

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

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SF 424 R&R Face Page

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Grant Number: 1 R01 CA210259-01A1

Title: Using Technology to Scale-Up an Occupational Sun Protection Policy Program

FOA: PAR16-238

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

Organization: Klein Buendel, Inc

Senior/Key Personnel: David Buller Ph.D

Organization: Klein Buendel Inc.

Role Category: PD/PI

Project Summary

A key goal in the Affordable Care Act is building a national culture of prevention through workplace health and safety initiatives. To achieve this goal, methods for scaling up evidence-based programs from research to wide- scale dissemination are needed to help balance effectiveness and cost. In many cases, there are pressures to reduce scale-up costs but at the expense of lower program implementation and effectiveness. A scale-up method that sacrifices effectiveness but reduces costs and reaches a larger number of employers may be acceptable. We will model the effectiveness and cost trade-off, along with the extent and representativeness of reach, when scaling up our evidence-based occupational sun protection intervention, *Sun Safe Workplaces (SSW)*, for national distribution. The intervention, which relies on personal contact with managers and in- person employee training (*SSW-IP*), created large improvements in comprehensive workplace sun safety (i.e., policy adoption and employee education) in a randomized controlled trial. We will compare the existing in- person program delivery methods (*SSW-IP*) to a lower-cost dissemination method that utilizes Internet technology (*SSW-T*), i.e., virtual meetings, social networking, online training, and program materials. The aims of the research are to: 1) estimate the program reach (number and representativeness) and implementation rates (i.e., adoption of policies and delivery of education on occupational sun protection) achieved by the *SSW-IP* and *SSW-T* in a model of national distribution to public safety and public works industries; 2) estimate the costs associated with the *SSW-IP* and *SSW-T* (i.e., intervention costs and induced employer costs) and compare the estimated program benefits (i.e., policy and education) to cost; and 3) estimate the effect and cost-effectiveness of *SSW-IP* and *SSW-T* in secondary outcomes of a) changes in workplace environments and procedures for sun safety and b) workers' sun safety practices. In a 5-year project, *SSW-T* will be created by redesigning our very effective *SSW-IP* methods to use the latest web conferencing, social networking, and online training technology for dissemination. The implementation rates (defined as policy adoption and education delivery) and costs associated with *SSW-IP* (n=50 employers) and *SSW-T* (n=150 employers) will be modeled in a randomized two-group pretest-posttest design, enrolling a national sample of 200 employers (i.e., firefighting departments and state departments of transportation). Unlike traditional randomized trials, the primary analysis will be of cost effectiveness to test the hypothesis that *SSW-T* can be delivered cost-effectively to an expanded group of worksites producing a lower implementation rate than *SSW-IP* but at substantially lower cost. Secondary analyses will compare the two scale-up strategies on implementation rate, differences in rate by employer groups (e.g., size and region), changes to workplace environment/procedures, and employee sun safety practices. The findings will have high impact by helping public health practitioners select the best strategy for scaling up evidence-based workplace health and safety programs to achieve this ACA goal.

Project Narrative

Comprehensive approaches that combine sun protection policy and education for outdoor workers can reduce their risk for skin cancer by reducing their exposure to solar ultraviolet radiation on the job. To effectively disseminate our evidence-based sun protection policy and education intervention, *Sun Safe Workplaces*, a balance of effectiveness and cost of scale-up methods is required. We propose to translate the intervention using a technology-based delivery method and compare the cost effectiveness of the original intervention and the intervention delivered by technology in a study that models national distribution strategies to public safety and public works sectors.

Specific Aims

An Affordable Care Act (ACA) goal is to build a national culture of prevention/wellness at workplaces.¹ Americans spend many hours in work environments that contribute to health risks through hazardous job exposure and demands, and inflexible work schedules.² A key to this goal is scaling-up evidence-based interventions.³ Unlike effectiveness trials that focus mainly on changing individuals, metrics for effective scale-up methods include how effective an intervention is at changing individuals' behavior when disseminated and the costs of scale-up. Effectiveness and costs must be balanced, for large resources are usually needed in scale-up. Unfortunately, scale-up methods sometime risk sacrificing intervention effectiveness to achieve cost savings to permit more organizations to benefit (i.e., to "reach" a larger and broader amount of the population).

An illustration may be helpful. Say an evidence-based intervention strategy costs \$2000 per worksite in a randomized effectiveness trial. This strategy may be unaffordable when scaled up to a large industry of 30,000 employers for it would cost \$60 million. Say, also, there is a less-intensive scale-up method costing only \$200 per employer that can reach the same industry for just \$6 million. Even if it is less effective (i.e., only 10% change compared to 30% with the original method), for the same cost, the less intensive scale-up method may be a cost-effective method because it will benefit far more worksites (reaching 30,000 worksites for \$6 million, resulting in 3,000 effected [10%]) than the original strategy from the randomized trial (reaching just 3,000 worksites for \$6 million [at \$2000/employer] with only 900 effected [30%]).

One workplace health risk that has garnered little attention is extreme amounts of solar ultraviolet radiation (UV) in outdoor work environments. The National Institute of Environmental Health Sciences⁴ has identified UV as a carcinogen associated with ocular damage and skin cancer,^{5,6} the most frequently diagnosed cancer in the country^{7,8} (i.e., 73,870 melanomas [with 9,940 deaths] and over 3.5 million non-melanoma skin cancers diagnosed in 2015). We developed *Sun Safe Workplaces (SSW)*, a state-of-the-art comprehensive occupational sun safety program. In a series of trials,⁹⁻¹¹ employers implemented education that motivated employees to increase sun protection. Most recently, SSW which combined worker education with policy promotion substantially increased the number of employers adopting sun safety policies (and more extensive and stronger policies) in a randomized trial (n=98 employers; Cohen's d=1.57; see Box 1). Moreover, the SSW intervention improved on an earlier intervention promoting sun safety policies to public school districts (see Box 2). Together, these results indicate that SSW is sufficiently effective to consider scaling it up nationwide.

We propose to model the implementation rate (defined as policy adoption and education delivery) and costs associated with two methods of scaling up SSW to two large industries – public safety and public works – to determine the most cost-effective scale-up strategy. The program delivery methods from our recent randomized effectiveness trial that relied on in-person interpersonal contact (*SSW-IP*) will be compared to a method that relies on Internet technology (*SSW-T*). Each strategy will be modeled in a random sample of worksites, 50 workplaces for *SSW-IP* and 150 workplaces for *SSW-T* with outdoor workers in fire safety and transportation. It is expected that *SSW-T* will be less costly than *SSW-IP* per employer reached, but it may achieve a lower implementation rate. We seek to determine if reach and implementation are sufficient to make *SSW-T* a cost-effective option over *SSW-IP* for national scale-up. The specific aims are as follows:

1. To estimate the program reach (number and representativeness) and implementation rates (i.e., adoption of occupational sun protection policies and delivery of sun safety education) achieved by the *SSW-IP* and *SSW-T* in a model of national distribution to public safety and public works industries.

2. To estimate the costs associated with the *SSW-IP* and *SSW-T* (i.e., intervention costs and induced employer costs) and compare the estimated program benefits (i.e., policy and education) to cost.
3. To estimate the effect and cost-effectiveness of *SSW-IP* and *SSW-T* on secondary outcomes of a) changes in workplace environments/procedures for sun safety and b) workers' sun safety practices.

In this 5-year project, *SSW-T* will be created by translating and enhancing our *SSW-IP* methods using the latest web conferencing, social media, and training technology to support virtual networks of managers and training of employees. *SSW-IP* and *SSW-T* in national distribution will be modeled in a randomized two-group pretest-posttest design, enrolling a national sample of 200 employers (i.e., fire departments and state departments of transportation [DOTs]) stratified by size and region. The aims are significant and innovative. We will identify the best strategy to reach employers nationwide on occupational sun safety. Reach is defined as number of employers implementing policy and education and representativeness of those employers. This information will generalize to dissemination of other workplace prevention and safety programs to help achieve an ACA goal. The *SSW* intervention will reduce UV exposure in the workplace, a risk that has received little attention, to reduce skin cancer prevalence and save substantial annual treatment and lost-productivity costs.¹²

The project will be led by Multiple Principal Investigators, Drs. David Buller and Barbara Walkosz at Klein Buendel, Inc. (KB). Co-Investigators (Co-I) include Dr. Allan Wallis from the School of Public Administration at the U. of Colorado Denver (UCD), Dr. Richard Meenan at Kaiser Permanente's Center for Health Research (KP), *Dr. Sherry Pagoto at U. Massachusetts Medical School (UMASS)*, and Ms. Mary Klein Buller from KB. Dr. Gary Cutter from Pythagoras, Inc. will be the biostatistician. This team conducted the *SSW* trial. Dr. Borsika Rabin will be an expert consultant on implementation science.

Research Strategy

3A. Significance

3A1. Occupational Skin Cancer Prevention

Evaluating dissemination strategies for an occupational sun protection program is significant for it addresses the U.S. skin cancer epidemic. Skin cancer is the most common cancer, with melanoma rates growing at 3% per year.¹³ The 8% of U.S. workers who labor outdoors are exposed to dangerous solar UV over many years.^{14,15} Lifetime UV exposure is linked to squamous cell carcinoma (SCC) and possibly deadly melanoma;¹⁶⁻¹⁹ intermittent, severe exposure may be related to melanoma, basal cell carcinoma and SCC.²⁰⁻²⁶ Occupational sun exposure receives limited attention,^{27,28} despite its link to skin cancer.^{6,29,30} While melanoma is associated less with outdoor work than non-melanoma skin cancers (NMSC),^{22,31,32} elevated risk of melanoma has been observed for outdoor work.^{26,33} Preventing NMSC is a priority due to its high prevalence (3.5 mil. cases in 2015⁸);^{34,35} recurrence;³⁶⁻³⁸ treatment disfigurement,³⁹⁻⁴² and costs (\$2.1 bil. for treatment; \$961 mil. for lost productivity¹²). Melanoma mortality produced \$66.9 bil. in lost productivity from 1990-2008⁴³ *and an estimated 166,261 years of productive life lost in 2006 (\$413,370 per individual⁴⁴).* Sun safety should be promoted at work because many workers fail to practice it.^{14,27,45-51} Sun safety also aligns with initiatives to prevent worker injury and improve well-being, prevent heat stress^{52,53} and cope with climate change.^{54,55}

3A.2. Dissemination of a Scaled-up Evidenced Based Occupational Sun Safety Program

This research is significant because it models costs, reach, and effectiveness of strategies to scale-up national dissemination of an evidence-based workplace health policy and education intervention, a public health priority.^{56,57} Scale-up is the effort to increase the impact of successful programs to benefit more people on a lasting basis⁵⁸ and is a DHHS Strategic Plan goal.³ Scale-up must lower cost and increase reach to provide greater access to benefits.⁵⁹⁻⁶¹ Programs have been successfully scaled-up for HIV treatment/prevention,^{62,63} obesity prevention,^{56,60} and health service delivery,^{63,64} yet a research-to-practice gap remains between effective programs and real world application.⁶⁵ Costs, retained effectiveness, and reach must be examined.⁶⁰

Several frameworks have guided scale-up such as collaborative models stressing planning, finances, and systems,⁶⁶ interactive systems approach focusing on tools and training,⁶⁵ and process models with steps such as EPIS (exploration, preparation, implementation, and sustainability).⁶⁷ We will use the **RE-AIM** framework (**R**each, **E**ffectiveness, **A**doption, **I**mplementation, and **M**aintenance)^{68,69} to inform the translation and public health impact of scale-up. Other frameworks, i.e., Diffusion of Innovation⁷⁰ or the Consolidated Framework for Implementation, share properties with RE-AIM,⁷¹ but RE-AIM, a robust and common framework for program dissemination,⁷² is the best fit for it can address costs and economic outcomes across general and multiple dimensions of the model^{73,74} including at organizational and individual levels.^{71,73} It applies to the health policy arena by estimating public health impact and integrating policies with health promotion strategies.⁷⁵ RE-AIM researchers believe cost influences several aspects of dissemination, e.g., cost affects intervention intensity that is positively related to effectiveness but negatively, to implementation.⁷⁶ We will adapt RE-AIM to incorporate cost as a primary factor – **(C)RE-AIM**. Information on costs (and intervention delivery resources) is: 1) essential for moving research into practice,^{57,68} 2) under-reported in dissemination and implementation,⁵⁷ and 3) a central component of our proposed SSW scale-up study. Our economic analysis will examine key resource elements that include distribution, effectiveness, and replication/implementation costs.⁵⁷

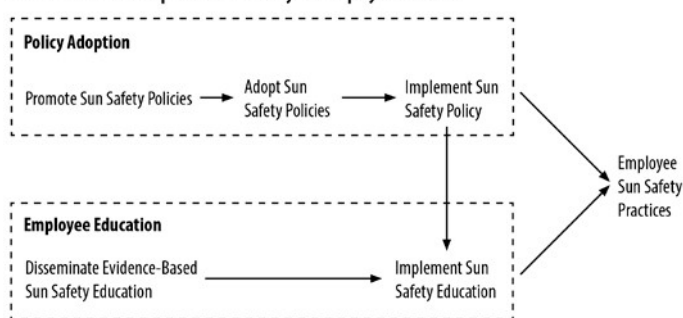
Going to scale with a research-tested intervention is more than replication in large populations. “Options, knowledge processes, and technologies” are expanded to build capacity and influence decision-makers⁵⁸ and understand the implementation and cost of programs.³ Interventions’

effectiveness sometimes decrease during scale-up,⁷⁷ due to reduced dose and fidelity⁷⁸ and adaptations to fit contextual/budget parameters,⁷⁷ so relatively large effect sizes are needed in the efficacy stage to retain an acceptable effect when scaled-up.^{77,78} Our *Sun Safe Workplaces (SSW)* program has sufficient effectiveness (see Box 1). Costs of national distribution will be daunting, so an affordable scale-up strategy is tested to see if it maintains sufficient intervention effectiveness.

3A.3. Workplace Policy and Employee Education for Occupational Sun Safety and Health

The research significantly advances workplace health and safety research by advocating policy changes, not just education, for chronic disease prevention.⁷⁹ Workplace programs are increasingly designed to prevent chronic disease (i.e., skin cancer) as well as acute injury (i.e., severe sunburn) to reduce health-care costs.¹ Health promotion models that incorporate policy with education can impact safety, disease management,⁸⁰ and disease prevention, e.g., physical activity, diet, obesity, and tobacco use.⁸¹⁻⁹⁴ Most workplace interventions have focused on education to improve employee knowledge and behavior,^{95,96} including on sun protection,⁹⁷ but ideal interventions incorporate policies geared to broad actions at all levels with education to achieve long term well-being.^{96,98-102} Policies and education work synergistically (Figure 1) by integrating health promotion and safety procedures,⁸⁰ clarifying personal/organizational responsibilities (e.g., who provides sunscreen and protective clothing), and formally directing employees to take precautions. Policies can overcome low perceived risk, personal preferences (say for tanning), and other barriers, as well as

FIGURE 1: Relationship of Worksite Policy and Employee Education



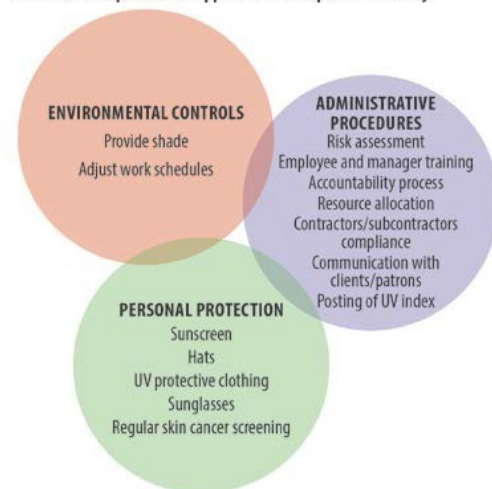
equalize gender and age differences in health practices,^{14,47,48} and improve safety and health outcomes⁸⁷⁻⁹⁴ by requiring worker education. Education may elevate managers' receptivity to policy to support/sustain sun safety.

Except for our *SSW* trial, most studies of occupational sun safety have focused on worker education^{22,97,103-108} which has improved sun safety by outdoor workers.^{9,22,48,97,103-109} For

instance, our *Go Sun Smart (GSS)* education reduced employees' sunburning (see Box 2).^{9,10} However, our more comprehensive *SSW* motivated employers to adopt policies for routine sun safety training plus environmental controls and administrative procedures that reduce UV exposure (Figure 2);¹¹⁰⁻¹¹⁹ establish organizational and individual agendas for sun safety; and integrate sun safety into an organization's operations (see Box 1). There was a large need for policy promotion: At baseline, few employers had sun safety policies; policies mainly addressed personal protection; environment/administrative procedures were rare; and most policies encouraged, not required, protection (requiring such practices has improved workers' sun safety).^{46,120}

While no estimates exist for worksites, a community skin cancer prevention program would prevent 20% of U.S. melanoma cases between 2020-2030 (21,000 yearly), saving \$2.7 billion in health care costs (\$250,000 yearly¹²¹). In New Zealand, a 10% reduction in severe sunburns would prevent 8.5% of melanomas attributable to sunburning; our GSS education program reduced sunburning. Australian data indicated interventions that achieve regular sunscreen use would prevent 9.3% of SCC and 14% of melanomas.¹²²

FIGURE 2: Comprehensive Approach to Workplace Sun Safety



3B. Innovation

In 2014, the Surgeon General issued a call to action¹²³ for policy and education to prevent skin cancer and CDC's Task Force on Community Preventive Services recommended occupational programs.¹²⁴ This project will be one of the first to show how an evidence-based comprehensive workplace sun safety policy and education program can be best scaled up for national dissemination by:

- Conducting an economic analysis that will model the cost-effectiveness of the *SSW-IP* and *SSW-T* to determine the balance of implementation rate and cost to achieve reach of a scaled-up program;
- Utilizing technology tailored to fit the technology resources of an outdoor workforce and enhanced to create a virtual network of managers for sun safety to scale-up *SSW* at the national level;
- Engaging the public sector in adoption of both policy and education to advance occupational sun safety;
- Evaluating employees to show effectiveness of a policy and education program for improving sun safety;

While some workplace modifications have addressed sun safety (e.g., workers compensation, insurance¹²⁵) comprehensive approaches are rare. The Occupational Safety and Health Administration (OSHA) issued a tip card with sun safety precautions¹²⁶ and some major unions/employers have guidelines on sun safety.¹²⁷

3C. Approach

3C.1. Overview of Approach

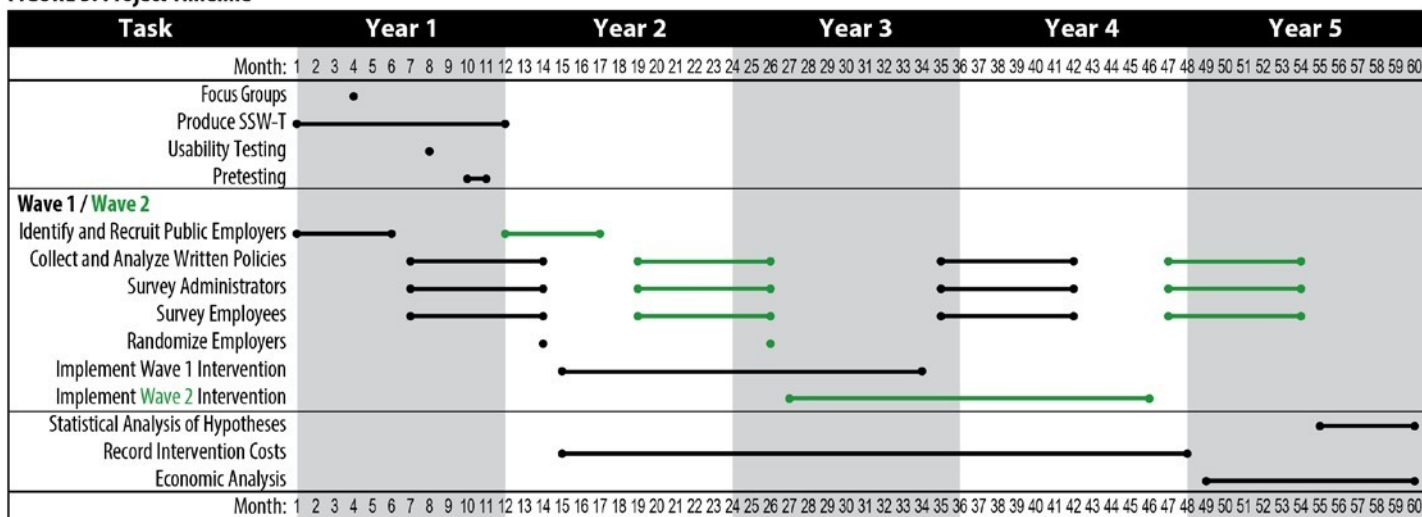
The specific aims will be achieved in a 5-year project (see Figure 3 for timeline) based on the **(C)RE- AIM** framework. In Year 1, our *SSW* intervention that was delivered by interpersonal contact and in-person training (*SSW-IP*) will be translated to a delivery platform using online technology (*SSW-T*) that should increase its **R**each (i.e., number and representativeness of employers). A randomized 2-group pretest-posttest trial in Years 2-5 will model a) the implementation rate of **A**dopting a policy and **I**mplementing education on sun protection (Aim 1), b) the **C**ost of delivery (Aim 2) of *SSW-IP* and *SSW-T* when scaled-up, and c) compare *SSW-IP* and *SSW-T* on cost-effectiveness. **E**ffects of policies and education on workplace environments/procedures and employees' practices that improve sun safety will be assessed (Aim 3). Employers (n=200) in public safety and public works industries (i.e., firefighters and transportation workers) will be stratified on size and region and recruited in two waves. Primary outcomes will be obtained by coding written policies and surveying managers.

3C.2. Sun Safe Workplaces Intervention (*SSW-IP*)

The original *SSW* (hereafter, *SSW-IP*) was designed by our team in an NCI-funded trial¹²⁸ (see Box 1), combining strategies from two of our successful interventions: The *Go Sun Smart (GSS)* worksite sun safety education program and *Sun Safe Schools (SSS)* school sun protection policy campaign (see Box 2). *SSW-IP* promoted comprehensive occupational sun protection (see 3A.3), i.e., adoption of sun safe policies and provision of sun safety education¹²⁹ to ensure employee sun safety was promoted and supported long term. Diffusion of Innovations Theory (DIT) and two theories of relationship development – social penetration theory^{130,131} and stages of relational development¹³²⁻¹³⁴ – were the theoretical basis. In DIT, organizational diffusion is achieved through changes in management, policies, and procedures^{70,135-137} facilitated by increasing perceived need for workplace sun safety, demonstrating that policy/education fit the organizational mission/ practices, and helping plan for policy/education, realizing that policies/education and/or the organization may need to change to improve fit and changes need to be clarified to managers/employees.¹³⁸⁻¹⁴⁰ *SSW-*

IP aimed to a) reduce managers' uncertainty^{141,142} about sun safety; b) highlight advice from national health authorities to build credibility/trust^{143,144}; and c) obtain commitment to adopt and implement the policies/education.¹⁴⁵⁻¹⁴⁷ *SSW-IP* staff, as outside change agents, tried to achieve two relational outcomes with managers: a) open communication channels and develop relationships with managers and b) engage in involved communication about policies/education on sun safety. Outside change agents have promoted adoption of safety/prevention programs by schools, hospitals, and businesses.^{137,148,149} *SSW-IP* staff "bundled" sun protection policy/ education with other worksite safety goals (e.g., hydration; frostbite and heat stroke prevention).^{140,150}

FIGURE 3: Project Timeline



SSW-IP consisted of personal visits with managers and materials promoting sun protection policies and education (see Figure 4).¹²⁹ A **Program Announcement Packet** was emailed to intervention worksites. A **SSW Website** had content on: skin cancer and UV, risk factors, personal risk assessment, workplace prevention strategies (i.e., sunscreen, sunglasses, hats, shade, scheduling), prevention at home, and online workplace audit and policy writing tool. The **In-person Meetings** between senior managers and project staff covered: 1) Introduction to *SSW*; 2) Sun Safety Practices in the Workplace; 3) Sun Safety Policy for Outdoor Workers; 4) Sun Safety Policy Adoption; 5) Sun Safety Policy Reinforcement and Maintenance (See Appendix A). In-person **Sun Safety Training** by staff during worksite visits fit into safety and wellness programs and covered: 1) The U.S. Skin Cancer Problem; 2) The Sun, UV Rays and Skin Cancer; 3) Assessing Your Personal Risk; and 4) Practicing Sun Safety. A **Sun Safety Tool Box** provided support materials for policy and education, i.e., worksite audit and facts sheets on sun safety and barriers to policy implementation (see Appendix B), and theory-based **Posters, Risk Assessment Brochures, and Tipcards** promoting sun safety to employees (See Figure 4). In monthly **Follow-up Contacts**, staff nourished the relationship with managers, supported their decisions to write policies and train employees, and problem-solved barriers.^{151,152}

Box 1: Preliminary Studies: Evaluation of Sun Safe Workplaces (SSW-IP)

SSW was tested in a randomized controlled trial with 98 public employers (i.e., cities, counties, and special districts) in Colorado (R01CA134705; PIs: Buller and Walkosz). Originally, 98 enrolled, completed pretesting and were randomized (25% participation; mean size=247 employees). At baseline, only 20% of employers had polices with at least 1 sun safety element (M=0.56 [out of 15], sd=1.44), mostly on personal protection not environmental/administrative controls. Also, administrators (n=825; 86% response rate) in more affluent areas (p=0.02) closer to the urban region (p<0.01) took more actions on sun safety.¹⁵³

SSW was very successful: At posttest, 51.2% of intervention employers had a sun safety policy

compared to 32.6% of controls (n=84 employers followed up; OR=6.96, p<0.01, adjusted for pretest and covariates, Cohen's d=1.57; intent-to-treat 42.0% v. 29.2%, OR=5.95, p<0.05). Compared to controls, intervention employers adopted more extensive policies (responders mean=3.27 v. 0.64 policy elements, $\chi^2=81.02$, p<0.01 adjusted for pretest/covariates, Cohen's d=1.05; intent-to-treat mean=2.61 v. 0.54, $\chi^2=73.79$, p<0.01) and stronger policies (responders mean=3.34 v. 1.01, $\chi^2=57.35$, p<0.01 adjusted for pretest/covariates, $\omega^2=0.28$, Cohen's d=0.97; intent-to-treat mean=2.73 v. 0.86, $\chi^2=51.95$, p<0.01¹⁵⁴). Employers closer to the urban Front Range were most likely to have a policy at baseline (p<0.01).¹⁵⁵ SSW closed this gap, with intervention employers farther from the urban Front Range adopting more extensive (p<0.01) and stronger (p<0.01) policies at posttest than closer employers. Greater exposure to SSW produced more extensive (# of meetings p=0.01) and stronger (meetings p<0.01; trainings p=0.02) policies. Compared to controls, intervention managers were more aware of sun protection policies, perceived higher skin cancer risk, and wore more sun protective clothing; they also reported that the employer was more likely to provide wide-brimmed hats to employees (p<0.05). Currently, we are assessing the impact of policies on employee sun safety practices (R01CA187191; PIs: Walkosz and Buller). In sum, SSW had a large effect on policy adoption, addressed a practice gap in non-urban workplaces, and increased managers' awareness and implementation of sun safety. Its effects are large enough to expect SSW to retain meaningful effectiveness in at scale-up.^{77,78}

3C.3. Translation and Enhancement of SSW with Technology (SSW-T) (Specific Aim 1)

The aims of translating SSW are to virtualize its in-person contacts, trainings, and policy tools, using web-based conferencing, social networking, and interactive, responsive training platforms, *along with electronic elements of SSW-IP*. Technology-based programs like SSW-T provide expanded reach, standardized, engaging content, and increased portability.¹⁵⁶ SSW-T should reduce costs of implementation by avoiding in-person visits and be more flexible to fit a worksite's schedule. The iterative development process will be led by Dr. Walkosz, assisted by Ms. Buller, and includes focus groups, usability testing and pretesting.

3C.3.1. Formative Focus Groups: Four focus groups with senior managers at fire departments and departments of transportation (DOTs) will discuss adoption processes for health/safety policies, safety training, means for contacting managers about sun protection, implementation of SSW-IP and SSW-T, preferred social network with other managers (e.g., Facebook, Twitter, Google+, LinkedIn), input on social media content, and current technology utilization/capacity. Managers (n=48) from various organizational levels (e.g., senior-most manager, human resources and department directors, risk manager) will be recruited (n=12 per group). Also, four focus groups will be held with front-line outdoor employees (n=48) from fire departments and DOTs. They will discuss technology use, sun protection practices, and preferences for delivery of safety/health training. Professional associations will assist recruitment; participants will meet eligibility criteria in 3C.5.1 and receive \$50. The 90-minute discussions will be led by KB's Project Coordinator on web-assisted conferencing, using a discussion guide created by our team. Analysis of transcripts led by Dr. Walkosz and performed by two research assistants will identify initial themes and develop a coding system in Atlas.ti® software (inter-rater reliability≥0.70), using comparative analysis methods, based on grounded theory and phenomenological

FIGURE 4: Sun Safe Workplaces Intervention Materials



approaches.¹³⁴ *Using an instructional design iterative development process,¹⁵⁷ focus group results will inform the initial production and program modifications. Design options, central to scale-up, include selection of technology platforms for managers and employee online training. Keeping the core of the educational materials, the employee focus groups will identify additional program content and elements (e.g., videos, animation, personal narratives, quizzes).*

3C.3.2. Production Procedures: SSW will be translated into a technology platform (SSW-T) in Year 1. SSW-T will have the same goals and similar components as SSW-IP and advocate that employers adopt comprehensive policy adoption and employee education. It will help managers understand the need for and improve knowledge of occupational sun safety and motivate them to use online tools for social networking, accessing/sharing resources, creating policy, and delivering employee training. The central components of the platform will enable virtual meetings with senior managers, create online community of managers, and provide education for employees. Multimodal, synchronous web-based video conferencing (e.g., Go To Meeting) will support **Virtual Meetings** and monthly follow-ups. To enhance knowledge sharing, idea generation, synergistic conversations, and collaborative learning,^{158,159} we will meet with up to 5 managers from different organizations in the same sector in each virtual meeting. As in SSW-IP, meetings will cover: (1) Introduction to SSW-T; (2) Workplace Sun Safety Practices; (3) Sun Safety Policy for Outdoor Workers; (4) Sun Safety Policy Adoption; (5) Sun Safety Policy Reinforcement and Maintenance. The **SSW Website** will contain the **Online Policy Writing Tool** for managers (see Appendix B).

Most online adults (74%) now use personal/professional social networking sites¹⁶⁰ and smart phones have increased accessibility. They create communities for information sharing and dissemination, interaction, and connections.¹⁶¹ Information on social media from knowledgeable peers can have a powerful impact.^{162,163} A private Online Community will be created using the social media platform selected in focus groups. Some employers have restrictions on access to online social networking sites (particularly ones like Facebook that are primarily for social purposes) so we will select a platform maximizing access at work and managers' preferences and utilization to promote logins. The platform must also allow for the creation of private groups in which only invited members can see content. Facebook, Google+, LinkedIn, and others allow this option. The purpose of the online social network is to distribute information and guidance on worksite sun safety to managers and provide a means for them to interact with one another about implementation experiences (see Appendix C). The social network feed, moderated by a community manager, will have daily posts about 1) workplace sun safety practices, 2) sun safety policy for outdoor workers, and 3) general skin cancer and sun safety information tailored toward males. Content from our training will be converted into social media posts and we will share content created by non-profit entities including Skin Cancer Foundation, Melanoma Research Foundation, Sun Safe Colorado, and CDC. Annual events will be promoted, e.g., Melanoma Awareness Month (May) and No Fry Day. We will design posts that elicit managers to share experiences with sun safety policies, based on recent research.¹⁶⁴ We will interview managers/employees affected by skin cancer and share their stories in the social network. We will encourage managers to share information with employees to reinforce sun safety policy. Every 3 months, we will host contests for photos of "best sun safety employee" posted in the community. Winners will be determined by "likes" and humor will be encouraged.

3C.3.3. Education for Employees: Online versions of the **Sun Safety Training** will be created in two formats: a) staff will train employees in Virtual Meetings using web-based conferencing or b) employees will access a stand-alone 30-minute multimedia training (e.g., animations, graphic illustrations). Training modules (The U.S. Skin Cancer Problem; The Sun, UV Rays and Skin Cancer; Assessing Your Personal Risk; and Practicing Sun Safety) can be viewed individually or in a single setting. Training will be guided by *formative research* and instructional design principles

such as the Dick and Carey model¹⁵⁷ to build a program that helps learners reach a defined goal using interdependent components and feedback loops. In addition, a **Sun Safety Tool Box** (see 3C.2 and Appendix B) with theory-based **Posters, Risk Assessment Brochures, and Tipcards** (see 3C.2) will be available for download from the SSW Website for use with employees. Managers will be encouraged to share information from the online community such as sun safe strategies targeted to men, trends in skin cancer research, participation in contests and sharing their experiences with employees.

Investigators will author content, with the focus groups' input; KB's media developers will create interface designs. Online materials will be authored in a Responsive Web Design approach to optimize user experience across platforms (computer, tablet, and smart phones), using HTML5, CSS and JavaScript. Microsoft SQL databases will control content and track use. Server-side components developed on Microsoft dotNet platform, using the C# programming language, will be hosted on KB's state-of-the-art server farm (see Resource pages).

3C.3.4. Usability and Pretesting SSW-T: SSW-T will be iteratively pretested in 3 ways with potential users. Ten senior managers who participated in the SSW trial will review and rate all SSW-T components for acceptability, readability, and utility in telephone interviews. Next, online programs will be tested for usability with 10 more senior managers, using protocol analysis. Managers will be given a set of tasks and talk aloud, while using SSW-T, about reactions, difficulties encountered, and solutions tried. Staff will take notes; KB developers and investigators will review results and revise the SSW-T to improve usability. Finally, 1 employer in Colorado that did not participate in the SSW trial will be recruited and SSW-T will be delivered to them in Months 10-11, noting any technology problems. Media developers will produce a final version in Month 12.

Box 2: Preliminary Study: Sun Safe Schools (SSS) and Go Sun Smart (GSS) Projects

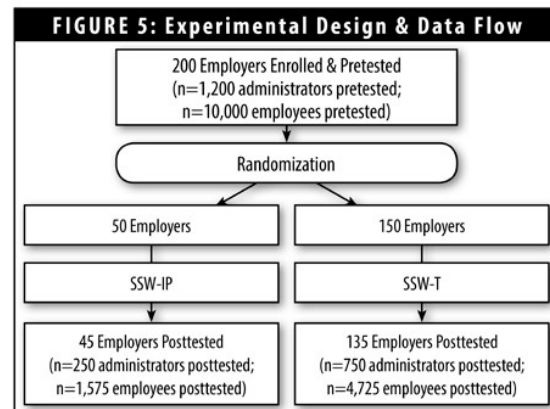
SSW-IP was based on two previously successful interventions. In the *Sun Safe School (SSS)* project (R01 CA100285, PI: Buller), sun safety policies for students were promoted to public school districts in S. California and Colorado. Using personal contacts and print/online resources, SSS increased board-approved policies in intervention districts (M=6.52) compared to controls (M=3.71, p=.016) in a randomized trial (n=112 districts).¹⁶⁵ The *Go Sun Smart (GSS)* program (R01CA81028, PI: Buller) comprised of training and printed/electronic messages improved employee sun safety in a group-randomized trial (n=26 ski area workplaces; n=7,125 employees pretested; n=2,111 posttested [sampled from pretested employees]): Intervention employees had a 14% reduction in sunburning, significantly more than controls (OR=1.63, p<0.05 adjusted for covariates) and reduced sunburning (OR=0.90, p<0.05) persisted into the next summer (along with more sun protection: sunscreen OR=1.34, p<0.05; protective clothing OR=1.15, p<0.05; protective eyewear OR=1.26, p<0.05).^{10,166} In a randomized dissemination trial (R01CA104876, PI: Buller; n=68 ski areas), ski area managers were convinced to implement GSS education by a strategy of personal visits and printed materials (mean=7.36 GSS items v. comparison mean=5.17 items, p<0.01 [1-tailed] adjusted for covariates).¹⁶⁷ This success persisted at 1-year and 5-7 year follow-ups.^{168,169} GSS improved workers' sun safety immediately¹¹ and at the follow-up¹⁷⁰ (R01CA159840, Multiple PI: Walkosz and Buller).

3C.4. Randomized Trial Design (Specific Aims 1-2)

A randomized trial will model SSW-IP and SSW-T in national distribution. Its primary goal is to compare reach and cost effectiveness of SSW-T to SSW-IP by estimating implementation rates (i.e., policy adoption and education delivery) and the cost of delivery to national samples. Comparison of implementation rates between strategies and across employers (representativeness) are secondary goals. The less personal, asynchronous technology platform of SSW-T may produce lower implementation than SSW-IP but SSW-T's virtual communications technology should network

managers together, increasing their motivation to take action and mitigating this reduced implementation rate. Whatever its implementation rate, *SSW-T* should reach more employers than *SSW-IP* for a lower cost and thus may be cost-effective. The sample provides sufficient precision for estimating implementation rates and detecting certain-sized differences in this rate.

Fire departments and state DOTs (n=200) will be enrolled in two waves (Wave 1 in Months 1-6; Wave 2 in Months 13-18) into a randomized, pretest-posttest 2-group experimental design (see Figure 5). They will be stratified by size (large v. small; median split on number of employees) and solar intensity (a proxy for climate and UV) and quotas will be set in multiples of 4, proportional to number of employers in each of 10 cells (2 sizes x 5 regions). Both variables were significant covariates in our past research.¹⁶⁷ We considered stratifying on urbanicity (baseline predictor of policy;¹⁷¹ see Box 1), but it is not possible to divide state DOTs on urbanicity since they work throughout a state. After pretesting in Months 7-14 (Wave 1) or Months 19-26 (Wave 2), employers will be randomized in a 1:3 ratio to the *SSW-IP* (n=50 employers) or *SSW-T* (n=150 employers) by Dr. Cutter, using a customized program. We considered pair matching but did not because a) the sample size is reasonably large; b) matching has not added much power in our past trials; and c) effective sample size is reduced where dropouts occur. The intervention period will last 20-months – Months 15-34 in Wave 1 or Months 27-46 in Wave 2 – after which posttesting will be completed in Months 35-42 (Wave 1) or Months 47-54 (Wave 2). Primary implementation outcomes will be assessed pre and post by coding written policies (with coders blind to condition) and surveying managers on sun safety education. Managers will report pre and post on workplace environment/procedures supporting sun safety and employees will report pre and post on sun protection practices on the job, both secondary outcomes.



Box 3: Preliminary Studies: Research on Technology-based Health Interventions

We are very experienced at maximizing technology interventions, including for low technology-resourced environments^{172,173} common in many outdoor worksites and on social media. Drs. Buller and Walkosz led research on web-based programs to reduce smoking by adolescents¹⁷⁴ (R01CA78206, PI: Buller), teach media literacy,¹⁷⁵⁻¹⁷⁷ prevent alcohol problems in college students (R01AA020157, PI: Dunn; R01AA14217, PI: Woodall), prevent risky sexual behavior by adolescents¹⁷⁸ (R01DA018575, PI: Woodall), support smoking cessation by young adults¹⁷⁹ (R01CA107444, PI: Buller), and promote HPV vaccines for adolescent girls¹⁷² (U19AI084081, PI: Wheeler and Woodall). Dr. Buller and KB programmers created smart phone and tablet computers interventions to improve sun protection by adults,¹⁸⁰ support smoking cessation¹⁷⁹ (R01CA107444, PI: Buller), and use location-based services to improve physical activity (R44DP004995, PI: Myers).

Currently, Drs. Buller, Walkosz, and Pagoto are evaluating a social media intervention to reduce mothers' permissiveness for adolescent girls to indoor tan (R01CA192652, PI: Buller and Pagato). Drs. Pagoto and Walkosz are creating the social media content delivered in a Facebook private group with a YouTube channel and Pinterest site. In other social media studies, Dr. Pagoto has compared social support for weight loss received from Twitter friends to in-person friends and family, finding users received more weight loss information (p's<0.01), were least embarrassed about weight (p's<0.01), and felt that Twitter friends were less judgmental (p's<0.01) than in-person friends and family, and tweets predicted weight loss (r= -.58; p<.05), and described the spread of a Twitter core-strengthening exercise challenge (i.e., daily 1- minute abdominal exercise) using a

hashtag (#PlankADay)¹⁸¹ showing that 4,941 users produced 76,746 tweets and 72% engaged in the exercise, and the challenge increased their enjoyment of exercise ($p < .001$).

3C.5. Target Populations and Recruitment Methods

3C.5.1. Target Populations: The target populations are fire departments and state DOTs and their senior managers and outdoor workers. Eligibility criteria for **employers** are a) being a fire department or DOT, b) located in the United States, c) agreeing to participate, d) providing written policies at pretest, and e) having at least 6 managers and 50 workers complete the pretest. An exclusion criterion is participating in our previous *SSW* trial. We have support from the Fire Protection Research Foundation, the research affiliate of the National Fire Protection Association, and the Western Association of State Highway and Transportation Officials (see letters of support in Sec. 12). Dissemination occurs in societal sectors,¹⁸² a collection of organizations operating in the same domain, with similar services, products or functions. Fire departments and DOTs constitute public safety and public works sectors. Professional associations create a loose network and intra-sector communication that addresses emerging issues.^{183,184} We have not secured agreements from individual fire departments or DOTs because their cooperation is part of the primary outcome. Recruiting them up front could bias the sample toward implementation of policy and education. Instead, professional associations will help recruit employers. The trial will be conducted in all 50 states, stratifying on size and solar intensity region, for a diversity of employers/employees (i.e., non-Hispanic white, Hispanic, African American, Asian, and Native American/Native Hawaiian; we will test if race affects outcomes), geography and climate that affects UV (UV is highest at low latitudes, high elevations, and in dry climates), and melanoma incidence.¹⁸⁵ There are over 30,000 fire departments (nearly 50,000 fire stations; 96% local fire departments) staffed by nearly 1.2 million personnel (1.04 million career, volunteer, and paid firefighters and civilian staff and non-firefighting personnel). Firefighters are at increased risk for many cancers, including melanoma and other skin cancers due to occupational and recreational sun exposure and occupational stress.¹⁸⁶⁻¹⁹⁰ In our *SSW* trial (Box 4), firefighters spent considerable time outdoors fighting wildland, forest, and other outdoor fires, responding to accidents and disasters, engaging in search and rescue, and training. Each state has a DOT that combined employ nearly 40,000 highway maintenance workers, as well as engineers, surveyors and other outdoor workers (at Colorado DOT [Box 4], 98% are male, 80%, non-Hispanic White, and 18%, Hispanic; males are least sun protective¹⁹¹ including at work¹⁹²; non-Hispanic whites are at risk for melanoma and skin cancer¹⁹³).

Box 4: Preliminary Studies: Prior Work with Fire Departments and DOTs.

We have experience working on sun safety with fire departments and DOTs. Local fire departments ($n=16$) were enrolled in the *SSW* trial. We conducted 30 in-person meetings and 16 trainings with 9 departments in the intervention group. From 2006-09, we delivered *Sun Safe Colorado*, a state-funded sun safety program. Among the 160 employers reached, multiple trainings were conducted with Colorado DOT. In a focus group with Colorado DOT employees and managers, key findings were that a) sun safety among highway workers is variable; b) if workers do not take precautions at the start of the day, they forget it; c) workers want to learn about re-application, the value of UPF protective clothing, and UV exposure on cloudy days; and d) supervisors can include sun safety in brief safety trainings at the start of the work day.

Eligibility criteria for **senior managers** include a) being in a senior management position; b) responsible for worksite safety/health policy and education; c) consenting to participate, and d) completing the pretest. In our *SSW* trial, this included city/county managers, human resources directors, risk managers, and managers of facilities, fire, roads and transportation departments. They were long-term employees ($M=13.9$ years) who made decisions about workplace safety at

least some of the time (94%) and worked some of the time outdoors (55%). Further, 52% were age 20-50 (M=47.6), 52% had a college/postgraduate degree, 74% were male, and 89% were white (3% Hispanic). Also, 30% had Type I or II skin (most susceptible to UV damage¹⁹⁴) and 13% had been diagnosed with skin cancer. Exclusion criterion is participating in our previous SSW trial.

Eligibility criteria for **employees** are a) being employed part/full-time at the employer, b) working at least part of daytime hours outdoors, c) consenting to participate, and d) completing the pretest survey. In an earlier project in which we trained workers at a variety of Colorado public and private employers, the employee population was 70% age 41-60, 49% male, 90% white, 4% Hispanic, and 47% with Type I or II skin.

3C.5.2. Recruitment Procedures: Dr. Buller will lead recruiting utilizing successful protocols from our SSW, SSS, and GSS projects (see Box 5), assisted by Drs. Wallis and Walkosz and approved by KB's, UCD's, and KP's Institutional Review Boards (IRBs). Project staff will identify eligible **employers** working with industry professional associations. Employers will be randomly ordered by Dr. Cutter and contacted by project staff, starting at the beginning of the list, by sending an invitation letter to the senior-most managers and following-up by telephone to have the employer participate. Refusals will be replaced with the next eligible organization.

The senior-most manager at each participating employer will provide email, mail, and telephone contact information for eligible **senior managers** (see 3C.5.1) who will be invited to complete the pretest and read a consent statement. See Box 5 for past success of these recruitment/retention procedures. The senior-most managers at each organization will also provide a list of eligible **employees** who work outdoors (see 3C.5.1) and Dr. Cutter will select a random sample of them. We will send surveys to the employer to be distributed to the selected employees, along with a consent statement. Employees can complete the survey and return them in pre-paid envelopes or go online to complete it. At least six managers and 50 employees need to complete the pretest for the employer to be eligible and randomized, so at least 5 managers and 35 employees will complete posttests. We have recruited large manager and employee samples using similar methods (see Box 5).

Box 5: Preliminary Studies: Past Studies with Large Samples of Organizations

Our recruitment goals are ambitious but we have successfully recruited, assessed, intervened, and followed very large samples of organizations in prior randomized trials. We enrolled and retained all 26 ski areas in the GSS effectiveness trial;⁹ enrolled 69 ski areas and retained 68 (98%) in the GSS dissemination trial;¹⁶⁷ and assessed sustainability of GSS 5-7 years after dissemination in 53 ski areas (77%).¹⁶⁹ We enrolled 112 public school districts in the SSS trial, intervened on 51 of 56 districts (91%; 2057 contacts [M=36.7/ district]), and retained 100 (89%) at 2-years.¹⁶⁵ In the SSW trial, we enrolled 98 employers, intervened on 46 of 50 employers (92%; 156 in-person visits [M=3.1/employer], 93 trainings [M=1.9/employer]; 1855 email/ telephone contacts [M=40.3/employer]), and retained 84 employers (86%) at 2-years.¹⁵⁵ In these trials, we recruited 469 ski area manager (72% of eligibles), 691 school administrators (33%), and 825 public administrators (86%), retaining 334 (70%), 281 (41%), and 523 (65%). We surveyed employees in the GSS effectiveness trial (n=7125 at pretest; 2119 at posttest [sampled from pretested employee]; 56% retention),⁹ GSS dissemination trial (n=2,228),¹¹ and GSS sustainability assessment (n=2,940). We traveled to 29 U.S. states/ Canadian provinces and collaborated with scientists at 10 institutions.

3C.6. Implementation of the SSW-IP and SSW-T in Model National Distribution

The interventions (see 3C.2 and 3C.3) will be launched in Month 15 (Wave 1) or Month 27 (Wave 2) (Figure 3), supervised by Dr. Walkosz. Program staff will contact managers at each employer with

program invitations and schedule the initial in-person/web-enabled visit in the first 6 months. Follow-up meetings will be scheduled as needed; managers will schedule employee education either by program staff or the online training. Printed materials will be sent to *SSW-IP* employers 3 times during the intervention. Staff will follow-up with managers through Month 34 (Wave 1) or Month 46 (Wave 2). Electronic materials will be published on KB's state-of-the-art web server (see Facilities and Resources for a description and Human Subjects for online security).

3C.7. Policy and Education Implementation Measurement Methods

Quantitative data collection will assess implementation of sun protection policy and education – coding of written policies and surveys with senior managers and employees. To triangulate our understanding of scale-up, qualitative semi-structured interviews with 40 senior managers will be conducted (Figure 6).

3C.7.1. Primary Outcome: Implementation of Occupational Sun Protection Policy: A composite score will assess presence, strength, intent, and responsibility in written sun protection policies using a coding protocol developed in the *SSW* trial and based on an earlier protocol from the *SSS* project¹⁹⁵ (see Boxes 1 and 2). It assesses 15 policy categories: engineering controls (physical environment of the workplace), administrative controls (workplace procedures), and employee education (workers' sun safety) (Box 6 and Appendix D). Each category receives a point (0, 1) for presence (total score=15) and a 3-level strength score (0=not allow/specify, 1=allow/ recommend, 2=require; total score=30). Policies on engineering controls (scheduling/shade) and sun safety practices

(hats/protective clothing) could exist for reasons other than sun safety (e.g., to prevent injury), so those categories receive a point (0,1) when sun protection is explicitly cited (total intent score=4). A 3-level responsibility score is assigned, noting who provides protection equipment (0=not specified, 1=employee, 2=employer; total score=10). These ordinal composite scores are as continuous and summed across categories. Human resources and safety documents will be excerpted and coded by research assistants (**blind to condition**). Drs. Buller and Walkosz will train coders until inter-coder reliability exceeds 0.70. Inter-coder reliability will be re-checked at the beginning, middle and end to ensure it remains high (>0.70). There is no basis for the minimum number of components that must be changed to improve workplace sun safety, so we will assess both presence and extent of change. The ordinal measures can detect expansion of existing policies.

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3C.7.2. Primary Outcome: Implementation of Sun Safety Education: Senior managers and employees will report on sun safety education provided to employees (Appendix D). The primary measure will be managers' reports of any training or any sun safety messages/materials distributed (e.g., newsletter articles, *SSW* website, or emails). Employees' reports of sun safety education will be secondary, validating managers' reports. In *GSS*, managers' and employees' reports of sun safety education were highly correlated (Box 6).¹⁶⁷ These measures will be obtained in senior manager and employee pretest and posttest surveys, conducted online and by mail. Participants will receive a letter of invitation, along with a printed survey and URL and QR code for the online survey. Surveys can be completed online in KB's Question Pro software running on a secure web server or by mail, returned in pre-paid envelopes. They will receive up to 5 email reminders at 7-day intervals and receive a sunscreen lip balm for completing the surveys. They will be assured that answers are confidential, will be used for analyses only, and will not be revealed to co-workers, superiors, or subordinates. Participants will provide name, address, home, work and mobile telephone numbers,

FIGURE 6: Timing of Data Collection

Data Collection	Pretest	Intervention Period	Posttest
Written Policy Coding	X		X
Administrator Survey	X		X
Employee Survey	X		X
Semi-Structured Interviews			X
Process Measures		X	
Cost Records		X	
Organizational Characteristics	X		

and email address of a person who can always locate them. All forms and procedures will be approved by KB's, UCD's, and KP's IRBs. We achieved high completion in our SSW trial with these mail/online methods, avoiding expensive telephone interviewing (see Box 6). Managers will be sampled by position at pretest and persons holding those same positions will be posttested. If position holders change, new position holders will be posttested and original person tracked and pretested. Employees will be sampled at pretest from employee rolls; we will track and posttest all employees pretested, including those who leave. To reduce multi-mode interviewing differences, we will follow Dillman^{196,197}: a) response options and labels are identical, invariant (avoiding visuals), and kept to a minimum, b) question structure is invariant, c) skip patterns are the same, e) unfolding questions are avoided, and f) response categories are reversed. Multiple modes introduce very small differences¹⁹⁸⁻²⁰³ that can be eliminated by standard demographic controls²⁰⁴ and do not affect estimates of relationships,²⁰² substantially improve response rates²⁰⁵⁻²⁰⁷ and may eliminate non-response biases better than statistical adjustments.²⁰⁶

3C.8. Intervention Cost Measurement Methods

Dr. Meenan will supervise recording of costs associated with the *SSW-IP* and *SSW-T*, following protocols from prior projects. Using a micro-costing approach, Dr. Meenan and project staff will identify resource allocations for each component of the *SSW-IP* and *SSW-T* (in-person and virtual visits; follow-up communications; staff-delivered and virtual training, web resources, and mailed materials). Both labor and non-labor elements associated with in-person and virtual meetings, staff-delivered and virtual trainings, printed materials, follow-up communications, and website resources, and induced employer costs of policy and education implementation, will be recorded. For personnel, the proportion of FTE across activities will be estimated by contemporaneous staff self-report. Senior manager and employee survey data will identify organizational changes induced by *SSW-IP* and *SSW-T* and attach cost estimates to each. We will use the accounting systems of the trial itself, supplemented with survey responses and additional primary data collection or external sources. Costs will be recorded in custom-made spreadsheets and summed to produce overall cost estimates.

3C.9. Measures of Secondary Outcomes

3C.9.1. Changes in Workplace Environments for Sun Safety: Managers will report changes in the work environments (providing shade and adjusting outdoor work schedules) or procedures (risk assessment, posting UV Index, and providing sunscreen, hats, protective clothing, and sunglasses) for sun safety, using questions created in *SSW* and *GSS* trials²⁰⁸ (Appendix D). To validate, trained staff (blind to condition) will visit 18 randomly-selected employers at posttest and record shade, posting of UV Index, sunscreen availability, employee clothing, hats, and sunglasses, and educational materials, using a protocol from our *GSS* trial.^{11,167}

3C.9.2. Other Policy-related Measures: We will measure two ancillary policy outcomes in the senior manager surveys. We discovered in the *SSW* and *Sun Safe School* projects that some managers followed unwritten informal operating procedures rather than written policies. Using questions from those trials, managers will report the presence and content of these informal procedures. Enforcement of any sun protection policies will be measured with items from the *SSW* trial (i.e., how well is policy being implemented and how well are staff complying with policy [very well, well, about average, poorly, or very poorly]).

3C.9.3. Employees' Sun Protection Practices: Employees will report a) frequency of sun protection at work (Appendix D), i.e., sunscreen with SPF 15+, long-sleeved shirts, long pants, hat with brim, sunglasses, shade use, limit exposure to midday sun, and have sunscreen, hat and eye

protection at all times (1=never, 5=always) and b) prevalence of sunburn in the past 3 months on the job (yes/no; number of times) from SSW and GSS trials (Appendix D). These are standard, validated, and reliable measures from past studies.²⁰⁹⁻²¹⁹

3C.10. Intervention Process Measures

Delivery of the SSW-IP and SSW-T to employers will be recorded with process measures: a) senior managers' attendance at the in-person (SSW-IP) and virtual visit/meetings (SSW-T) (name/title; number of managers; date; topics; duration; ratings of managers' interest in sun safety), b) performance of in-person sun safety education (SSW-IP), c) use of online sun safety education (SSW-T), d) use of SSW website (SSW-IP and SSW-T), e) use of SSW Google+ site (SSW-T), f) mailing of printed materials (SSW-IP), and g) participation in follow-up contacts. Staff will record process measures in intervention logs or track them through customized web server logs. Managers will log on to online training, SSW website, and SSW Google+ site using IDs supplied by project staff (they will select passwords) and SQL software will record their use of these online features²²⁰ (i.e., date/number of times accessed, pages viewed, and time spent with online features).

Box 6: Preliminary Studies: Assessing Worksite Sun Safety Policies, Education and Practices

Our team has experience with sun safety assessments. The sun protection **policy coding protocol** will be based on SSW (R01CA134705) and SSS (R01CA100285) (inter-coder reliability>0.90)^{195,221} (see Boxes 1 and 2). It is practical rather than theoretical and derived from recommendations by health agencies in the United States, Australia and Canada.¹¹⁰⁻¹¹⁹ We have interviewed over 3300 **senior administrators / managers** on sun protection policy and education at 278 workplaces using measures of perceived need and support for workplace sun safety, implementation of policy and education, job/demographic characteristics, skin type, and skin cancer history. Administrator reports of sun safety education has correlated with employees' reports ($r=0.23-0.52$), supporting their validity. We have interviewed over 12,000 **employees** on sun safety practices at over 100 worksites, using the measures of sun safety practices and sunburn prevalence proposed here.^{9-11,216}

3C.11. Measures of Factors Moderating Implementation

Variables that might moderate implementation suggested by (C)RE-AIM and Bingham's model of innovation in local governments²²² will be measured to describe representativeness. Standard published measures will be used where possible (cited below; see Appendix D); psychometric analysis will be conducted on new items (reliability>0.60). To shorten scales, we will select items with the largest association with total score.

- **Organizational factors:** size (i.e., number of employees reported by employer; used to stratify the sample), employer type (fire department, DOT), job type (public works, public safety), number of female managers, and annual operating budgets (to assess slack resources) (latter two reported by employers).
- **Community characteristics:** size (population), education, affluence (from the U.S. Census) and mean annual hours of sunshine (from National Weather Service; used to stratify the sample).
- **Manager and employee characteristics:** skin cancer history (has doctor told you that you had skin cancer [yes/no and type]; from our GSS trials¹¹); skin sun sensitivity (always burn, unable to tan/ usually burn but can tan if try/sometimes mildly burns, tan easily/rarely burn, tans easily²²³); job characteristics (years working in industry, job title, work mostly outside/mostly inside/outside and inside equally) and demographics (age, sex, education, race, Hispanicity, marital status, children in home) from our GSS trials¹¹; opinion leadership (validated scale, reliability $\alpha=0.86$; managers only),²²⁴ innovativeness (validated scale; reliability $\alpha=0.94$; managers only),²²⁵ and readership of professional publication (managers

only).²²²

3C.12. Semi-structured Interviews with Managers

Qualitative information on scale-up will be obtained in semi-structured interviews with senior managers, focusing on policy and education,^{226,227} facilitators/barriers to implementation (e.g., benefits, adverse outcomes, political, social, and personal context factors), acceptability/compatibility of policy/education, and changes to policy/education or to the organization to improve fit.^{77,78} Forty employers will be selected at random (n=10 in *SSW-IP* and 30 in *SSW-T*) and one manager per employer (n=40) who is knowledgeable about safety, supervision, and training for outdoor employees will be interviewed. Trained staff will conduct 1-hour semi-structured interviews at posttest by telephone, following a protocol modified from our *GSS* trial (see Box 7). Interviews will be audiotaped, transcribed, and analyzed using Atlas.ti software. Themes on engagement with the scale-up method, decision-making on policy/education, and facilitators/barriers of implementation will be summarized and used to adjust analyses of quantitative data and provide unique, in-depth insights on scale-up.

Box 7: Semi-structured Interviews on Sustainability of *GSS* Sun Safety Education

In 2012-13, we interviewed senior managers (n=56) at 48 ski areas on sustained use of *GSS*, following industry-wide dissemination (mean interview time=45-60 minutes). Analysis of transcribed audio recordings (inter-coder reliability ≥ 0.70) revealed two predominant themes: 1) Sun safety integrates well into general safety and training and 2) *GSS* successfully influenced the employers' sun safety culture. Other themes included: a) risk managers, HR, and supervisors of outdoor workers were responsible for implementing *GSS*; b) employee training and sunscreen reminders were key to promoting sun safety; c) lack of observable benefits contributed to discontinuance of *GSS*; and d) changes in health and beauty norms and public education produced a cultural shift toward more sun safety. This interview protocol will be modified in the proposed research (see 3C.12).

3C.13. Data Management Procedures

Data management will be performed by KB's data managers using well-established procedures (see Appendix E) and supervised by Dr. Cutter. Missing responses will be identified and checked to ensure that entries missed were not intentionally skipped. A random sample of 10% of manually-entered forms will be double entered; if error rate exceeds 1%, all forms will be double entered. Sophisticated editing/quality assurance procedures (e.g., manual and computerized audits) will be implemented. SAS software (V9.3 or higher) will be used in analyses. Analyses will be done on data collected (case-wise deletion) and by imputation for missing data. Data may not be missing at random (NMAR), so we will estimate the effect of this missingness by assigning all lost individuals to an extreme category, in either direction. We will perform imputation utilizing Markov Chain Monte Carlo – Data Augmentation Method, a 2-step iterative procedure to obtain $P(\theta|Y_{\text{obs}})$, which can handle various amounts of missing data using SAS PROC MI and use a variety of covariates and propensity scores.

3C.14. Primary Economic Analysis of Scale-Up Strategies (Specific Aims 1 and 2)

The primary analysis will model the cost-effectiveness of *SSW-T* relative to *SSW-IP*, based on the estimated rate of employers who implement policies and education and the cost of delivering each intervention. Secondary analyses will explore the representativeness of employers who implement.

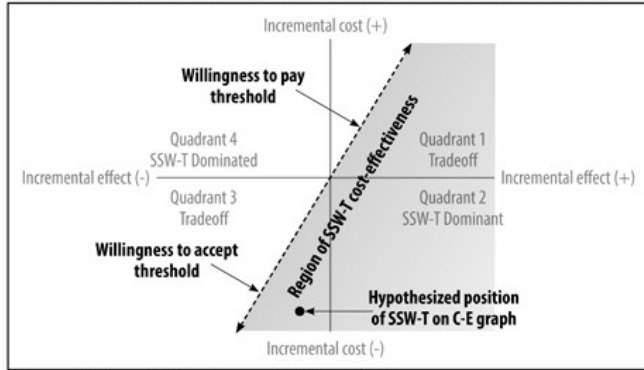
3C.14.1. Statistical Power for Primary Analyses: The proportion of employers adopting sun safety policies and education in the *SSW* trial was used to estimate the sample size of employers.

To be conservative, we expected implementation to be slightly lower in the proposed *SSW-IP* than *SSW* and designed the sample size of the *SSW-T* group to be larger, on the possibility that *SSW-T* produces a lower implementation rate than *SSW-IP*. First, we estimated the sample size needed for *SSW-IP*. In the *SSW* trial, 15 intervention employers adopted sun safety policies (proportion=0.365 of 41 employers followed up; intent-to-treat proportion=0.300). We assumed that *SSW-IP*, when scaled-up nationwide, would achieve a policy implementation rate of 0.300. Similarly, in the *SSW* trial, the proportion of employers implementing education was 0.80 (40 of 50), but we assumed that *SSW-IP* will have a lower rate of implementing education of 0.600. We further expected up to 10% of the organizations to be unavailable/refuse to provide follow-up data. A sample of 50 employers assigned to the *SSW-IP*, with 45 providing full data, allows for 95% confidence intervals (CI) for proportions of 0.166 to 0.434 when true proportion adopting policies is 0.300 and 0.457 to 0.743 when true proportion of employers providing education is 0.600. For *SSW-T*, the sample was designed to have similar precision even if the proportion implementing policies and education is one-tenth as large as the *SSW-IP*, i.e., 0.030 implementing policy and 0.060 implementing education. A sample of 150 employers, with 135 providing full data, assigned to *SSW-T* allows for 95% CI for proportions of 0.001 to 0.059 when true proportion adopting policies is 0.030 and 0.020 to 0.100 when the true proportion providing education is 0.060. Comparisons of policy and education both have >80% power to test implementation rate differences between interventions. The smallest sample size would be 42 and 84 respectively, but 84 does not provide for an estimated nonzero lower limit of the 95% CI for implementation, a key figure for calculating cost-effectiveness. Thus, the sample size was increased to provide a nonzero lower limit of the 95% CI. Based on our *SSW* and *SSS* projects, 711 employers will be invited, 263 will agree to participate (37%), 200 will complete pretesting and be randomized (in a 1:3 ratio) (76%), and 180 will complete follow-ups (90%). We will invite 8 senior managers per employer (n=1600), pretesting 1200 (6 per employer; 80%) and posttesting 960 (5 per employer; 80% follow-up).

3C.14.2. Statistical Analysis of Implementation Rates: Analyses will be supervised by Dr. Cutter, Project Biostatistician, assisted by Ms. Liu, KB's Biostatistical Manager. Descriptive analyses will estimate the proportion of employers per intervention that adopt policy and education. For policy, the proportion of employers who implement any policy will be estimated. (We will also assess extent [number of elements] and strength [0=not allow/specify, 1=allow/recommend, 2=require summed across policy components] of policy.) For education, we will estimate implementation in 3 ways, i.e., if at least 1 manager reports education for employers, if all managers report it, and the average number of managers who report it. In our *SSW* and *GSS* trials, requiring all managers to report education was too stringent and accepting a single manager criterion may too liberal, so we may opt for the average. Implementation will be defined conservatively, i.e., employer **both** adopts policy and delivers education, and liberally, i.e., **either** policy or education.

3C.14.3. Economic Evaluation. The economic evaluation will explore whether *SSW-T* can be delivered cost-effectively to worksites producing a lower implementation rate than *SSW-IP* but at substantially lower cost. "Cost-effective" means *SSW-T* should be chosen despite lower implementation than *SSW-IP*, if one can accept a lower cost savings per each "foregone" worksite that *SSW-T* generates ("foregone" worksites do not implement with *SSW-T*, but would with *SSW-IP*). We will use an incremental cost-effectiveness ratio (ICER) to summarize the economic effects of *SSW-T* ("intervention") relative to *SSW-IP* ("control"). The ICER is the incremental program cost (C) of *SSW-T* per incremental change in implementation rate (E [for effect]): $ICER = (C_{SSW-T} - C_{SSW-IP}) /$

FIGURE 7: Approach to Cost Effectiveness Analysis Comparing SSW-T v. SSW-IP*



*"Incremental" refers to the difference between SSW-T minus SSW-IP.

($E_{SSW-T} - E_{SSW-IP}$). In Figure 7, SSW-T is cost-effective relative to SSW-IP if the ICER is in the gray area to the right of the dashed line, which represents the dollar value of an additional unit of effect (i.e., either maximum willingness to pay (WTP) for an additional implementing worksite or minimum willingness to accept (WTA) cost savings in lieu of a “foregone” worksite). If the ICER is to the left of the dashed line, SSW-IP is considered cost-effective relative to SSW-T. If SSW-T were both less costly and more effective than SSW-IP, a negative ICER

would imply economic “dominance” of SSW-T over SSW-IP. Conversely, a positive ICER (e.g., both numerator and denominator negative) would indicate the average cost savings for a “foregone” implementing worksite that would have implemented sun safety policy under SSW-IP but not under SSW-T. In this case, cost-effectiveness depends on one’s willingness to accept a given level of SSW-T cost savings from a “foregone” implementing worksite at or below SSW-T’s cost savings (see Figure 7). We will not have access to WTP/WTA data from participating agencies or worksites, so we cannot state definitively that either SSW-T or SSW-IP will be cost-effective relative to the other. However, we will strive to validate our ICER results using external comparators (e.g., budgets for known implemented health-related policies and programs). Note that this is not an analysis of SSW-IP simply delivered “as is” to more worksites. Content remains the same, but the delivery mechanism and associated resources (i.e., input matrix) differ between SSW-IP and SSW-T.

For policy purposes, development costs will be considered “sunk” and excluded, so the economic evaluation will be that of an existing program. However, to the extent possible, SSW-T development costs will be tracked and reported as appropriate. Research and evaluation costs will be removed. Univariate and multivariate sensitivity analyses will model representativeness. Workforce size will be examined to evaluate SSW-T’s ability to (cost-effectively) contact individual workers. SSW-T may be cost-effective but if mostly small worksites implement, SSW-T’s representativeness (i.e., “reach”) is limited among individual workers. Further, we will calculate ICERs within each of the five regions, with similar ratios indicating representativeness across regions. Our cost analysis will not include or account for potential feedback effects, such as business interactions that expose other worksites to SSW-T or long-term health outcomes, such as reduced skin cancer incidence.

3C.15. Secondary Analyses

A series of secondary analyses are planned to compare statistically the implementation rates and changes in workplace environment/procedure changes and employee sun safety between interventions and evaluate representativeness of implementation. All analyses will be performed using SAS 9.3, using a 2-tailed $p=0.05$.

3C.15.1 Comparison of Policy and Education Implementation: Analyses will test the **hypothesis:** Compared to employers in SSW-IP, fewer employers receiving the SSW-T will a) adopt policies and b) deliver education to employees. The unit of analysis will be the employer, using logistic regression analyses and Poisson regression (or negative binomial regression, if the assumptions of the Poisson model is not fulfilled) (i.e., Proc LOGISTIC, Proc GENMOD, Proc GLIMMIX), adjusting for significant ($p<0.10$) covariates. (We will also test research questions on whether policy extent and strength differ between SSW-IP and SSW-T.) **Representativeness** of implementation achieved by SSW-T will be explored by adding to the regression models stratifying variables (i.e., size and region) and other moderators potentially affecting implementation, revealed

in the semi-structured interviews (see 3C.12). These variables will be added as fixed factors and their interactions with condition examined at $p=.05$ (2-tailed), unadjusted for multiple comparisons. Interactions will need to be large to be detected. Using the correlation structure from the primary outcome variables, we will assess order effects to determine which components may drive the implementation of policy and education.

3C.15.2. Comparison of Changes in Environments/Procedures and Employee Sun Protection Practices (Specific Aim 3): Analyses will explore research questions on whether the interventions differ in sun safe environments/procedures and sun protection by employees. For changes in environment/procedures, the unit of analysis is the employers and interventions will be compared with logistic or Poisson regression as in 3C.15.1, adjusting for clustering within employer with GLIMMIX in SAS and pretest values. We will extend the economic analysis by recalculating ICERs based on 1) number of employers that changed environment/ procedures and 2) number of employees that report pre-post improvement in sun protection. The former addresses implementation, i.e., program cost required to generate positive change at the workplace level. The latter addresses effectiveness, i.e., program cost required to motivate positive behavior change by employees.

3C.15.3. Statistical Power for Secondary Analyses: We estimated the power in the secondary analyses *SSW-IP*, $n=50$ and *SSW-T*, $n=150$ for comparisons between the two interventions based on proportion implementing policies and providing education. As noted, we assume the proportion of employers in *SSW-IP* who implement a policy is 0.300. The rate may be lower in the *SSW-T* but by how much is unknown. Thus, based on the rate of 0.300 for employers in *SSW-IP*, we estimated power for a range of proportions implementing policy in *SSW-T* for $n=45$ for *SSW-IP* and $n=135$ for *SSW-T* (expecting 90% with complete data). Power for comparisons exceeds 80% for proportions of 0.110, 0.075, and 0.030 in *SSW-T*. Likewise, for the expected 0.600 in *SSW-IP* that implement education, power for comparisons exceeds 80% for proportions of 0.300, 0.150, and 0.060 in *SSW-T*. Finally, for employees' reported sun protection practices, sample size is adjusted for the design effect due to clustering within employers (i.e., intra-class correlation [ICC]), which inflates variance and Type I error, making significance testing too liberal. We assumed 35 employees per organization on average and a total of $n=1575$ in *SSW-IP* and $n=4,725$ in *SSW-T* followed up at posttest (70%). Adjusting for an $ICC=0.02$, which usually is much lower for individual behaviors, reduces effective sample size to $n=938$ in *SSW-IP* and $n=2,872$ in *SSW-T*, but a small difference in proportions of 0.60 to 0.652 is detectable with 81% power. If more employees are available, our power is conservative and this trial is well powered for small effect sizes. Based on *SSW* and *SSS* projects, we will invite 70 employees per employer ($n=14,000$), pretesting 10,000 (50/employer; 70% participation rate) and posttesting 6,300 (35/employer; 70% follow-up).

3C.15.4. Ancillary Analyses of Mediation by Intervention Exposure: Employers' engagement with *SSW-IP* and *SSW-T* may differ and affect implementation rates achieved by the scale-up strategies. We will explore mediation of policy/education implementation rates by program exposure assessed by process measures (see 3C.10), using mediational analyses from Judd and Kenny²²⁸ and elaborated by MacKinnon.²²⁹ To satisfy the conclusion of mediation, significance will be determined via interval estimation using a bootstrap estimate.²³⁰ Ratio of indirect to total effect will estimate proportion of effect mediated by engagement.

3C.16. Strengths and Limitations to Approach

The research has several strengths. The sample is national, increasing generalizability. Established recruitment and intervention implementation protocols and models and measures will be used (see

Boxes 5 & 6). Randomization should equalize employers/employees across conditions. Analyses will bring the cost element to the fore. Data collection staff will be blind to condition. The primary analysis tests impact of scale-up on organizational changes (policy and education), which are often process measures. It is challenging to change organizations during wide-scale dissemination so organizational change needs to be studied, as well as effect of these changes on workers' behavior. Potential problems were minimized. We will not reveal participation to supervisors and keep responses confidential to minimize selection bias. Social desirability biases in self-reports will be reduced by including valid, easy to administer, and low cost items^{216,219,231-233} and having randomization equalize bias across condition. Only immediate implementation (reach and cost-effectiveness) is measured; future assessments of Maintenance are relevant if *SSW-IP* and/or *SSW-T* are cost-effective.

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