabetes specifically [25]. It also describes how professionals as individuals can become more involved in affecting public policy at the city, state, and federal levels. The Evidence-Based Behavioral Medicine column includes a synopsis of the Cochrane Review on community-wide interventions for physical activity [26]. Finally, the issue includes columns reporting news from the National Institutes of Health (NIH) [27] and the Centers for Disease Control (CDC) [28], with a special emphasis on funding priorities and opportunities relevant to translational research in obesity and type 2 diabetes.

PROGRESS AND THE NEXT HORIZON

That we populated an entire special section on the implementation of lifestyle interventions for obesity and type 2 diabetes is a good indicator of the volume of the work in this area. Implementation research has been performed in a wide variety of settings. As Whittemore [23] suggests, the setting with the greatest efficacy and sustainability thus far is the clinic, although weight loss outcomes across all settings are less than the original DPP. Although community settings are the most likely to reach diverse populations, they produced the lowest weight losses, with the notable exception of the YMCA. It is not clear why clinic settings produce better outcomes than community settings. Community-based implementation studies routinely create equal partnerships with community members and stakeholders throughout the implementation process, make efforts to identify and overcome the unique barriers experienced by the target population, and spend a great deal of time insuring intervention materials are culturally sensitive and relevant. Possibly affecting outcomes may be that community settings are more likely to use non-professionals to deliver the intervention which could potentially affect intervention fidelity. Also, community participants, often economically disadvantaged, may have fewer resources to participate in an intensive intervention. Another factor worth exploring is that a lifestyle intervention program may not be as directly compatible with the mission of a community organization (e.g., church) as clinics where health care is the primary mission. Extra work may be necessary to unite the healthy lifestyle mission with the mission of the organization and the likelihood of conflicts could be greater. The extent to which each or any of these factors contribute to less weight loss outcomes requires further study. Future research should examine the relationship between these factors and outcomes to determine how to maximize the potential of community settings, given they are the best gateway to diverse populations. An additional research direction could be to determine how to reach a more diverse population in the clinic, as it may have higher potential for adoption and sustainability.

ADOPTION AND SUSTAINABILITY REMAINS A CHALLENGE

Consistent with the systematic review by Jackson [9], sustained adoption and sustainability appear to be occurring less frequently than hoped in the

implementation studies reported in this special section. The cost of lifestyle interventions has traditionally been singled out as the primary implementation challenge, but this is likely the case because lifestyle interventions are one of very few efficacious health services that are not reimbursed by public and commercial health insurance companies. In the inaugural issue of *Translational Behavioral Medicine*, Spring eloquently discusses the double standard that currently exists in the investment in treatment versus prevention, with far higher standards on rapid return on investment for the latter [29]. Until this health care philosophy shifts, cost will be the burden of either the institution or the patient, neither of which can easily afford it. Institutions can seek state or local grants for financial support but this type of support is often time limited and can be highly vulnerable to elimination in uncertain economic times. Even in the scenario of widespread third party reimbursement, it is not clear to what extent this would impact community-based implementation of lifestyle interventions which are typically delivered by nonprofessionals whose work may not be reimbursable.

The obvious approach to reduce the cost of a lifestyle intervention is to reduce the number of visits; however, this invariably reduces the impact on both weight and other clinical endpoints [9, 23]. Research that utilizes novel and cost-effective ways of preserving efficacy while reducing burden is needed. Technology-supported interventions have been suggested as key to this endeavor [30] and emerging research in this area appears promising [31–36]. Research is needed to determine the level and type of human support needed to facilitate adequate adherence to technology-based intervention tools. Because technology is developing faster than research is being produced to address these questions, the challenge is to insure that emerging technology is based on evidence-based strategies known to impact important health outcomes[37]. Other novel approaches to reduce intervention intensity could emanate from research that improves our understanding of how to harness social networks, identify the "hubs" of social influence, thereby allowing us to virally spread healthy lifestyle behaviors throughout a community in the same way that unhealthy lifestyles and risk for obesity organically spreads through social networks as originally observed by Christakis and Fowler [38]. Social media may be one mechanism by which this can be facilitated.

INTERVENTION INTENSITY IS NOT THE ONLY BARRIER TO ADOPTION

Although intervention intensity is often pointed to when implementation fails to sustain and is the focus of many efforts to improve sustainability, several other factors may be as or even more important. Barriers cited by both low-intensity single session programs (e.g., [14]) and high-intensity multi-session programs (e.g., [17, 21, 26]) include staff turnover, loss of academic and/or community "champion" of the program, program reliance on grant funding, no plan or commitment to turn funding over to the site, lack of commitment from staff who are trained to deliver the intervention, and reliance on research staff for integral functions of the program. An implementation research project does not necessarily guarantee sustainability even with the best community–academic partnership and a high initial level of institutional commitment because this can all change over time. We are only beginning to understand factors affecting the transition from implementation to long-term sustainability. Studies that evaluate institutional commitment (at program initiation and throughout), staff commitment, program costs, and the feasibility of all procedures necessary to sustain the service would shed light on the key factors necessary for a sustainable program. Prior to implementation, a detailed financial plan (as opposed to only verbal commitment) for the program following the implementation should be developed to insure that sustainability is feasible. Plans made in advance to insure that the program can sustain under circumstances of staff turnover may also be important. These plans should be revisited throughout to account for any changes in funding, staff, and other circumstances, which appear to occur often and rapidly in community settings.

An interesting and under recognized challenge raised in this issue is staff reluctance to implement the program. In two studies, some staff members expressed concern during training about absorbing the role of a lifestyle counselor given their feeling taxed in their current role [15, 21]. Some expressed skepticism about the program's efficacy in the target population, as was the case for direct care workers trained to be lifestyle counselors for consumers with severe mental illness [15]. Some also reported their own difficulty wrestling with healthy lifestyle changes which reduced their self-efficacy to help others make such changes. A disconnection between institutional and staff commitment underscores the importance of securing commitment at all levels, never assuming a trickle-down effect. As a way of insuring commitment among interventionists, one study trained the entire direct care work force of a community mental health clinic and through that process identified and selected the most committed and interested staff members to lead the lifestyle intervention groups [15]. They selected staff members who expressed a high level of enthusiasm during training, actively participated, and reported weight loss during training even though that was not a stated goal of training. Another approach used to address staff concerns is to involve staff in the process by modifying intervention materials to address the challenges they identify [15, 21]. The

implementation process should include an assessment of staff commitment and self-efficacy for enacting lifestyle changes in their target population. In the event that the work force has a high rate of obesity, is largely inactive, and/or exhibits unhealthy dietary behaviors, applying the intervention to them prior to training could be a helpful first step. Unfortunately, lifestyle counseling is not typically included in training programs for allied health care professionals or community health workers. Such training would not only disseminate this skill base more widely but also help to overcome some of the issues that arise during implementation and adoption.

INTENSIVE LIFESTYLE INTERVENTIONS ARE ALIVE AND WELL IN MANY PLACES

Several community-based DPP lifestyle intervention programs are in practice, although not necessarily in conjunction with an implementation research study. A list of 18 active programs across eight states and Canada can be found on the website for the University of Pittsburgh Diabetes Support Center (http://www.diabetesprevention.pitt.edu/default.aspx), an organization that offers DPP lifestyle intervention training nationally and internationally. Settings listed include hospitals/clinics (n=12), military bases (n=3), WIC center (n=1), the diabetes support center itself (n=1), and a department of public health (n=1). The vast majority of these programs, are in hospital/clinic settings, which suggests again that clinics might be particularly feasible settings for sustainability. Perhaps, clinics have the overhead to financially support these programs, are experienced at obtaining local/state agency grants for programming or have systems in place to charge patients for services. Twelve (67%) of the 18 programs responded to an email inquiry about their funding sources. Two reported funding from the local department of public health funds, three had internal funding, three had research grant funding, three charged patients for enrollment (US $20, $34, and $225), one had local private foundation funding, and three were partially funded through a commercial health insurance plan. Some had more than one funding source. Research is needed to learn the processes by which these exemplars have overcome sustainability challenges. This could provide a roadmap for other settings who may be interested in initiating a lifestyle intervention program. Particularly useful would be case studies from settings that have successfully procured third party reimbursement for their service.

In 2010, the Centers for Disease Control launched the National Diabetes Prevention Program (NDPP), an initiative that provides (1) a grant program for community-based diabetes prevention program model sites, (2) training for lifestyle intervention instructors, (3) evaluation, monitoring, and technical assistance for programs, and (4) health marketing to raise awareness among providers and high-risk populations to increase program referrals (CDC) [39]. The inaugural partners of the NDPP include the YMCA and UnitedHealth Group. In 2010, 22 programs were launched across the USA and 20 more are expected to launch in 2011. Both the Diabetes Support Center and the NDPP are outstanding resources for formalized training in lifestyle intervention programming which could help maximize intervention fidelity in both community- and research-based efforts, particularly in efforts where interventionists have minimal background or training in nutrition, physical activity, and behavioral modification. The networks of programs created by the Diabetes Support Center and the NDPP provide an opportunity to study the process of adoption, factors associated with successful sustainability, and overall effectiveness of existing programs. Many other programs likely exist both nationally and internationally but are not a part of national initiatives or have not been published in the literature. A network that includes all existing programs would help us understand just how widespread the adoption of lifestyle interventions has become. Policy makers could then be informed of the demand for this service and associated outcomes. Consequently, the public health impact of having a lifestyle intervention as a reimbursable service could be more accurately estimated.

CONCLUSION

Intensive lifestyle interventions are being adopted throughout the nation, and a growing body of research is identifying the settings, circumstances, and processes by which sustainable adoption occurs. Sustainability remains a challenge, although studies are providing important insights into the barriers as well as the playbook to overcoming them. Qualitative data on the process of implementation is as essential as quantitative data on endpoints, given the complexity of real world settings and the multitude of challenges encountered. Several sustainable lifestyle intervention programs are currently in existence and provide an opportunity to study factors key to successful adoption (e.g., [10, 11, 39]). The demand for lifestyle interventions is high as measured by the unmatched effort to provide this service in so many settings despite the absence of third party reimbursement during the 10 years since the original DPP findings were published. YMCAs and clinical settings demonstrate the most promising outcomes and potential for sustainability. Future implementation work can benefit from understanding the challenges and facilitators documented in the first generation of implementation studies. The increasing magnitude of national initiatives and grassroot efforts to implement and disseminate lifestyle interventions over the

past 10 years suggests forward movement toward widespread implementation.

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