Protocol

Disseminating Public Health Evidence to Support Prevention and Control of Diabetes Among Local Health Departments

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A Stepped Wedge Cluster Randomized Controlled Trial

We will conduct a stepped wedge cluster randomized controlled trial of 12 local health departments (LHDs) in Missouri to evaluate the effectiveness of active D&I approaches on perceived individual and organizational capacity for evidence-based decision making in prevention of diabetes and other chronic diseases.

LHDs will be randomly assigned to three groups that crossover to receive the intervention with measurements at 8-month intervals. No LHDs receive the intervention at baseline. All participating 12 LHDs will receive the intervention, however, for varying durations; group 1 crosses over from control, i.e., usual practice to receive the intervention activities first and for a total of 24 months, group 2 crosses over second and receives the intervention for 16 months, and group 3 crosses over last and receives the intervention activities for 8 months. The intervention activities include a flexible “menu” of D&I approaches that account for local contextual and organizational factors. Dissemination strategies are designed to build workforce and organizational capacity, and may include training in evidence-based public health, technical assistance through a knowledge broker, providing targeted messages/emails with a short summary of the research and actions that might be taken based on the evidence, and organizational changes to assist agency leadership in prioritizing, incentivizing and incorporating the use of EBPPs. LHD practitioners can choose intervention activities from this "menu". This "menu" approach avoids the pitfalls of a “one-size-fits-all” process that is unlikely to be effective across the 12 participating LHDs. Therefore, this study will not attempt to evaluate a single D&I intervention activity but will pursue active, multi-modal approaches, since these are supported in the literature.

Local Health Department Enrollment

Of the twelve LHDs selected, at least 3 will come from LHDs in counties with high diabetes disparity (highest tertile). Once all LHDs are recruited, each will be randomly assigned to one of three groups with four LHDs to a group. At least one LHD from high diabetes disparity will be randomly assigned to each group. Each group of LHDs will cross over to the intervention at 8-month intervals. To account for varying sample sizes for small versus large LHDs, we will limit our sample to LHDs with at least 5 employees working in or supporting chronic disease control and on the upper end no more than 22 individuals in larger LHDs. We will also include an additional 5-10 individuals (an average of 8) from partner agencies in each local community that include non-governmental organizations (e.g., local hospital, American Diabetes Association) and governmental organizations outside of the health sector (e.g., universities, parks/recreation, schools).

LHD selection will be based in part on the total number of full-time equivalent (FTE) employees (number of FTEs increases with size of population served by LHD), number of employees working in or supporting diabetes or chronic disease control, and diabetes burden, specifically mortality rate for diabetes as underlying cause (a measure of health disparity). Of the 12 LHDs selected and recruited, at least three will come from LHDs in counties from the highest tertile of mortality rate for diabetes as underlying cause. To be eligible, LHDs are required to have ≥5 employees working in or supporting diabetes or related areas in chronic disease control, which includes program areas of diabetes prevention and management, obesity prevention, physical activity, nutrition, cardiovascular health, school health, and cancer screenings. In addition, each LHD must have a designee to work with the study team on aspects of the intervention. LHDs will be assigned to one of three groups (four LHDs to each group) using simple random concealed allocation performed by the statistician.

LHDs with a total number of FTEs ≥35 or serving a population of ≥200,000 are anticipated to have an adequate number of employees working in diabetes and chronic disease control. The project manager (RP) contacted directors at LHDs with 25-34 FTEs and serve a population of <200,000 (8 LHDs) to determine if their LHD has ≥5 employees working in diabetes prevention and management, obesity prevention, physical activity, nutrition, cardiovascular health, or cancer screenings; 5 of the 8 LHDs met this criterion. Of eligible LHDs (17 of 115 LHDs), those with the greatest diabetes burden (i.e., in the highest tertile for mortality rate for diabetes as underlying cause) followed by LHDs with the largest total number of FTEs employees will be contacted and recruited. Random assignment of the first 12 selected LHDs to groups will be performed. The principal investigator will invite local health directors from each selected LHD to have their employees working in diabetes and chronic disease control participate in the study. If any LHD declines, the next LHD according to total number of FTE employees will be selected. All employees working in or supporting diabetes and chronic disease control in participating LHDs will be invited into the study (complete listing), and a purposive sample of individuals from partner agencies (other governmental and non-governmental) in each LHD local community will also be invited. LHDs' key partners will be recruited into the study with the help of the chronic disease managers and other practitioners. We anticipate a range of 5 to 22 participants from the LHDs, coupled with staff from partner agencies for an average of 22 per jurisdiction.

Participants will be diabetes and chronic disease control directors, program managers and staff, and leadership from recruited LHDs in Missouri as well as staff from their key partner agencies. It is anticipated the participants will be from diverse backgrounds including health educators, epidemiologists, community health nurses, and persons with business backgrounds.

Each LHD will have a designee (most likely the lead chronic disease staff person) who will provide the project coordinator a contact list of staff and practitioners working in and supporting chronic disease control, agency leadership, and staff at key partner agencies. The project/study coordinator will send an email to the list of contacts at the measurement time points (baseline, and three 8-month intervals) inviting them to participate in the dissemination survey. For the network analysis instrument, the invitation will occur at baseline and the last measurement time point.

Table. Stepped wedge group randomized study design.
Shaded cells represent intervention periods (24 months, 16 months, or 8 months).

	Months			
	1-2	3-10	11-18	19-26
Group 1 (4 LHDs)		**24 months**		
Group 2 (4 LHDs)			**16 months**	
Group 3 (4 LHDs)				**8 months**

Individual Participant Consent Process

For the web-based/online surveys (dissemination survey and network analysis instrument), the first page will be a cover letter containing all elements of consent. The cover letter will include a portion where individuals will be able to choose the statement that best describes how the individual would like to proceed ("Yes, I would like to take the survey," or "No, I prefer not to take the survey."). If a person clicks "Yes, I would like to take the survey," this will indicate her/his consent and s/he will be directed to the start of the survey. If a person clicks "No, I prefer not to take the survey," this will indicate s/he does not consent and s/he will be directed to the end of the survey and no follow up invite/reminders will occur. Project staff will conduct follow up through email and telephone contact. In all contact with potential participants, project staff will emphasize that participation is voluntary. Specifically, health department personnel will be informed that if they choose to take part, they can change their mind and leave the survey. Further, they will be informed that any refusal to participate or withdrawal will not involve a penalty or loss of benefits to which they are otherwise entitled.

Intervention: Individual and Organizational Capacity Building Activities

The capacity building (intervention) activities seek to build workforce and organizational capacity, and to effectively package and provide information so that it is timely, relevant, and useful for various local-level practitioners. There will be a menu of capacity building (intervention) activities in which each LHD can choose depending on what the LHDs deems important, relevant and feasible. The intervention period for groups begins with workshops as described below. A full set of examples of capacity building activities is shown in an attached table (Intervention Activities). A narrative summary of potential activities are listed below.

1. Targeted dissemination workshops – promoting the use of EBPPs will be modeled after successful workshops that have been conducted to promote evidence-based decision making (Brownson et al., 2009, Gibbert et al., 2013). The workshops will seek to enhance participants' abilities to: understand the role of EBPPs in addressing the diabetes burden; identify diabetes control strategies recommended by evidence-based reviews (e.g., the Community Guide); adapt EBPPs to address health disparities; address organizational barriers to EBPPs; and take action steps to move toward implementation and evaluation of EBPPs. All workshops incorporate principles of science-based training, including: an informal setting, team training, experiential learning, and small group activities applicable to real world experiences. A sample workshop agenda with a brief description of the modules is attached to this IRB form (EBPH Workshop Agenda).

2. Knowledge brokers – provide a link between research and practitioners by developing a mutual understanding of goals and cultures, collaborating with end users to identify problems for which solutions are required, and enhancing access and use of research evidence in practice and policy. This dissemination strategy has been used more in Canada than in the US. Although the public health literature is sparse with evaluations of knowledge broker impact, there is considerable evidence of effectiveness in other fields, particularly from business and agricultural sectors (Hargadon 2005, Verona et al., 2006, Zook 2004). The knowledge broker activities include: assistance with needs assessments and strategic planning that incorporate EBPPs; consultation on overcoming barriers to EBPPs; help with grant writing that incorporates information from evidence-based sources; and participation in the dissemination workshops described below. Interaction with the brokers will be one-on-one (broker to individuals and teams within the LHD) and it includes face-to-face contact, and remote telephone, email, and video communication.

3. Organizational changes – during the intervention period for each LHD, the research team will work with the LHDs to identify and implement a range of strategies to foster organizational change consistent with Institutional Theory that is part of the project's conceptual framework. Examples of strategies that will be employed will seek to: identify ways agency leadership can prioritize use of EBPPs, develop incentives for use of EBPPs, and incorporate EBPPs as a core component of agency practices (e.g., performance reviews, contracts with local partners).

Data Collection

To evaluate the impact of these intervention activities, we will:

1) ask staff/practitioners working in/supporting chronic disease control at each LHD, and their partner organizations to complete the online dissemination survey at four time points (baseline and three 8-month intervals);

2) ask for LHD records - program plans and progress reports that LHDs submits to funders, such as the Missouri Department of Health and Senior Services at two time points (baseline and the last data time point);

3) ask for information on the external partnerships of each LHD (baseline and the last data time point), and then ask LHD leadership - manager level and above to complete the online network analysis survey at two time points (baseline and the last data time point). The surveys will be designed for minimal time burden (about 20 minutes).

Power Analysis

This study uses a stepped wedge cluster randomized design. Based on our preliminary studies and values of ICC in the literature, we estimated a range of effect sizes and ICCs. ICC estimates are the most difficult to obtain. We calculated a median ICC from similar studies and developed a range based on a 50% decrease and increase around the median (range 0.009 to 0.027). The sample size requirement is based on testing hypotheses with a power of >90% and the overall Type I error of 5% given 12 clusters (LHDs). The null hypotheses suggest there would be no change in the scores from baseline of three outcomes—awareness, adoption, and maintenance—in all three groups of LHDs (no change). Drawing from our previous work, we hypothesize that the scores will be 17%, 20%, 14% higher for awareness, adoption, and maintenance from baseline to end of study, respectively. Following Baio et. al., and using the most conservative estimates of effect sizes and ICCs, we estimate a need for 12 LHDs, 3 steps or groups (of LHDs), and 10 subjects in each LHD (total = 120) to ensure 5 at the last measure/end of study (total = 60).

Analysis Plan

Descriptive statistics for participant and LHD characteristics and main outcomes will be conducted by trial mode. We will calculate gap in each skill for EBDM by subtracting availability from importance Likert rating (possible range of -10 to +10). An overall skill gap will be created by taking the average across all 10 skill items. We summed all 8 possible EBIs to calculate an “EBI score” which had a possible range of 0-8. For organizational culture items, we grouped and averaged Likert items within six main focus areas based on previous work: awareness of culture supportive of EBDM, capacity and expectations for EBDM, resource availability, evaluation capacity, EBDM climate cultivation, and partnerships to support EBDM (20). A confirmatory

factor analysis using data from all four time points according to standard procedures demonstrated adequate fit and strict measurement invariance of the factor structure used for the national survey in an earlier study phase. We used linear mixed-effect regression models for each outcome with LHD and Participant entered as random intercepts, trial mode (control or intervention) as fixed effect, and time as a categorical fixed effect. Public health degree, years worked in the public health field, job position category and accreditation status were entered as fixed effects. Kenward-Rogers approximations will be used to determine significance of fixed effects, a common approach in fitting restricted maximum likelihood models in order to produce acceptable Type 1 error. Where models violated assumptions of homoscedasticity, robust models will be approximated. Survey data will be cleaned initially in SPSS and then managed and analyzed in R.

Table. Summary of individual and organizational capacity building (intervention) activities

Domain	Activity	Description
Accreditation	Accreditation preparations	Local health assessment and plan, formalized decision making, documentation of evidence, documentation reviews, site visit, approval
Access to scientific information	Targeted messages	Participants will receive an email indicating that a systematic review related to diabetes or chronic disease control is available
Workforce development	Evidence-based decision making (EBDM) training (dissemination workshops)	In-state, in-person multi-day training in EBDM skills, 9 modules, as initial study intervention (this is the kick-off activity for the entire study)
	Supplemental brief EBDM skill trainings	Provided by study team or state chronic disease unit, in-person or webinar, as part of this study, with 3 states emphasizing evaluation skills
	Non-study national trainings	Hosted in-person EBDM-related skill trainings by national organizations and/or encouraged out-of-state training beyond those required by funders
	Quality improvement	Quality improvement or performance management trainings, guidance
	New employee EBDM orientation	Via archived webinars or course materials, facilitated discussions, meetings
Leadership, management supports	Chronic disease leadership teams expect EBDM	Leaders and supervisors continually ask ‘what is the evidence’, communicate EBDM expectations to staff, champion EBDM, encourage use of data for decision making, encourage skill building
	Use of data for decision making	Use data to prioritize programs, develop work plans, and monitor progress; share performance measures, data on intranet or centralized data systems
	Centralized data systems	Dashboard development to prioritize, measure, and track objectives and link to evidence base; share performance measures and data
	Meetings incorporate EBDM	Work unit and cross-section meetings address EBDM, present evidence, plans; (in leadership and in training)

	Performance reviews and EBDM	Work unit employee evaluations include objectives on EBDM learning and application
	Hiring practices address EBDM	Job descriptions, interview questions address EBDM; hire people with public health competencies; hire specialty staff including evaluators and epidemiologists
	Participatory decision making	Staff and partner input obtained, sharing of information for decision making
	Common language for EBDM	Creating and using common EBDM language across program areas
	Administrative reorganization for coordination	Organizational restructuring at the unit or section levels to increase coordination across programs and conduct joint projects across programs
Organizational changes	EBDM engrained	EBDM an embedded inseparable aspect of day-to-day work; strong expectation from leadership; high priority
	Learning orientation	Culture supports professional development and ongoing learning, providing links to webinars, bringing in guest speakers
Relationships and partnerships	Partnerships with in-state universities	Ongoing partnering for evaluation, trainings, internship placement
	Partner technical assistance and training	Phone and in-person guidance for partners' evidence-based work plans, evaluation, logic models; Provide EBDM trainings to partners
	Relationship building	Active steps to build or maintain positive partner relationships with open communication, trust, mutual respect, ensuring partner engagement and coalition development
Financial practices	Performance-based contracting	Funded partners required to implement evidence-based approaches as prescribed or selected from a menu, with performance objectives, work plans, and evaluation; holding contracted partners accountable for evidence-based interventions
	Proposals approved internally for EBDM prior to submission to funder	Local health department pre-approval process for grant applications to funders with requirements to show objectives, evidence basis, performance measures, evaluation plan