

## Examples of Funded Grants in Implementation Science

### **Overview**

The National Cancer Institute (NCI) frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let Implementation Science (IS) post excerpts of their dissemination and implementation (D&I) grant applications online.

### **About**

We are grateful to the investigators and their institutions for allowing us to provide this important resource to the community. To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application), where applicable. In addition, we only include a copy of SF 424 R&R Face Page, Project Summary/Abstract (Description), Project Narrative, Specific Aims, and Research Strategy; we do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., performance sites, key personnel, biographical sketches).

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# 424 R&R and PHS-398 Specific

## Table Of Contents

### Table of Contents

Examples of Funded Grants in Implementation Science.....	1
Table Of Contents .....	2
SF 424 R&R Face Page.....	3
Project Summary.....	4
Project Narrative .....	5
Specific Aims.....	6
Research Strategy.....	8
References.....	24

## SF 424 R&R Face Page

**PI:** Hannon, Margaret A

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**Title:** Increasing Implementation of Evidence-Based Interventions at Low-Wage Worksites

**FOA:** PAR10-038

**FOA Title:** Dissemination And Implementation Research In Health (R01)

**Organization:** University Of Washington

**Department:** Health Services

**Senior/Key Personnel:** Margaret Hannon Ph.D.

**Organization:** University of Washington

**Role Category:** PD/PI

## Project Summary

Cancer and other chronic diseases are leading killers and disablers in the United States, and low-income Americans are at high risk for these diseases. Multiple evidence-based interventions (EBIs) exist to improve chronic disease risk behaviors, such as cancer screening, healthy eating, physical activity, and tobacco cessation, yet EBI reach to community settings is poor. Among community settings for reaching low-income adults, worksites stand out because most low-income adults are employed, but worksite implementation of health-promoting EBIs is low. Half of American workers work in small or low-wage worksites, where implementation of these EBIs and readiness to implement are especially low. Even though decision-makers at these worksites are often motivated to promote worker health, they usually have no dedicated wellness staff and face three major barriers in implementing EBIs: 1) lack of awareness of the potential benefits of EBIs, 2) lack of knowledge to choose EBIs, and 3) lack of financial and personnel resources to implement EBIs. Non-profit organizations and others who would assist these worksites face their own barriers. Organizational readiness to implement EBIs is not well understood, and few validated measures are available, especially for worksites. Without reliable and valid measures of worksite readiness, those who would assist them have difficulty: a) identifying worksites that are ready, and b) helping decision-makers get ready to increase their odds of implementation success. The proposed research will address both sets of barriers and contribute to dissemination and implementation research by testing the efficacy of a worksite EBI dissemination program, *HealthLinks*, developed in partnership with the American Cancer Society, a non-profit organization operating nationwide. *HealthLinks* is based on Greenhalgh's diffusion of innovations framework and Rogers' diffusion of innovations theory and addresses small and low-wage worksites' barriers by providing free on-site information and recommendations for EBIs and by providing free on-site programs and temporary staffing to assist implementation. We will test *HealthLinks* via a 3-arm randomized controlled trial. Worksites will receive either 1) *HealthLinks*, or 2) an enhanced version of *HealthLinks* that addresses small worksites' lack of personnel by adding worker wellness committees, or will 3) serve in a delayed control group that receives *HealthLinks* at study end. We will measure worksites' EBI implementation at baseline, 12 months (at the end of the intervention period), and 24 months (to assess maintenance one year after the intervention ends). This design will test the effectiveness of both *HealthLinks* and of worker wellness committees. We will also measure the effect of both on workers' health behaviors at baseline, 12 months, and 24 months. Finally, we will develop, pilot-test, and validate a measure of worksite readiness to implement EBIs.

## Project Narrative

The proposed project will answer key questions about implementing evidence-based health promotion interventions at small and low-wage worksites. Small, low-wage worksites will be randomized to receive *HealthLinks* (a free American Cancer Society program to disseminate evidence-based interventions), *HealthLinks+* (which will include creating worksite wellness committees as part of the program), or to serve in a delayed control group. This approach will identify successful strategies for implementing evidence-based interventions at low-wage worksites to improve workers' cancer screening, healthy eating, physical activity, and tobacco cessation.

## Specific Aims

Cancer and other chronic diseases are leading causes of death in the United States.<sup>2,3</sup> Several preventable risk behaviors, including inadequate physical activity, poor eating habits, missed cancer screenings, and tobacco use, increase disease risk.<sup>4-6</sup> Several evidence-based interventions (EBIs) significantly improve each of these risk behaviors.<sup>1</sup> The challenge is to implement these interventions successfully in community settings, especially settings that reach low-income and less-educated people at greatest risk.

Worksites can implement EBIs to support workers' cancer screening, healthy eating, physical activity, and tobacco cessation; they can also promote evidence-based services, such as state-sponsored tobacco quitlines. However, most worksites do not offer comprehensive health promotion programs (evidence-based or otherwise).<sup>7</sup> [Many employers cite lack of capacity (personnel expertise and time) as a key barrier to implementing EBIs,<sup>8,9</sup> and employers who have dedicated staff time to health promotion are more likely to have EBIs in place.]<sup>7,10</sup> However, research addressing these implementation issues for worksites wishing to offer EBIs has not kept pace with research developing new worksite interventions.<sup>11</sup> [The proposed project will address both of these gaps. We will test the effectiveness of a worksite health promotion program and we will also advance implementation research by (a) testing the impact of adding a capacity-building component to the worksite health promotion program and (b) creating and validating a measure of worksite readiness to adopt and implement EBIs.]

We partnered with the American Cancer Society (ACS) to create and test *HealthLinks*, a program to disseminate EBIs to worksites and provide implementation support. The EBIs are from the *Guide to Community Preventive Services* and include using small media to promote cancer screening, increasing access to and awareness of healthy food options, increasing access to physical activity facilities, using point-of-decision prompts to promote physical activity, sponsoring physical activity programs that offer individual choice of activity and increased social support, and telephone-based support for tobacco cessation.<sup>1</sup> The *HealthLinks* approach is based on Greenhalgh's diffusion of innovations framework,<sup>12</sup> as well as Rogers' diffusion of innovations theory.<sup>13</sup> We pilot-tested *HealthLinks* with 23 small worksites; it significantly increased their implementation of EBIs.<sup>14</sup>

In the proposed project, we will formally test *HealthLinks* and also the effect of adding worksite wellness committees (to build internal capacity<sup>12,13,15</sup>) on worksites' adoption, implementation, and maintenance of EBIs. We will also measure the effect of *HealthLinks* on workers' health behaviors.

**Specific Aim 1:** Test the effectiveness of two approaches for increasing worksite implementation of EBIs. To meet this aim, we will perform a randomized controlled trial with worksites as the unit of randomization. Worksites will be randomly assigned to receive *HealthLinks*, receive *HealthLinks* + worksite wellness committees, or serve in a delayed control group that receives *HealthLinks* at the end of the study. We will measure worksites' implementation of EBIs at baseline, 12 months, and 24 months follow-up.

**Specific Aim 2:** Measure the effect of *HealthLinks* and *HealthLinks*+ on workers' health behaviors. To meet this aim, we will survey workers at all worksites participating in the trial at baseline, 12 months, and 24 months follow-up. We will measure workers' cancer screening, eating habits, physical activity, and tobacco use at baseline, 12 months, and 24 months follow-up.

In addition, we will develop and test a measure of worksite readiness to implement EBIs. Lack of readiness to change is often cited as a cause of implementation failure, yet readiness for implementation of worksite health promotion is not well understood, and although many surveys exist to measure organizational readiness, few have been systematically validated. Of those that

have, none were developed for or tested with worksites.<sup>16</sup> Creating a reliable, valid measure of worksite readiness to implement health promotion EBIs will enhance our ability to [identify worksites that are likely to succeed in their efforts to adopt and implement EBIs, as well as help worksites that are not ready identify what they need to do to improve their odds of implementation success. If so, this would be an important tool for subsequent dissemination efforts.]

Specific Aim 3: Adapt and validate a survey to assess worksites' readiness to adopt and implement EBIs. To meet this aim, we will conduct three activities: a) adapt the survey, using "think-aloud" interviews with ~15 employers, b) pilot-test the adapted survey with 100 employers, and c) validate the survey, using baseline assessments of readiness-to-change as predictors of site-level implementation of EBIs in worksites participating in the trial at 12 and 24 months. [Note: We will recruit a separate sample of employers for activities a and b in our first year, prior to the trial.] We will examine the association of baseline readiness with implementation of EBIs and the changes in readiness scales associated with different intervention arms.

# Research Strategy

## 3.a Significance

### 3.a.1 Overview

This section provides: 1) a summary of the literature on chronic diseases and the risk behaviors we are addressing; 2) a summary of EBIs to improve worker behaviors; 3) the status of EBI implementation by smaller employers; 4) the importance of organizational readiness to implement EBIs and the lack of strong tools to measure readiness; 5) the need for dissemination and implementation projects, like the one we propose, to advance the field; and 6) a summary of our preliminary studies and related work in this area. [Note: We use 3 terms quite specifically throughout this proposal. *Behaviors*, such as physical activity, are actions that workers can take to protect or improve their health. *Evidence-based interventions (EBIs)*, such as providing access to physical activity facilities, are evidence-based approaches that worksites can take to improve worker behaviors. *Dissemination programs*, such as *HealthLinks* and *HealthLinks+*, the 2 we will test, seek to increase worksite adoption and implementation of EBIs.

### 3.a.2 Chronic diseases and their risk behaviors are a leading cause of mortality

Chronic diseases are leading causes of mortality and morbidity among working-age adults and are associated with modifiable risk behaviors. Five chronic diseases – cancer, chronic lower respiratory disease, diabetes, heart disease, and stroke – account for more than 50% of deaths for adults in the United States<sup>2,3</sup> and are also leading causes of disabling conditions.<sup>17</sup> Researchers have identified risk behaviors that are associated with these chronic diseases, including tobacco use, unhealthy eating, physical inactivity,<sup>5,6</sup> and lack of age-appropriate screening for breast, cervical, and colorectal cancer.<sup>4</sup> Improving these behaviors would lead to substantial reductions in death and disability<sup>6,18</sup> and significant savings in medical costs.<sup>19</sup>

### 3.a.3 Evidence-based interventions improve risk behaviors and prevent chronic disease

The *Guide to Community Preventive Services*<sup>1</sup> (hereafter referred to as the *Guide*) has conducted systematic evidence reviews and identified successful interventions for improving these behaviors.<sup>20-27</sup> Ten of the recommended interventions to improve these behaviors are applicable to small, low-wage worksites. Table 1 provides quantitative information from the *Guide* on the effectiveness of each of these interventions.

**Table 1. Effectiveness of EBIs Recommended by the *Guide*<sup>1</sup> as Appropriate for Worksites**

Intervention	Behavioral Measure of Effectiveness	Median Net Increase, %
Breast, cervical, and colon cancer screening		
Small media	Completed mammography, Pap test, fecal blood test	7.0, 4.5, 12.7 absolute
Breast cancer screening		
Reduced out-of-pocket costs	Completed mammography	11.5, absolute
Group education	Completed mammography	11.5, absolute
Healthy eating		
Healthy foods awareness and access	Weight loss	NA
Physical Activity		
Access to facilities	Exercise score	13.7, relative
Point-of-decision prompts	Stair use	2.4, absolute
Programs with individual choice	Time spent in physical activity	35.4, relative
Social support	Time spent in physical activity	44.2, relative
Tobacco Cessation		
Telephone support	Tobacco cessation, 12 months	2.6, absolute
Reduced out-of-pocket costs	Tobacco cessation, 9 months	7.8, absolute

### 3.a.4 Evidence-based interventions (EBIs) can be implemented at worksites

Worksites offer an important opportunity to implement EBIs.<sup>28,29</sup> More than 64% of the adult population in the U.S. is employed,<sup>30</sup> and workers spend a significant proportion of their waking hours at work.<sup>31</sup> Worksite interventions, therefore, have broad reach. Worksites are also small communities where social environments can be

changed to promote health,<sup>32</sup> and peer community of co-workers can influence behavior and provide social support.<sup>33</sup> As noted above, several interventions recommended by the *Guide* are appropriate for the worksite.<sup>1</sup> Yet findings from national surveys indicate that most employers have not adopted the EBIs that prevent cancer and other chronic diseases.<sup>9,34</sup> [Note: We use *worksite* to describe the physical place where workers are and *employer* to describe both the decision-maker who decides whether to adopt worksite health promotion and the implementer who actually performs worksite health promotion activities.]

Although employers' EBI implementation is low, their motivation to prevent chronic diseases is high. Employers are increasingly recognizing the effects of chronic diseases and chronic-disease-causing behaviors on their bottom lines.<sup>35</sup> Chronic diseases affect labor costs through many means, including rapidly rising health care costs,<sup>36</sup> productivity losses from missed work, decreased on-the-job effectiveness, and turnover when a worker becomes too ill to return to work.<sup>37</sup> As employers turn to health promotion interventions to address these concerns, 2 key questions are: 1) Can worksites successfully adopt and implement EBIs, and 2) Do these changes actually improve workers' health behavior?

A small number of studies have investigated the effectiveness of dissemination programs aimed at increasing worksite-level EBIs (as opposed to using the worksite as a channel to reach individual workers). The *New York Healthy Heart Program* assessed worksite support for worker cardiovascular health using *Heart Check*. This dissemination program focused on creating or expanding heart-healthy worksite programs and policies, including improved food choices and smoke-free policies. Among dissemination worksites, investigators observed average relative increases in *Heart Check* scores of 65% over 3 years.<sup>38</sup> ACS's dissemination package *Workplace Solutions* was successful in changing worksite insurance benefits, policies, programs, and communications regarding chronic disease prevention.<sup>39</sup>

Several studies revealed changes in workers' health behaviors following worksite-level interventions. For example, in the *Working Well Trial*, investigators detected significant improvements in worker nutritional habits as a result of improved food offerings, worker programs, and interactive promotional efforts.<sup>40</sup> The *Seattle 5-a-Day* study yielded similar findings from an intervention that tested a combination of organizational and individual-level approaches to improving fruit and vegetable consumption among workers.<sup>41</sup> Workers at intervention worksites still had higher fruit and vegetable consumption more than 4 years later.<sup>42</sup> The *Healthy Directions – Small Business* study combined worksite and individual-level interventions; workers at intervention worksites significantly increased physical activity.<sup>43</sup> Our proposed study builds on these studies by taking advantage of the evidence base from the *Guide*, testing a dissemination program that addresses several health risk behaviors, and recruiting worksites that will reach workers with high rates of these risk behaviors.

### 3.a.5 Small and low-wage worksites have high-risk workers and limited health promotion/EBI capacity

Employers that are most likely to offer worksite health promotion interventions are those with 1000 or more workers,<sup>7,34,44</sup> yet most employers are small and mid-sized.<sup>45</sup> Furthermore, small and mid-sized employers are more likely to employ low-wage workers, who are at greater risk for health disparities, and are less likely to offer health insurance to their workers.<sup>45,46</sup> Small employers are a relatively underexplored target audience with the potential to reach a large proportion of low-wage and uninsured workers. Prior worksite research indicates that small and mid-sized employers are interested in health promotion, willing to participate in research,<sup>47,48</sup> and able to make positive changes in the worksite environment.<sup>43,49</sup>

Small and low-wage worksites face two major barriers in adopting and implementing EBIs for their workers: 1) lack of information needed to find, choose, and adapt EBIs for their worksites; and 2) lack of resources required to implement EBIs. Small employers need help in selecting EBIs, and

they need EBIs that are low-cost or free and take little time to implement. *HealthLinks* promotes evidence-based policy approaches and free programs. All 50 states provide breast and cervical cancer screening and treatment free-of-charge for low-income and uninsured women, as well as telephone quitlines for tobacco cessation for smokers. About half of the states, including Washington, also now provide colon cancer screening to low-income and uninsured men and women. These programs are underused, serving only a small proportion of those eligible to receive these services.<sup>50,51</sup> Very few worksites promote these services,<sup>10,52</sup> even though linking their workers with these state-provided resources would be a simple, inexpensive, and effective way to improve their health.

### 3.a.6 We Need Measures to Identify Worksites Ready to Adopt and Implement EBIs

Across industries, at least two-thirds of major change initiatives fail.<sup>53</sup> Researchers have identified clusters of organizational factors, such as employee attitudes about change, leadership support, and slack resources, that are evident at baseline and strongly predict implementation. These are collectively referred to as organizational capacity or readiness to change.<sup>54-56</sup> Studies report organizational readiness as a predictor of outcomes such as success in the implementation of a range of health service programs by hospitals;<sup>57</sup> success in implementing quality improvements for cardiac surgery programs<sup>58</sup> and adoption of evidence-based treatment practices.<sup>59</sup> These studies have often reported very large effect sizes associated with readiness scores, such as an  $R^2$  of 0.47 for explaining short-term implementation of quality improvements for cardiac surgery programs<sup>58</sup> and an area under the ROC curve in excess of 0.84 for distinguishing successful from unsuccessful implementation of change efforts in hospitals.<sup>57</sup> We are unaware of studies measuring and examining readiness-to-change in worksites.

Since 2006, two systematic literature reviews have examined studies of organizational readiness-to-change across sectors.<sup>55,56</sup> Weiner and colleagues identified 43 unique instruments for measuring organizational readiness.<sup>56</sup> Only seven were publicly available and had undergone systematic assessment of psychometric properties, meaning construct, content, and criterion validities.<sup>60-66</sup> None of these seven measures were created for or tested in worksites. [Another recent review of measures of capacity for new knowledge and receptive context for change was unable to recommend any measures of these antecedents to readiness, as no measure was used in more than one study and many did not report measures' psychometric properties.<sup>67</sup>] In the present study, we will adapt a measure of organizational readiness to change developed and originally validated to help guide interventions to support implementation of evidence-based clinical practices.<sup>68</sup> The survey includes scales measuring both the organizational context (e.g., slack resources) and leaders' perceptions of EBIs, including their perceived compatibility with existing practices and workers' attitudes. [We believe this survey could be an important tool for subsequent dissemination of *HealthLinks*.]

### 3.a.7 We Need Dissemination and Implementation Research Focused on What Works in Small Worksites

As we have shown above, several EBIs address cancer screening, healthy eating, physical activity, and tobacco cessation and are appropriate for worksites. We are focusing on EBIs from the *Guide*; many other worksite researchers have developed effective interventions for worksites as well.<sup>41,43,49,69,70</sup> What we lack is a way to deliver EBIs to five million worksites across the United States. Most worksites are small and have limited capacity to adopt and implement EBIs.

The *Guide* EBIs, although evidence-based, have two characteristics that warrant further study. First, not all of the studies that informed the *Guide* reviews were conducted in worksite settings. Of those that were, several studies focused on large or white-collar worksites, meaning that the EBIs may not have been tested with low-wage or low-education participants. Second, the *Guide* EBIs are strategies; any organization wishing to adopt and implement them must translate them into an intervention appropriate for their constituents. We and ACS have spent significant time dealing with

the second issue and have created toolkits to translate each EBI into a concrete worksite intervention. To address both issues, we need to test how these EBIs are adopted by and implemented at small, low-wage worksites and what effect the EBIs have on workers' behaviors.

[Worksite wellness committees (WWCs) may be one path toward helping small, low-wage worksites adopt and implement EBIs. Worksites with a paid wellness staff person are more likely to have health promotion programs in place than workplaces that do not,<sup>7</sup> and worksites with WWCs have more tobacco EBIs in place than worksites that do not.<sup>10</sup>] Some worksite interventions that resulted in worker behavior change have incorporated WWCs into the intervention process.<sup>41,71,72</sup> Other studies have examined whether characteristics of WWCs or the amount of time they spend is associated with implementation.<sup>73,74</sup> [What is unclear is whether creating a WWC actually causes subsequent increases in implementing EBIs.] We are unaware of any studies that have explicitly tested the effect of WWCs on EBI implementation and maintenance success. We believe that WWCs may boost worksites' implementation and maintenance of EBIs by building internal capacity for implementation as well as fostering the development of worksite champions for the EBIs (both capacity and champions are associated with greater adoption and implementation.<sup>12,13</sup>) The critical question, which we will test in the proposed project, is whether creating and maintaining a WWC leads to greater implementation and maintenance of EBIs. We will have a 2-year follow-up period at both the worksite and worker levels to evaluate what the worksites implement, whether they are able to maintain that implementation for a significant length of time, and whether worksites receiving *HealthLinks+* will be able to maintain greater implementation at 2-year follow-up.

### 3.a.8 Preliminary Studies

*HealthLinks* was conceived by staff at the American Cancer Society, Great West Division (ACS) as a dissemination program to promote healthy eating, physical activity, and tobacco cessation in small, low-wage worksites. We pilot tested *HealthLinks* with 23 small worksites (15-200 workers) in Mason County, Washington. We initially contacted 69 employers; 23 agreed to participate (33% participation rate), and 20 completed follow-up assessment 6 months after the intervention. We assessed worksites' implementation of the following EBIs at baseline and 6 months after starting *HealthLinks*: providing access to and promoting awareness of healthy foods, providing access to physical activity facilities, offering a physical activity program including choice of activity and social support, creating a tobacco ban policy, and promoting the Washington State Quit Line. At baseline, the worksites had, on average, 35% implementation of these EBIs (range 9-60%). At follow-up, the worksites reported 57% implementation of the EBIs ( $p < .001$ ), a significant and promising improvement (the in-press manuscript presenting this study is presented in Appendix 1).<sup>14</sup>

[We are currently delivering *HealthLinks* to worksites in South Seattle/South King County, Washington, as part of Public Health-Seattle & King County's Communities Putting Prevention to Work initiative (funded by the Centers for Disease Control and Prevention). Due to funding requirements, we do not have a control group in this study. We added cancer screening to the behaviors *HealthLinks* promotes. We have been able to establish the feasibility of our recruitment approach with small and low-wage worksites in King County, as we were able to recruit 45 such worksites over a 6-month period; the feasibility of establishing WWCs in these worksites, as most worksites that have completed *HealthLinks* formed WWCs; and the feasibility of our approach to recruiting workers to take health behavior surveys at the worksite, as 79% of workers present during the worker surveys participated to-date.] In the proposed study, we will test *HealthLinks* in a randomized study and test whether we can improve the effect size we found in the pilot test by adding a study arm that will include worker wellness committees.

### 3.a.9 Expected Outcomes

By the end of the funding period, we will have tested the effect of 2 dissemination programs vs. a delayed control on worksites' implementation of EBIs and on workers' health behaviors. We will also have adapted and validated a measure to assess worksites' readiness to adopt and implement EBIs.

We will conduct these activities collaboratively with ACS, so that findings will inform their future practice with small, low-wage worksites. We expect that our findings will inform other dissemination and implementation research and workplace health promotion research by testing the effectiveness of an on-site dissemination program for small/low-wage worksites, the usefulness of WWCs as an implementation strategy, and the creation of a valid readiness measure for worksites.

### 3.b Innovation

#### 3.b.1 Testing research questions from a dissemination research framework based on a systematic review

To guide this research, we will use a modified version of the dissemination research framework (Figure 1) proposed by Greenhalgh et al. after their systematic review of dissemination research from both the health care and organizational change literatures.<sup>12</sup> The framework addresses what is needed to change both individual behaviors and the organizational practices that facilitate those behavioral changes.<sup>75</sup> Our

modifications are partly based on Glasgow’s RE-AIM framework<sup>76</sup> and Rogers’ work on diffusion of innovations.<sup>13</sup> [Note: In the following description of the framework, key words in bold type direct attention to related concepts in the framework.]

In Figure 1, the **Intervention Resources** and **Collaborative Linkages** components describe the process by which we developed *HealthLinks* with ACS, our partner and the **change agency** for *HealthLinks*, the **dissemination package** we will study. The arrows connecting the **User Organizations** (low-wage worksites) with Intervention Resources show how we use feedback from employers in the pilot-test of *HealthLinks* and in our qualitative studies to shape and refine *HealthLinks*.

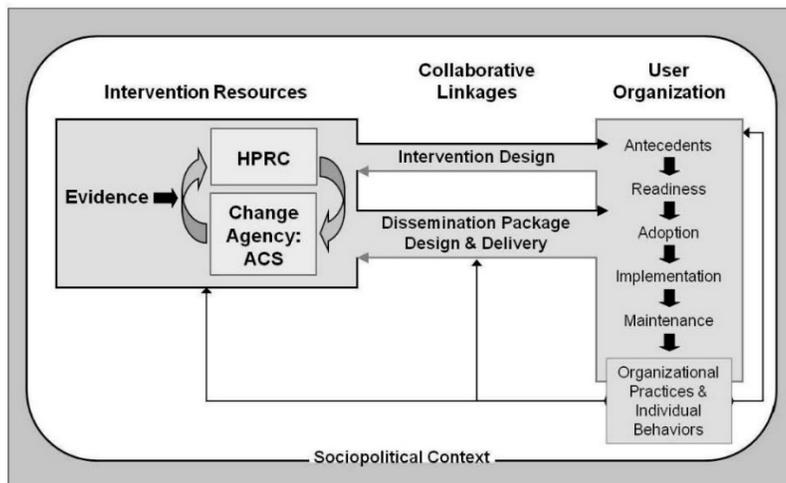
In the proposed study, we will be exploring the right side of Figure 1 (the components under User Organization) in much more depth. We will test whether and to what extent *HealthLinks* increases worksites’ **organizational practices** (implementing and maintaining EBIs) over a 2-year period, and we will test whether and to what extent adding WWCs increases *HealthLinks*’ effectiveness (Specific Aim 1). We will test whether and to what extent *HealthLinks* affects **individual behaviors** (workers’ health behaviors) over the same 2-year period (Specific Aim 2). Finally, we will adapt and validate a measure of worksites’ readiness to **adopt** EBIs which assesses specific hypothesized **antecedents** to effective adoption and implementation. This will produce a cumulative **readiness** score, which we will use to determine whether we can predict worksites’ **implementation** and **maintenance** success (Specific Aim 3).

#### 3.b.2 Testing WWCs as a strategy to increase EBI adoption and maintenance

As discussed above, small, low-wage worksites want EBIs but lack the resources to select and implement them.<sup>8,77</sup> In these worksites, EBIs must be “priced right,” inexpensive enough for widespread adoption but resourced enough to effect change in worksite practices and worker behaviors. One key question is how to increase implementation resources at the worksite, without incurring increased costs. We will test whether adding WWCs to *HealthLinks* improves EBI adoption, implementation, and maintenance over 2 years.

#### 3.b.3 Creating a new measure of worksite readiness to implement EBIs

Figure 1: HPRC Framework for Dissemination Research



Based on: Greenhalgh et al., *The Milbank Quarterly* 2004; 82(4)

Not all worksites are ready to implement EBIs.<sup>48,77</sup> We need better measures of readiness so that ACS and other health promotion entities serving worksites can focus their limited resources on the small, low-wage worksites most likely to succeed (and make recommendations to other worksites for changes that will boost their implementation success). We will create a worksite readiness measure based on a readiness measure developed and validated in clinical settings for implementation of evidence-based clinical practices.

### 3.b.4 Collaborating with a partner with capacity to deliver dissemination programs to worksites

Interventions developed by researchers often have minimal reach because they are not feasible and scalable<sup>76,78</sup> and because there is no partner organization ready to use them. ACS National Home Office (NHO) has an Employer Initiative that includes staff dedicated to developing and delivering dissemination programs to worksites nationwide.<sup>79</sup> ACS’s Great West Division (GWD) is a partner on this grant and is ready to implement changes suggested by the results of our research as they continue to deliver *HealthLinks* to worksites in the region. Both ACS NHO and ACS GWD have already reached hundreds of worksites with different dissemination programs;<sup>79</sup> they have proved their capacity as a dissemination partner.

## 3.c Approach

### 3.c.1 Overview

Our first aim is to test the effectiveness of *HealthLinks* and *HealthLinks* + WWCs (hereafter “*HealthLinks*+”) on increasing *worksite* implementation of EBIs, in comparison with a delayed control group of worksites. Our second aim is to test the effect of *HealthLinks* and *HealthLinks*+ on *workers’* health behaviors. To meet Aims 1 and 2, we will conduct a 3-arm randomized controlled trial of 90 worksites (30 per arm), with randomization at the worksite level. We will measure worksite implementation of EBIs and worker health behaviors at baseline, 12 months, and 24 months follow-up. Our third aim is to adapt and validate a measure (developed for use in clinical settings) to assess worksites’ readiness to adopt and implement EBIs.<sup>68</sup> We will interview 15 employers, revise the instrument based on their feedback, and then pilot-test the instrument with 100 employers to determine its feasibility, test-retest reliability, and association with current EBI implementation at their worksites. We will administer this revised readiness measure to employers in the randomized trial to determine whether it can successfully predict implementation success.

### 3.c.2 Specific Aim 1 and Specific Aim 2: Testing the Effectiveness of *HealthLinks* and *HealthLinks*+

#### 3.c.2.a Design

We will perform a 3-arm randomized controlled trial to test and compare the effectiveness of *HealthLinks* and *HealthLinks*+ on (a) *worksite* implementation of EBIs to promote cancer screening, healthy eating, physical activity, and tobacco cessation and (b) *worker* cancer screening rates, healthy eating habits, physical activity levels, and tobacco cessation attempts. Worksites will be the unit of randomization and will be randomly assigned to one of 3 groups. The first group will receive *HealthLinks* upon study enrollment, the second group will receive *HealthLinks*+ upon study enrollment, and the third group will receive *HealthLinks* after completing the 24-month follow-up measures (delayed control). We will

use worksite and worker surveys to collect baseline and follow-up data on worksites’ implementation of EBIs and workers’ health behaviors. Worksites will be randomized after we have received their

**Table 2. Study Design and Measurement Timeline**

Worksite Type	Time Point, in Months			
	Baseline	0-11 mos.	12 mos.	24 mos.
<b><i>HealthLinks</i></b>	O <sub>imp</sub> , O <sub>beh</sub> R	X	O <sub>imp</sub> , O <sub>beh</sub>	O <sub>imp</sub> , O <sub>beh</sub>
<b><i>HealthLinks</i>+</b>	O <sub>imp</sub> , O <sub>beh</sub> R	X	O <sub>imp</sub> , O <sub>beh</sub>	O <sub>imp</sub> , O <sub>beh</sub>
<b>Delayed Control</b>	O <sub>imp</sub> , O <sub>beh</sub> R		O <sub>imp</sub> , O <sub>beh</sub>	O <sub>imp</sub> , O <sub>beh</sub> X

O<sub>imp</sub> = Survey of Worksite Implementation of Evidence-based Interventions

O<sub>beh</sub> = Survey of Worker Health Behavior, Awareness of and Participation in Worksite Interventions

R = Randomization of Worksites

X = *HealthLinks* Delivery

worksite and worker baseline surveys. Table 2 outlines the study design.

The primary outcome of this study is worksites' implementation of the EBIs *HealthLinks* promotes. The secondary outcome of the study is workers' cancer screening, nutrition, physical activity, and tobacco use behaviors. We hypothesize that (a) worksites receiving *HealthLinks* or *HealthLinks+* will have greater EBI implementation than worksites in the delayed control group and (b) worksites receiving *HealthLinks* or *HealthLinks+* will see more change in workers' health behaviors than worksites in the delayed control group.

### *3.c.2.b Study population*

We will recruit worksites located in King County, Washington. We selected King County to allow us to be within a 2-hour drive of the worksites in order to control study costs and exert quality control over *HealthLinks* and *HealthLinks+*. We will recruit worksites from the following industries: Accommodation and Food Services; Arts, Entertainment, and Recreation; Educational Services; Other Services Excluding Public Administration; and Retail Trade. In King County, each of these industries has an annual average wage <\$40,000, substantially lower than the county's annual average wage of \$58,112.<sup>80</sup> We selected these industries to maximize our project's potential reach to low-wage workers (these industries account for 29% of all workers in private firms in King County). To meet our goal of testing the process of implementing EBIs in small worksites, we will recruit worksites with 20-200 workers.

We estimate that more than 3000 worksites will meet the eligibility criteria for our study, based on a) Washington State data about number of firms in each of our target industries and b) national data about distribution of firms by number of workers.<sup>80,81</sup> We will use North American Industry Classification System (NAICS) codes to identify prospective employers in these industries from a Survey Sampling International list including all worksites in King County, Washington. We plan to recruit 90 worksites. Recruitment procedures are described in detail in section 3.c.2.d.

Based on our prior studies, we anticipate that the workers at these worksites will have higher health risk behaviors and are more likely to be Spanish-speaking than the general WA population.<sup>46,82</sup> All worker-level study materials and measures will be available in Spanish and English.

### *3.c.2.c Preparation activities*

We will conduct 3 different types of activities during the first 12 months to complete preparations for the randomized controlled trial [(Aim 3 activities, described in section 3.c.3, will also take place during this time)]. First, we will convene ACS and Public Health – Seattle & King County (PHSKC). We will solidify shared expectations regarding each partner's roles and responsibilities and establish a regular meeting schedule and key points of contact for any study issues that arise between partner meetings. Second, we will hire and train new staff, including at least one bilingual staff member who speaks Spanish, to recruit worksites, obtain worksite and worker measures, and deliver *HealthLinks* and *HealthLinks+*. ACS GWD will be involved in the hiring and training process, and one of their staff (who has experience delivering *HealthLinks*) will supervise project staff. Third, we will finalize all of our materials and measures (see current versions of key materials and measures in Appendices 2-6), and assemble key materials from PHSKC promoting state-sponsored programs to workers. All of these materials will be translated into Spanish.

### *3.c.2.d Recruitment*

*Recruiting worksites.* Recruitment will be ongoing during months 13-24 of the proposed project. We will use a joint recruitment protocol with ACS to mimic "real-world" delivery of *HealthLinks* and *HealthLinks+* as closely as possible. From the Survey Sampling International list, we will identify the worksites that meet our eligibility criteria and randomly sequence the list for recruitment order. Study staff will make the initial contact with the worksite and identify the person with decision-making power over worksite health promotion (in our experience with worksites this size, this will likely be the worksite owner/CEO or the human resources manager). During this initial contact, staff will

briefly screen worksites to ensure they meet study eligibility criteria and will introduce the project to the decision-maker. In order to participate, eligible employers must be willing to a) be randomized to treatment or comparison groups, b) allow their workers to complete brief surveys at the worksite at baseline, 12 months, and 24 months follow-up, and c) complete all study activities, including going through the *HealthLinks* or *HealthLinks+* protocol if assigned to one of the treatment groups and completing worksite measures at baseline, 12 months, and 24 months follow-up. [We will also use a second recruitment protocol that was successful in our current *HealthLinks* study. Group Health Cooperative (GHC) will identify employers among their purchasers that meet our eligibility criteria; GHC account managers will contact eligible employers and introduce them to study staff; study staff will then contact the employer and complete the screening procedures described above (see Letter of Support from GHC).]

If the employer is both eligible and interested, staff will arrange to meet with the employer at the worksite. The study procedures and expectations will be explained to the employer, and employers who are willing to participate will be enrolled in the study. [Using these recruitment procedures, we have successfully recruited over 120 worksites in previous and ongoing projects.]

When employers agree to participate, they will complete 3 steps prior to being randomized to one of the 3 study arms: 1) Employers will sign a memorandum of understanding (MOU), which outlines the basic study procedures and expectations for data collection; 2) the employer will complete the worksite profile and baseline implementation survey (described in section 3.c.2.f), which measures the worksites' current implementation of EBIs; 3) Staff will work with the employer to identify dates and times for the worker survey. Research staff will administer the worker survey (described in section 3.c.2.f) at the worksite to all eligible workers willing to participate. Once these 3 steps are completed, worksites will be randomized to one of the study arms using a standard random numbers table.

*Recruiting workers.* We will work with the employers to identify an appropriate date and time for administering worker surveys at the worksite. Most employers prefer that we "set up shop" in a break-room or other common location and administer the survey to as many workers as possible throughout the course of one workday. We will promote the survey to workers in advance of the survey date using the communication channels the employer believes will reach the most workers. We will also offer workers a small cash incentive (\$5) to complete the survey. Following these procedures, our colleagues have been successful in attaining high response rates ( $\geq 70\%$ ) in surveys of small worksites.<sup>83</sup> [We are using these procedures with worksites in our current *HealthLinks* study and have a response rate of 79%.]

Once the employer has identified dates and times for the worker survey, our staff will collaborate with the employer to promote the survey to workers. The day of the survey, research staff will administer the survey to all workers who are willing to participate and who meet the eligibility criteria. The survey packets will contain the survey, a brief cover letter about the project and the employer's support for the survey, and the \$5 incentive. Workers who do not wish to complete the survey will not be required or pressured to participate.

#### *3.c.2.e HealthLinks and HealthLinks+ procedures*

Worksites randomized to the 2 treatment arms will receive either *HealthLinks* or *HealthLinks+*. Both *HealthLinks* and *HealthLinks+* promote the following EBIs, based on the *Community Guide* strategies.<sup>1</sup>

**Table 3: Evidence-based Interventions Promoted in *HealthLinks* and *HealthLinks+***

<b>Behavior</b>	<b>Community Guide-Recommended EBIs Compatible with Worksites</b>	<b>Interventions Promoted in <i>HealthLinks</i> and <i>HealthLinks+</i></b>
<b>Breast, Cervical, and Colon Cancer Screening</b>	<ul style="list-style-type: none"> <li>• Use small media, such as posters and brochures</li> </ul>	<ul style="list-style-type: none"> <li>• Distribute brochures and post posters to educate workers about cancer screening guidelines</li> </ul>
	<ul style="list-style-type: none"> <li>• Provide group education</li> </ul>	<ul style="list-style-type: none"> <li>• Provide brief education sessions at the worksite, including benefits of screening and information about reduced costs described below</li> </ul>
	<ul style="list-style-type: none"> <li>• Reduce out-of-pocket costs of screening</li> </ul>	<ul style="list-style-type: none"> <li>• Promote the Washington Breast, Cervical, and Colon Health Program to uninsured workers; include information about local providers, screening free of charge, and treatment coverage for those diagnosed with cancer</li> <li>• Promote benefits coverage at those worksites with insurance benefits</li> </ul>
<b>Healthy Eating</b>	<ul style="list-style-type: none"> <li>• Increase access to and awareness of healthy food options</li> </ul>	<ul style="list-style-type: none"> <li>• For worksites that sell food, create policies to offer healthy options, label them, and price them competitively</li> </ul>
	<ul style="list-style-type: none"> <li>• Increase access to healthy food options</li> </ul>	<ul style="list-style-type: none"> <li>• For all worksites, create policies to support offering healthy foods at meetings and events</li> </ul>
<b>Physical Activity</b>	<ul style="list-style-type: none"> <li>• Increase access to facilities</li> </ul>	<ul style="list-style-type: none"> <li>• Negotiate discounts at local gyms for workers</li> </ul>
	<ul style="list-style-type: none"> <li>• Use point-of-decision prompts</li> </ul>	<ul style="list-style-type: none"> <li>• Post “Use the Stairs” signs</li> </ul>
	<ul style="list-style-type: none"> <li>• Offer programs with individual choice of activity</li> </ul>	<ul style="list-style-type: none"> <li>• Offer ACS Active for Life program,<sup>84</sup> an evidence-based program that offers individual choice of activity and builds social support</li> </ul>
	<ul style="list-style-type: none"> <li>• Increase social support</li> </ul>	
<b>Tobacco Cessation</b>	<ul style="list-style-type: none"> <li>• Offer telephone-based support</li> <li>• Reduce out-of-pocket costs for medications and counseling</li> </ul>	<ul style="list-style-type: none"> <li>• Promote the Washington State Tobacco Quit Line via brochures and other small media; include information about quit line services</li> </ul>
	<ul style="list-style-type: none"> <li>• Reduce out-of-pocket costs for medications and counseling</li> </ul>	<ul style="list-style-type: none"> <li>• Promote benefits coverage at those worksites with insurance coverage for tobacco cessation</li> </ul>

[The *HealthLinks* intervention protocol is summarized in Table 4. A research staff member serves as the interventionist and delivers *HealthLinks* via a series of on-site meetings with the employer. During the Assessment phase and the Recommendations phase, the interventionist meets with a main contact at the worksite (usually the Human Resources lead). During the Implementation phase, the interventionist meets with the main worksite contact to implement new policies, programs, and communications; the interventionist also provides workers with a series of “lunch and learn” brief group educational sessions that support and promote the policy(s) and program(s) the employer adopts. Each phase of *HealthLinks* is described in detail below, followed by a description of the *HealthLinks*+WWC procedures.]

**Table 4. HealthLinks Intervention Protocol**

<b>Assessment Phase</b>	
Occurs during study enrollment	
Interventionist conducts on-site surveys	
Worksite Profile and Implementation survey	
Worker surveys	
 <b>Recommendations Phase</b>	
Occurs during Months 1-2	
Interventionist presents report summarizing current EBI implementation and gaps and worker survey results (aggregate)	
Interventionist delivers Implementation Toolkits for recommended EBIs	
Worksite contact and interventionist develop EBI implementation plan	
 <b>Implementation Phase</b>	
Occurs during Months 3-12	
Worksite contact implements EBI policies and programs	
Worksite contact and interventionist develop communications materials promoting state EBI programs and new worksite policies/programs	
Interventionist delivers on-site educational sessions to workers	
Interventionist telephones/emails worksite contact monthly	
 <b>Maintenance Phase</b>	
Occurs during months 13-24	
Worksites may contact interventionist; otherwise, no contact initiated by research team	

*HealthLinks*. Worksites receiving *HealthLinks* will go through the following procedures. In the Assessment phase (which occurs during study enrollment), research staff will measure current worksite implementation of cancer screening, nutrition, physical activity, and tobacco cessation EBIs (with the baseline worksite *Implementation* survey). In the Recommendations phase (months 1-2), staff will create a tailored *Recommendations Report* based on the baseline *Implementation* survey responses and deliver the report in a face-to-face meeting with the employer (the *Recommendations Report* template is presented in Appendix 2). The *Recommendations Report* summarizes the worksite’s current implementation of EBIs and makes recommendations for improvements.

When the staff person meets with the employer to deliver the *Recommendations Report*, s/he will also bring *Implementation Toolkits* for each of the recommended EBIs. The *Implementation Toolkits* will include checklists outlining the steps to implement each EBI, as well as appropriate supporting materials (see Appendix 3 for a sample

*Implementation Toolkit*). For example, the policy- oriented toolkits include relevant sample policies, a checklist for creating a new policy, and a timeline. The toolkits promoting state resources include ready-to-post (or distribute) posters, brochures, and email text describing the resources and eligibility criteria and how to access the resources. [The Recommendations phase concludes with staff and the employer creating an EBI implementation plan. The implementation plan will include a schedule of future visits or contacts with the interventionist, and how to promote the newly adopted EBIs to workers.

During the implementation phase (months 3-12), the employer begins adopting the recommended EBI policy(s) and program(s) and promoting them to workers.] The interventionist will make brief presentations at the worksite to workers to help present or start newly implemented EBIs. For example, if a worksite implements *Active for Life* (a physical activity program), the interventionist will make a presentation to workers introducing them to the program, summarizing the program steps, and giving information about recommended physical activity levels and creative ways to fit more physical activity into the workday. Worksites with Spanish-speaking workers would also receive Spanish-language versions of any materials for direct distribution to workers; [one or more of the interventionists will also speak Spanish and will be able to deliver these presentations in Spanish as needed. The interventionist will contact worksites at least once per month by email or telephone during this period to offer implementation assistance.

After the implementation phase, worksites will enter the maintenance phase (months 13-24). They will be able to contact the interventionist for technical assistance. The interventionist will not

proactively contact worksites during this final period.]

*HealthLinks+*. The *HealthLinks+* protocol is the same as described above, with one modification. First, the interventionist recommends that the employer form a worksite wellness committee (WWC) during the *Recommendations Report* meeting. S/he will provide an *Implementation Toolkit* for WWCs and will offer to help with kick-off meetings, etc. The role of the WWC will be to lead implementation of the worksite's recommended EBIs. Once the WWC is formed, it will become the primary contact for our staff. The interventionist will attend the initial WWC meetings, with the goal of helping the WWC [develop a regular meeting schedule and an EBI implementation plan.] The WWC will work with the interventionist to:

- Determine how best to promote cancer screening guidelines and the state-sponsored cancer screening program to workers (if the worksite insures most workers, the WWC will determine how best to promote the cancer screening benefits to workers) and distribute materials accordingly
- Determine which healthy eating policy is most appropriate for the worksite, based on whether and how the worksite offers food for sale, and implement the policy
- Determine which physical activity interventions are most appropriate for the worksite and its workers (if *Active for Life* is chosen as one of the physical activity interventions, plan and implement *Active for Life*)
- Determine how best to promote the state-sponsored tobacco quit line to workers and distribute the materials/messages accordingly (if the worksite insurance plan includes tobacco cessation coverage, the WWC will also determine how best to promote the cessation benefits to workers)
- [Create a schedule for the on-site brief presentations delivered to workers by the interventionist
- Determine how best to maintain the EBIs and continue to promote them to workers over the 2-year intervention and follow-up period]

### 3.c.2.f Measures

We will collect measures at both the worksite and worker levels. In this section, we describe main outcome measures as well as descriptive and process measures we will collect from worksites and workers.

*Worksite Descriptive and Outcome Measures*. When we call employers to participate in the study during recruitment, we will conduct screening surveys to determine whether worksites meet eligibility criteria and identify employers' reasons for refusing the study. Once an employer has agreed to participate, we will collect information about the characteristics of the worksite with the *Worksite Profile* survey (see Appendix 4). [This survey measures **antecedents** in our model: worksite industry, size, average annual salary, annual worker turnover, percentage of workforce employed full-time, insured by the employer, and percentage of workforce belonging to a union. It also captures whether the worksite is the company's headquarters and workforce demographic characteristics (race/ethnicity, age, and gender). We will use the *Worksite Profile* survey to describe the participating worksites, ensure that our randomization procedures were effective, and as potential covariates in outcome analyses.] The *Worksite Profile* survey will be administered at the same time as the *Implementation* survey (after the worksite has agreed to participate and prior to randomization).

The *Implementation* survey measures EBI **adoption** and **implementation** in our model, and includes items that characterize worksite implementation of EBIs promoting cancer screening, healthy eating, physical activity, and tobacco cessation. For each of the EBIs, the survey includes 5 to 10 items assessing level of implementation. [For example, for the physical activity EBI of offering programs with individual choice of activity, items include: 1) does the worksite offer a physical activity program [t remaining questions are asked of employers who do offer a program], 2) how

many months does the program run, 3) what percent of workers have access to the program, 3) does the program allow participants to choose their own types of activities, 4) does the program allow participants to set their own physical activity goals, 5) does the company promote the physical activity program to workers, 6) what communication channels are used, and 7) how frequently are these communications sent (see Appendix 5 for full scale). Items are combined using a weighted algorithm to form an implementation score from 0-100 for each EBI, with 0 indicating no implementation and 100 indicating full implementation.] The *Implementation* survey will be administered at baseline (prior to randomization), at 12 months, and 24 months follow-up (the 24 months follow-up will measure **maintenance** of adopted EBIs).

*Worksite Process Measures.* [Staff will collect the following process measures at worksites in the *HealthLinks* and *HealthLinks+* arms of the study. For each meeting with the employer, the interventionist will log the meeting date, length, attendees, engagement of attendees in the meeting, and implementation barriers anticipated or reported by employers. The interventionist will log the date and number of attendees at the educational sessions for workers; s/he will also log which *HealthLinks* communications materials are distributed at the worksites (date and number). The interventionist will track physical activity program kick-off date, number of participating workers, and number of training sessions and support materials provided. In addition, the interventionist will log every employer-initiated contact (date and what was requested). For worksites receiving *HealthLinks+*, the interventionist will track the WWC meetings (dates, attendance, and topics covered).] These process measures will document a) that *HealthLinks* was delivered as intended, b) worksites' requests for implementation support, and c) the implementation barriers worksites encountered.

*Worker Descriptive and Outcome Measures.* We will collect measures from workers at all participating worksites at baseline, 12 months, and 24 months follow-up, using the recruitment procedures described in section 3.c.2.d. Our primary goal with the Worker survey is to learn whether the worksite's implementation of EBIs has any effect on workers' health behaviors (**individual behaviors** in our model). We will measure workers' demographic characteristics, overall health status, and current health behaviors regarding cancer screening, nutrition, physical activity, and tobacco cessation using BRFSS questions (see Appendix 6). Using BRFSS questions has 2 advantages: 1) These questions are available in Spanish, and 2) We can compare workers' responses to state BRFSS results for low-income workers.

*Worker Process Measures.* As process measures, we will include items in the *Worker* survey that measure workers' awareness of worksite EBIs. We will measure workers' participation in EBIs, [awareness of EBI policies, and awareness and perceived usefulness of worksite communications and educational presentations.] (Dr. Valenzuela, of PHSKC, will use a standard translation/back-translation process to create a Spanish-language version of these additional survey items.) These process measures will enable us to test whether workers' awareness and perception of worksite implementation changed over the 24-month study period and changed in accordance with worksites' reported EBI implementation.

### 3.c.2.g Statistical analyses

*Specific Aim 1.* The primary outcome is worksites' implementation of EBIs, scored as a proportion (0-1.0 scale). A multivariate linear regression model will be used to test the main effects of treatment condition (*HealthLinks*, *Healthlinks+*, delayed control) and time (baseline, 12 and 24 months follow-ups), and the interaction effect. [To take into account the correlations between observations at different time points within the same work site, estimation will be implemented using a generalized estimating equation with an autoregressive working correlation matrix of order 1. Robust standard error and tests will be performed to obtain valid test results for correlated data. The model will include worksite size (20-49 v. 50-200 workers) and industry as covariates; in our prior studies, these two characteristics are associated with worksites' EBI implementation.]

**Power analysis.** We propose a sample size of 90 worksites (30 per group) for this study. We calculated the power of detecting a change (if it exists) under various scenarios, which were based on the pilot study described in section 3.a.8. That study had a mean implementation score of .35 (sd= .17) at baseline and of .57 (sd=.21) at 6-month follow-up. We used the software PASS<sup>85</sup> to calculate power for testing the hypothesis with a 5% significance level. We assumed the following:

no or little change in score over time in the delayed group, an increase for *HealthLinks*, and higher increase for *HealthLinks+*. For each scenario, the combination of mean scores are shown in the first column of Table 5, followed by the power to detect differences in groups, times, and interactions in

**Table 5. Power Analysis for Primary Outcome, Worksite Implementation of EBIs**

	Power for					
	Intervention Effect		Time Effect		Interaction	
	SD=.17	SD=.21	SD=.17	SD=.21	SD=.17	SD=.21
D: .30, .30, .30 HL: .30, .40, .40 HL+: .30, .45, .50	.99	.92	.97	.86	.75	.55
D: .30, .30, .30 HL: .30, .40, .45 HL+: .30, .50, .55	1.0	.99	1.0	.98	.93	.77
D: .30, .35, .35 HL: .30, .40, .45 HL+: .30, .50, .55	.99	.92	1.0	1.0	.75	.55
D: .30, .35, .35 HL: .30, .45, .40 HL+: .30, .55, .50	.99	.92	1.0	1.0	.75	.55

D = Delayed group; HL = HealthLinks; HL+ = HealthLinks+

the subsequent columns. We did the power calculations under standard deviations of .17 and .21 (both observed in the previous study), assuming autocorrelation of order 1 with a value of .5, using the Wilks statistics. Values for the mean scores are on a range around the observed values of the previous study. For example, the 3<sup>rd</sup> row depicts the situation where the scores observed for the delayed group are .30 for the baseline and .35 for both follow-ups (a small increase without intervention); corresponding values for the *HealthLinks* group over time are .30, .40, and .45, while for *HealthLinks+* they are .30, .50, and .55. In that scenario, we have power to detect effects of the intervention of at least .92. Note that the last row has a pattern of increasing score at 12 months and decreasing at 24 months, but the power is the same. Given this power scenario, we are optimistic that we would retain adequate power to detect intervention effects even if several worksites did not complete the study.

[The power analysis is conservative because we did not assume any site-level covariate information is being used in the randomization procedure and in the analysis, Since the sample size per group is not large, unmatched randomization may not be able to balance covariate distribution. We propose using the method of optimal nonbipartite multivariate matching<sup>86</sup> before randomization to improve covariate balance among treatment groups. Unlike usual blocking design that is applied mostly to one or two blocking variables, optimal nonbipartite matching will maximize balance for multiple covariates. We will consider matching based on worksite size, industry, whether worksite is headquarters for the company, and proportion of workers insured. Apart from matching, we will use the optimal data augmentation method<sup>87</sup> for analysis to improve the power of statistical analysis. This data augmentation technique is a recent advance that could further improve covariate balance and power when there is residual imbalance after nonbipartite matching.]

**Specific Aim 2.** The outcome is the proportion of workers at each worksite who are appropriately screened for breast, cervical and colon cancer, have healthy eating habits, meet physical activity recommendations, and do not smoke. A multivariate logistic regression model will be used to test the main effects of treatment condition (*HealthLinks*, *Healthlinks+*, delayed control) and time (baseline, 12 and 24 months follow-ups), and the interaction effect. [Similar to the Specific Aim 1, a generalized estimating equation with robust standard error estimates will be used in the statistical analysis.]

### 3.c.2.h Potential Challenges and Solutions.

The first potential challenge is meeting recruitment goals; we need to recruit 90 worksites to

participate and have approximately 12 months to do so. To meet this challenge, we are taking several measures. First, we have ensured that we have a large pool of worksites that meet our location, industry, and size criteria. [Second, we plan to have 3 staff involved in recruitment activities. Third, we will partner with Group Health Cooperative, an insurer with significant market share among employers meeting our eligibility criteria; they will refer their employers to our recruitment staff. These approaches were successful in meeting our recruitment goals for our current and prior *HealthLinks* studies.] In the unlikely event that we exhaust our list of worksites prior to recruiting 90, we will go to Snohomish County (immediately north of King County) to complete recruitment.

Other potential challenges of the trial involve measurement; we are collecting measures at both the worksite and worker levels over a 2-year period and acquiring complete data may be difficult. At baseline, we will be able to meet this challenge by requiring worksites to provide both worksite and worker measures before they are officially enrolled in the study. We are confident that the study-expectations MOU worksites will sign upon enrolling and the fact that we're providing all worksites with implementation support (after follow-up, for the worksites in the delayed control group) will help us obtain follow-up data from participating worksites and their workers. In three prior studies with worksites, we have maintained participation through follow-up data collection with 87 to 100% of our worksites.

### 3.c.3 Specific Aim 3: Adaptation and Validation of a Worksite Readiness-to-Change Measure

In the proposed study, we will adapt for use in worksites an organizational readiness-to-change assessment (ORCA) developed and validated in clinical settings.<sup>68</sup> We define organizational readiness as “organizational members’ beliefs, attitudes, and intentions regarding the extent to which changes were needed and the organization’s capacity to make those changes.”<sup>62</sup> The ORCA assesses: a) the perceived strength of evidence for the EBI, including fit with worksite leaders’ and workers’ needs and values (Evidence scale), and b) favorability of the worksite context (for change in general as well as change specific to EBIs), including past experiences implementing EBIs, and perceived commitment from management (Context scale).<sup>68</sup>

The survey has previously been validated<sup>68</sup> and is one of the few organizational readiness surveys to have been fielded prospectively and show evidence of predictive validity.<sup>88</sup> However, the ORCA was developed for implementation of evidence-based *clinical* practices, and although many of the concepts and survey items should apply equally to implementation of worksite health promotion programs, many will not. Consequently, significant revision is likely necessary. A draft version of the adapted scale is in Appendix 7.

#### *3.c.3.a Procedures*

*Adapt ORCA.* During the first year of funding, we will adapt the survey using think-aloud interviews with a sample of employers. (These employers will be separately recruited, not employers participating in the RCT.) The think-aloud interview is a usability-testing method for survey development to understand if items are accurate reflections of respondents’ thoughts.<sup>89,90</sup> Generally, think-aloud interviews produce 80%-90% of issues within the first 5 participants,<sup>91</sup> and therefore we anticipate conducting adaptation activities with 5-20 participants. Based on the think-aloud analysis, we will draft a revised survey, with the primary goal of tailoring for the worksite context and eliminating items that make no sense in the worksite setting.

*Pilot-test adapted ORCA.* We will then pilot-test the adapted survey with approximately 100 employers. (These employers will be separately recruited, not employers participating in the RCT.) We will conduct internal-scale reliability analyses: Cronbach's alpha, a scale-level measure of reliability, and item-rest correlation, an item-level measure of reliability.<sup>92</sup> Items or subscales exhibiting poor scale reliability will be eliminated from the scale.

*Test ORCA's predictive validity.* We will validate the adapted survey in the RCT study sample using baseline assessments of readiness to change as predictors of site-level implementation of

EBIs. We will administer the adapted ORCA survey along with the *Implementation* survey at baseline, 12 months, and 24 months follow-up. We will examine the association of baseline readiness with change over time in implementation of EBIs, and the changes in readiness scales over time associated with different intervention arms. Based on our past studies, we anticipate that worksites in the RCT will vary widely in their ORCA scores; worksites that are ready to enroll in a study that offers free health promotion support are not necessarily ready to implement EBIs.

#### *3.c.3.b Statistical Analyses*

The predictive validity analyses will use multivariate regression where the dependent variable is worksite-level EBI implementation score (e.g., the primary outcome of the RCT), and the independent variables are mean score on ORCA scales (the Evidence and Context scale scores) and three covariates: 1) intervention arm (*HealthLinks* vs. *HealthLinks+* vs. delayed control), 2) industry (5 categories), and 3) worksite size (20-49 vs. 50-200 workers).

The predictive validation analyses will serve 2 purposes. First, we will assess whether baseline readiness to change is an effect modifier for implementation of EBIs. [We hypothesize that a higher baseline readiness to change would lead to stronger impact of *HealthLinks* and *HealthLinks+* on EBI implementation.] We will examine the relationship of implementation change to overall aggregate scores on the principal ORCA scales, as well as the relationship to specific subscales, such as questions measuring the role of opinion leaders or the perceived strength of research evidence for the EBIs. Second, we will compare changes in ORCA scores from baseline to follow-up to determine if *HealthLinks* and *HealthLinks+* have any effect on readiness to change. This comparison could help corroborate the causal pathway, i.e., that receiving *HealthLinks* influences organizational conditions such as the perceived evidence supporting the EBIs.

#### *3.c.3.c Implications*

If the adapted ORCA demonstrates predictive validity, we will develop training for ACS staff in using the ORCA for national dissemination efforts in two ways. First, we will develop pilot prognostic benchmarks or threshold levels, either of the overall ORCA score or combinations of specific subscales, that reflect an acceptable probability of success to justify investing resources in given worksites. Second, we will develop templates for a site-specific, diagnostic feedback report that identifies potential strengths and deficits, e.g., at one work site, they may doubt the benefits of EBIs, and at another, believe in the benefits but doubt the compatibility with their work place culture, calling for different messaging and engagement strategies.

#### 3.c.4 Plans to Report and Disseminate Research Results

To inform the dissemination, implementation, and worksite health promotion literature, we will give presentations at national conferences and publish journal articles. For the proposed project to have maximum effect nationwide, we will need to maintain our engagement with ACS throughout the project and plan future activities with them to scale up delivery of *HealthLinks* or *HealthLinks+* (assuming that one, or both, is effective). Once the primary results are determined, we plan to present the findings to ACS leaders at national and division levels. Our goal will be to integrate the most effective dissemination program(s) and readiness measures into ACS's practice with worksites nationwide.

### 3.c.5 Project Timeline

	Year 1		Year 2		Year 3		Year 4		Year 5	
	Q1-2	Q3-4								
Convene partners	X	X	X	X	X	X	X	X	X	X
Adapt worksite readiness survey	X									
Worksite readiness survey cognitive testing	X									
Worksite readiness survey pilot-test		X								
Hire and train <i>HealthLinks</i> staff		X								
Translate materials and measures	X	X								
Recruitment & Baseline measures			X	X						
Intervention implementation			X	X	X	X	X			
Follow-up measures						X	X	X		
Analysis		X	X	X	X	X	X	X		
Delayed intervention						X	X	X		
Sustainability planning						X	X	X	X	X
Manuscripts/presentations		X	X				X	X	X	X

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