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OSH Program Evaluation in Manufacturing and Small Business

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List of Abbreviations

EP: Exposure Prevention

OHA: Occupational Health Association

OSH: Occupational safety and health

OSHA: Occupational Safety and Health Association

SBEI: Small Business Exposure Index

Abstract

Programmatic or systematic approaches to occupational safety and health (OSH) have long been acknowledged as essential to the prevention and control of occupational injury and illness. In the last two decades, OSH programs or management systems have emerged internationally as a major strategy for addressing workplace safety and health. OSH program regulations and voluntary guidelines have been developed or are under development in numerous countries, including the US.

In this project, we developed methods for assessing the scope and quality of OSH programs, and assessed the effectiveness of interventions to improve OSH programs. Our OSH program measures were derived from OSHA's 1995 Program Evaluation Profile; the OSH program measures gauge the degree to which an organization systematically manages OSH, rather than the presence or absence of a program/management system. This assessment approach is broadly applicable, transparent, and simple to administer. Results from field application of this assessment instrument in two intervention trials indicate that it has reasonable discriminatory power and is well matched to the range of prevalent OSH programs in the American manufacturing sector, in both large (average 750 employees) and small/medium (average 96 employees) companies. Most manufacturing sites scored in the 60-80% range on a 100-point OSH program scale (suggesting acceptable quality programs), with roughly some sites scoring below 60% (suggesting poor programs).

In the intervention study in large manufacturing sites, management-focused intervention led to consistently greater improvement in intervention versus control sites across all OSH program measures, with significantly greater improvements in a measure of 'management commitment and employee participation'. The intervention in small/medium sites was not associated with greater improvements in intervention versus control sites.

With respect to implications for policy and practice, these findings suggest: (1) the observation of substantial room for improvement at most sites supports the need for intervention in the OSH program area; (2) The observed intervention–related improvement in 'management commitment and employee participation' suggests likely benefits from intervention in this area; (3) Further empirical research is needed to improve and validate OSH program assessment methods and to evaluate the relative effectiveness of various intervention approaches.

Significant Findings

"OSH programs in manufacturing and small business" built on two randomized controlled intervention trials: "WellWorks-2" (1996-2000), and "Cancer Prevention in Small Business" (1999-2003). This project substantially expanded the occupational health analyses and data collections beyond the primary health promotion emphasis in each of these parent trials. Cross-sectional (aims 1-3) and experimental analysis methods (aim 4) were applied to address four specific aims:

1. characterize OSH programs and construct composite organization-level OSH program measures at baseline in large and small manufacturing worksites
2. determine the relationship between OSH program measures and WellWorks Exposure Prevention ratings at baseline in large and small manufacturing worksites

3. determine the relationship between OSH program measures and individual-level employee self-reports of OSH conditions at baseline in large and small manufacturing worksites
4. determine the impacts of WellWorks interventions on OSH program measures using experimental designs in large and small manufacturing worksites

WellWorks-2 Trial

OSH program measures were constructed using baseline WellWorks-2 data (17 large manufacturing worksites) (specific aim 1). Measures of 'management commitment and employee involvement,' 'hazard analysis,' 'hazard prevention and control,' 'training and education' and 'overall program score' were generated for baseline and follow-up data, and experimental analysis for intervention-associated change was examined. We observed a consistent pattern of greater improvements in OSH program scores in intervention versus control sites, as hypothesized (specific aim 4). Improvement in "management commitment and employee participation" was significantly greater in intervention versus control sites.

We conducted baseline analyses of the WellWorks-2 walk-through occupational health assessment (OHA) data (which yields Exposure Prevention ratings). While this instrument was developed as part of WellWorks-2 project, it was used in comparisons to OSH program data in this project (specific aim 2). Preliminary analyses of WellWorks-2 data comparing Exposure Prevention rating mean scores to OSH program scores by site showed no relationship between the two, but further analyses are on-going. Analyses comparing individual level employee self-reports with OSH program measures have yet to be conducted (specific aim 3).

Cancer Prevention in Small Business Trial

The quantitative OSH program assessment instrument was substantially revised to make it more suitable for assessing informal as well as formal OSH program features in the Small Business study. In parallel, a qualitative OSH program assessment instrument consisting of a series of open-ended questions was successfully administered. The WellWorks-2 OHA walk-through instrument was also substantially revised for use in the Small Business trial. These data were analyzed along with baseline OSH program scores. Finally, to complement the pre- and post-assessments, an on-going qualitative assessment was conducted during the intervention period, with site intervention staff being interviewed bi-weekly by co-investigators to collect qualitative data.

Analyses of the relationship between the adaptation of WellWorks-2 Exposure Prevention ratings to the small business setting (SBEI) and OSH program measures are in progress. The SBEI measures have only recently been completed. We anticipate completion of analyses and reporting on these results in the near future (specific aim 2).

Individual level employee self-reports of working conditions were greatly reduced in the pre-testing of survey instruments, rendering assessment of specific aim 3 in the Small Business trial infeasible. This was largely because pre-testing indicated the need for the survey instruments to be translated into Spanish, Portuguese and Vietnamese, and one-on-one interviewer-administered in-person in the language of preference of the interviewee.

In the Small Business trial, we used a randomized control trial design to assess whether a management-focused intervention to improve the OSH program was effective, but instead, compared to a minimal intervention control. We observed that the total OSH program score improved by four points (out of 100) for the intervention sites, and decreased by four points in the control condition sites; this difference by condition was not statistically significant. Qualitative findings suggest that the baseline program scores may have been inflated owing to social desirability introduced in the interview process. We are now conducting additional analyses on manager surveys of OSH programs to assess this potential source of bias in our data.

Translation of Findings

Regarding OSH programs, we developed an instrument, based on OSHA's proposed OSH program rule that employers, employees, health and safety experts and committees can use to assess essential elements of sound OSH programs. The instrument includes binary indicators that can be summed to a weighted "overall program score" reflecting "management commitment and employee participation," "workplace analysis," "hazard prevention and control," and "education and training." Our studies indicated a broad range of performance on these indicators in both small and large manufacturing worksites, suggesting that there is need for improvement in OSH systems in this sector. We can also recommend from our findings that qualitative assessments be conducted in parallel to quantitative scoring in order to better capture informal approaches to systematically managing OSH, as well as formal ones. This is particularly important in small to medium sized companies, which tend to rely more on informal than formal measures that are more common in larger companies.

The OSH program instrument is also sensitive to detecting change in the context of interventions designed to improve an OSH program. Comparison of pre- and post-intervention scores for small and large manufacturing sites indicated statistically significant positive changes in the total OSH program score. Among large manufacturing worksites, using a randomized control trial design, we found that management-focused interventions led to significantly improved OSH program scores.

Scientific Report

Background of the Project

This project was submitted in response to a request for proposals in "Intervention Effectiveness Research" (priority area 1 in RFA-OHA-99-002). Intervention effectiveness research that is generalizable to as many work contexts and hazard types as possible would most efficiently advance this new research priority. OSH programs (also known variously as comprehensive OSH programs, worker protection programs, injury and illness prevention programs, and accident prevention programs) are universally important for all workplaces and occupations. They are relevant to both safety (e.g., injury) and health (e.g., illnesses) outcomes. Based on evidence relating strong OSH programs to improved safety performance and incomplete voluntary implementation in general industry, OSHA drafted an OSH program rule. However, OSH program measurement methods are poorly developed to date, and the applicability of OSH programs to hazardous exposures and consequent occupational illness and diseases outcomes remains to be established. In addition, the applicability of an OSH program rule to small business raises specific concerns that must be addressed in order for OSHA to proceed with rulemaking. Research in these areas is urgently needed to strengthen the scientific basis of a proposed OSHA

standard that would represent a nation-wide intervention in all industrial sectors. This proposal addresses the development of OSH program measures and the evaluation of the effectiveness of interventions to improve such measures. Furthermore, we will conduct this research in both large and small manufacturing businesses, providing the important opportunity to compare and contrast the two.

Two health promotion trials, funded by the National Cancer Institute, entitled WellWorks-2 (1996-2000) and WellWorks-Small Business (1999-2003), provide a unique opportunity to develop measures of OSH programs and to assess the effectiveness of WellWorks interventions in improving OSH programs. WellWorks-2 addresses the question: Does the addition of worksite health protection increase the effectiveness of worksite health promotion? The effectiveness of a 16 month integrated health promotion/OSH protection intervention was compared to a traditional health promotion intervention in a randomized, controlled design 17 large manufacturing worksites that employ at total of roughly 10,000 workers.[1] WellWorks-Small Business compared the effect of a similarly integrated intervention to controls that receive minimal intervention in 24 small manufacturing business (50-150 employees).[2] The intervention and the evaluation in both projects are based on a theory-driven ecological model encompassing individual, organizational, and environmental levels of influence. In addition to the primary health promotion outcomes, both trials include the secondary outcome of hazardous chemical exposure, assessed using measures of Exposure Prevention based on walk-through occupational hazards assessment (OHA) conducted by a WellWorks staff industrial hygienist.[3] The Exposure Prevention rating protocol yields an ordinal rating of hazardous chemical exposure consisting of parallel ratings of potential for, and protection from, hazardous substance exposure in a given work area. Ratings from various work areas are combined into a site-wide mean Exposure Prevention rating.

Because intervention-associated changes at the environmental level were hypothesized to occur largely though changes at the organizational level, WellWorks-2 added an OSH program measure at baseline. The WellWorks instrument was derived from OSHA's 1995 Program Evaluation Plan, which was developed to support OSHA consultation services, inspection efforts, and the current rulemaking on comprehensive OSH programs.[4] We characterized OSH programs using baseline data from WellWorks-2, and evaluated the impacts of the WellWorks-2 intervention on OSH programs. We then adapted our OSH program measures to the small business context, collected OSH pre- and post-intervention data, and evaluated the impacts of interventions on OSH programs in small business settings. Addition of OSH program measures to the WellWorks trials provided a unique opportunity to assess organizational level OSH measures in relation to OSH measures at the individual (employee) and physical environmental levels (Exposure Prevention ratings).

Specific Aims

Within the context of the on-going WellWorks trials, our specific aims will utilize cross-sectional (Aims 1-3) and experimental designs (Aim 4) to:

1. Characterize OSH programs and construct composite organization-level OSH program measures at baseline in large and small manufacturing worksites;
2. Determine the relationship between OSH program measures and Exposure Prevention ratings at baseline in large and small manufacturing worksites;

3. Determine the relationship between OSH program measures and individual-level employee self-reports of OSH conditions at baseline in large and small manufacturing worksites; and
4. Determine the impacts of WellWorks interventions on OSH program measures using experimental designs in large and small manufacturing worksites.

The specific aims are similar for the large and small manufacturing worksite projects, with the exception that the revised OSH program measures for the small business context will include parallel quantitative and qualitative assessment methods. .

Procedures and Methodology

Specific aims 1-3 used cross-sectional designs; specific aim 4 employed experimental designs. Our OSH program measures were developed based on OSHA's 1995 Program Evaluation Profile. These measures were first applied in the WellWorks-2 trial,[5] and subsequently revised for application in the Small Business trial that followed.[6] The OSH program, intervention, and intervention effectiveness evaluation methods are detailed in turn below for the WellWorks-2 trial and its small business successor.

WellWorks-2 OSH Program Assessment, Intervention, and Effectiveness Evaluation Methods

WellWorks-2 OSH Program Assessment Methods

All baseline OSH program assessments were conducted by one WellWorks-2 staff industrial hygienist. Because this industrial hygienist was subsequently involved in intervention delivery, all post-intervention assessments were administered by a second staff industrial hygienist to avoid bias. In order to make baseline and final assessment methods comparable, both hygienists were involved in the development of the OSH program assessment instrument and a detailed protocol for its administration. Data collection methods were thus standardized to the extent feasible given the need for different assessors at baseline and final. One assessment was done per site with one informant, the person most responsible for OSH on site. These face-to-face interviews were conducted on-site with OSH managers or other specifically OSH-responsible persons (including occupational health nurses at two sites) where available (14 sites at baseline; 13 at final), and with human resource or personnel directors at other sites (one site at baseline; two sites at final). The same site representative was interviewed at baseline and final at nine of the sites.

OSH program assessment interviews were conducted directly following detailed walk-through assessments of the physical work environment.[3] In most cases, the site representative who hosted the walk-through assessments was also the interviewee for the OSH program assessment. While OSH program interviews took 1.0-1.5 hours to administer, the total time for the work environment walk-through and OSH program assessments was one to two days per site. The time between (pre-randomization) baseline assessments and (post-intervention) final assessments averaged 24 months (range 22-26 months).

OSH programs were assessed using an instrument adapted from the OSHA's 1995 Program Evaluation Profile.[4] Our adaptation included 91 binary indicator variables (detailed in Table 1) grouped under OSHA's four program 'Essential Elements' of: management commitment and employee participation (43 indicators), workplace analysis (11 indicators), hazard prevention and

control (eight indicators), and education and training (14-29 indicators, depending on variable number of potential exposures for which training might be required). Percentages of OSH-favorable responses were then multiplied by OSHA weights for each Essential Element,[4] and totaled as an overall program score on a 100-point scale. OSHA Essential Element weights were as follows: management commitment and employee participation (highest possible contribution of 36/100 points), workplace analysis (28/100 points), hazard prevention and control (24/100 points), and education and training (12/100 points).[4]

Data were also collected on several indicators that were not used for quantitative scoring. These include the numbers of full-time employees with OSH as their primary responsibility, the qualifications of such staff (i.e., safety professional, industrial hygienist, occupational health nurse, and other), and the percentage of OSH staff work time devoted to handling Workers' Compensation claims. Other questions included whether the organization is self-insured for Workers' Compensation, whether any employees are potentially exposed to a range of hazards with detailed OSHA standards (i.e., lead, cadmium, asbestos, noise, and other), and whether any employees are subject to medical surveillance for such specific hazards.

WellWorks-2 Intervention Methods

The 16-month intervention began following completion of baseline assessments. WellWorks-2 encouraged companies to adopt a pro-active, upstream preventive approach, going beyond compliance with legal standards set by OSHA.[1, 3] Management was targeted as representative of the organization because management has both primary control over, and primary responsibility for, providing a safe and healthy work environment. Though the management of hazardous substance issues was targeted in particular, the upstream approach was emphasized as applicable to all aspects of OSH.

Operationally, the WellWorks-2 management intervention was conducted primarily through contacts with middle and upper management, led by a WellWorks-2 staff industrial hygienist. In non-OSH intervention control worksites, WellWorks-2 health promotion staff provided consultation to management on tobacco control policies, food service and catering policies over the 16-month intervention period.

Baseline OSH program assessments, in combination with walk-through assessments of the physical work environment,[3] identified site-specific OSH needs and were used to tailor the intervention at integrated intervention sites, particularly to guide on-going management- or organizational-level intervention. Baseline OSH program assessment data were reviewed in detail by WellWorks-2 staff and qualitatively summarized in reports presented at the beginning of the intervention period both orally and in written form to OSH staff, management, and unions (if present) at each of the intervention worksites. These baseline reports were attended typically by five to ten middle and upper managers, usually including OSH mangers, general managers, and department heads. Multiple copies (depending on size and number of departments) of written reports were distributed at the oral presentation. WellWorks staff presenters encouraged the circulation of the reports to middle and upper management.

During the intervention period, management intervention methods included one-on-one consultation and technical assistance with managers, group educational sessions to management,

group educational sessions and consultation with OSH committees, and communication through written materials. Quantitative intervention process tracking documented a mean of 18 OSH-specific management contacts in the intervention sites (with a mean total of 25 management contacts including health promotion), versus no OSH-specific management contacts in control sites (mean total of nine management contacts on health promotion).[7] Contacts during the intervention period were most commonly with OSH managers and other middle management (e.g., OH nurse, human resources personnel), sometimes upper management (e.g., Production Manager, Manufacturing Manager, Operations Manager), but rarely with top management (e.g., Vice President of Manufacturing Operations, Controller).

Site-specific management consultations focused on achieving improvements in OSH program elements by advocating for (a) upper management commitment to OSH, integration of OSH as a core business function, and the involvement of upper managers in OSH activities and decision-making; (b) employee participation in OSH management structures (such as OSH Committees, hazard analysis procedures, and near-miss or accident investigation strategies), (c) improvement in human and material resources for hazard analysis, control, and prevention—based on industrial hygiene (hierarchy of control) principles; (d) on-going OSH education and training for salaried as well as hourly employees, and revision and improvement of OSH training and education activities.

Finally, we developed tailored (site-specific) WellWorks-2 newsletters towards the end of the intervention period, including one or more OHS improvement success stories for each site. These were distributed to all middle and upper management at each intervention site.

WellWorks-2 Effectiveness Evaluation Methods: Frequency distributions of baseline OSH program scores are presented as histograms for each Essential Element and for the total score. Because the same baseline scores were assigned to each of the three sites for the single, large multi-site company, baseline assessments are presented for 15 sites.

For each Essential Element and the total, change scores were computed by subtracting baseline from final scores. The difference in mean change scores between intervention and control sites was tested using mixed model analysis of variance with randomization block included as a random effect and intervention group as the fixed effect. Including randomization block controls for the within block correlation in the outcome; for the three worksites in the single large company, intra-block correlation was introduced by the use of identical baseline measures. All p-values are reported as two-sided. Using baseline score distributions, we estimated 80% power to detect a mean improvement of 19 points for the total program score at a 5% significance level in the intervention group (assuming within worksite correlation of baseline and final scores of 0.5 and no change in the control group).

Small Business Trial OSH Program Assessment, Intervention and Effectiveness Evaluation Methods

Small Business OSH Program Assessment Methods

At baseline, a Small Business study staff industrial hygienist assessed each worksite's OSH program by conducting an in-person interview with the staff person identified by management as being most responsible for health and safety. This included directors of human resources (n=7),

production managers (n=6), environmental health and safety managers (n=6), occupational health nurses (n=2) and miscellaneous others, including in one case, the company president. Interviews lasted approximately one hour. Responses to all questions were recorded directly on the OSH program assessment interview form. Interviews were not tape-recorded to encourage respondents to speak candidly about potentially sensitive topic areas. The interview protocol was approved by an institutional review board, and signed informed consent was obtained from all respondents.

Our OSH program assessment instrument was originally developed for the WellWorks-2 study in larger manufacturing worksites.[5] It had been adapted from OSHA's 1995 Program Evaluation Profile to characterize companies' OSH programs and to facilitate the "scoring" of OSH programs for pre- and post-intervention effectiveness assessment. For the present study in small worksites, we removed several items that we deemed inappropriate to smaller worksites and also added a set of open-ended questions (described below). Our measures included 47 binary indicator variables (detailed in Table 1) grouped under the same four OSHA program essential elements described above: management commitment and employee participation (15 indicators for management commitment and 12 for employee participation), workplace analysis (seven indicators), hazard prevention and control (six indicators), and education and training (seven indicators). We then multiplied percentages of "OSH-favorable" responses by weights determined by OSHA for each essential element, and totaled an overall program score on a 100-point scale. Weights for each essential element (highest possible contribution in points) were as follows: management commitment and employee participation (36/100 points), workplace analysis (28/100 points), hazard prevention and control (24/100 points), and education and training (12/100 points).

Data were also collected on several indicators that were not used for scoring. These included: whether the company had any health and safety incentive programs; the numbers of full-time employees with OSH as a specific responsibility and for what percentage of their time; whether any employees were potentially exposed to a range of hazards covered by detailed OSHA standards (i.e., lead, cadmium, asbestos, other); and whether worksites did any air sampling to monitor exposures to such hazards.

We supplemented closed-ended questions with a set of open-ended questions to accomplish several objectives. First, qualitative research methods are well-suited to exploring new areas not yet well understood, and can aid in understanding the "hows" and "whys" underlying responses to close-ended questions.[6] Because we had not used our assessment tool in small businesses previously, we wanted to optimize our ability to capture informal approaches to managing OSH (which were anticipated to be more likely in small businesses versus larger ones), as well as additional descriptions from respondents about how and why they manage health and safety in the ways they do. Second, we wanted to assess respondents' perceptions of their OSH program assets, priorities, needs and barriers to further characterize small business OSH programs and to enhance the suitability and relevance of intervention strategies for worksites randomized to the study's treatment condition.

The interview began with a general open-ended question related to OSH management ("Please describe how health and safety is handled at this worksite") to allow respondents to describe

their approaches in their own words. This was followed by the measures assessing the four program elements described above. Respondents were then asked if they would like to provide any additional information about these four areas. A series of open-ended questions concluded the interview. The interviewer asked the respondent to assess company performance ("What does your company do well in terms of health and safety?"; "What do you think are areas for improvement?"); to suggest how he or she might improve OSH performance ("Is there one of more of the four program elements that might be priority areas for improvement?"; "What would help your company to improve and sustain these program elements?"); and to describe barriers to success ("Can you describe any particular barriers you see to sustaining any of these program elements?").

Small Business Intervention Methods

The 18-month intervention began following completion of baseline assessments. As in WellWorks-2, in the Small Business study, we encouraged companies to adopt a pro-active, upstream preventive approach, going beyond compliance with legal standards set by OSHA.[1, 3] Management was targeted as representative of the organization because management has both primary control over, and primary responsibility for, providing a safe and healthy work environment. Though the management of hazardous substance issues was targeted in particular, the upstream approach was emphasized as applicable to all aspects of OSH.

Operationally, the WellWorks-2 management intervention was conducted primarily through contacts with middle and upper management, led by a project staff industrial hygienist. In non-OSH intervention control worksites, project staff provided consultation to management on tobacco control policies.

Baseline OSH program assessments, in combination with walk-through assessments of the physical work environment,[3] identified site-specific OSH needs and were used to tailor the intervention at integrated intervention sites, particularly to guide on-going management- or organizational-level intervention. Baseline OSH program assessment data were reviewed in detail by project staff and qualitatively summarized in reports presented at the beginning of the intervention period both orally and in written form to OSH staff, management, and unions (if present) at each of the intervention worksites. These baseline reports were attended typically by two to three middle and upper managers, usually including OSH mangers, general managers, and department heads. Multiple copies (depending on size and number of departments) of written reports were distributed at the oral presentation.

During the intervention period, management intervention methods included one-on-one consultation and technical assistance with managers, group educational sessions and consultation with OSH committees, and communication through written materials. Process tracking data revealed that we delivered a mean of 6.7 contacts per worksite regarding OSH issues, compared with 1.9 for physical activity; 1.6 for nutrition; and 1.0 for smoking cessation.

Site-specific management consultations focused on achieving improvements in OSH program elements by advocating for (a) upper management commitment to OSH, integration of OSH as a core business function, and the involvement of upper managers in OSH activities and decision-making; (b) employee participation in OSH management structures (such as OSH Committees,

hazard analysis procedures, and near-miss or accident investigation strategies); (c) improvement in human and material resources for hazard analysis, control, and prevention, based on industrial hygiene (hierarchy of control) principles; and (d) on-going OSH education and training for salaried as well as hourly employees, and revision and improvement of OSH training and education activities.

Finally, we developed tailored (site-specific) newsletters towards the end of the intervention period, including one or more OHS improvement success stories for each site. These were distributed to all workers at each intervention site.

Small Business Intervention Effectiveness Evaluation Methods

We calculated frequency distributions of OSH program scores and present these as histograms for each essential element and for the total score. Responses to the open-ended questions were typed from field notes and imported into the qualitative data management software QSR N*Vivo® for analysis. Qualitative analysis was conducted as follows: after reading through the interview notes in their entirety, two of the authors (C. Roelofs and E. Barbeau) coded and analyzed the data using: (a) a start list of codes based on the structure of the interview and the four program elements, and (b) a set of pattern codes based on emergent themes.[6] The qualitative data were summarized and are presented by code and "theme."

For each Essential Element and the total, change scores were computed by subtracting baseline from final scores. To assess intervention effectiveness, he difference in mean change scores between intervention and control sites was tested using analysis of variance. P-values are reported as two-sided.

Results and Discussion

Below we outline achievements on each of the four specific aims in each of the two parent trials.

Specific Aim 1: Characterize OSH programs and construct composite organization-level OSH program measures at baseline in large and small manufacturing worksites.

We accomplished this aim. Detailed scientific reporting on this aim is embodied in two peer-reviewed publications included in Appendix A:

- LaMontagne A, Youngstrom R, Lewiton M, Stoddard A, McLellan D, Wallace L, Barbeau E, and Sorensen G. Assessing and intervening on OSH programs: effectiveness evaluation of the WellWorks-2 intervention in 15 manufacturing worksites. *Occup Environ Med* 2004; 61: 651-660.
- Barbeau E, Roelofs C, Youngstrom R, Stoddard A, Sorensen G, LaMontagne A. Assessment of occupational safety and health programs in small businesses. *Am J Ind Med* 2004; 45: 371-379.

In summary, for the WellWorks-2 study, we: (1) developed a transparent and broadly-applicable method for assessing occupational safety and health (OSH) programs or management systems, and (2) assessed OSH programs in the study sample of manufacturing worksites. We based our assessment instrument on the U.S. Occupational Safety and Health Administration's 1995 Program Evaluation Profile. Scores were generated from 91 binary indicator variables grouped

under four 'essential elements'. 'Essential element' scores were weighted to contribute to an overall program score on a 100-point scale as follows: management commitment and employee participation (highest possible contribution of 36/100 points), workplace analysis (28/100 points), hazard prevention and control (24/100 points), and education and training (12/100 points). Seventeen large manufacturing worksites were assessed at baseline. We discovered considerable variation in essential element scores across sites at baseline as judged by our instrument, particularly in 'management commitment and employee participation' and 'workplace analysis'. Most sites scored highly on 'hazard prevention and control' and 'training and education'. For overall OSH program scores, most sites scored in the 60-80% range at baseline, with four sites scoring below 60%, suggesting weak programs. We conclude that the OSH program assessment method used is (1) broadly applicable to manufacturing work settings, and (2) suggests needs for improvement in OSH programs in most such worksites.

Also in accord with this aim, for the Cancer Prevention in Small Business Trial, we adapted the OSH program assessment we developed for the WellWorks-2 trial so as to make the instrument more relevant to the small business context. Our measures included 47 binary indicator variables (detailed in Table 1) grouped under OSHA's four program essential elements: management commitment and employee participation (15 indicators for management commitment and 12 for employee participation), workplace analysis (seven indicators), hazard prevention and control (six indicators), and education and training (seven indicators). We supplemented closed-ended questions with a set of open-ended questions. Our findings were that scores for each element ranged widely, with distribution of most scores being quite positively skewed. Barriers to addressing OSH included lack of time and in-house expertise, and production pressures. External agents, including as corporate parents, liability insurers, and OSHA, played an important role in motivating OSH programs. We conclude that small businesses in our sample are able to mount comprehensive programs, however, they may rely on outside resources for this task. Being small may not be a barrier to meeting the requirements of an OSHA program management rule.

Specific Aim 2: Determine the relationship between OSH program measures and WellWorks OHA measures at baseline in large and small manufacturing worksites

Specific Aim 3: Determine the relationship between OSH program measures and individual-level employee self-reports of OSH conditions at baseline in large and small manufacturing worksites

We conducted baseline correlation analyses of the WellWorks-2 Exposure Prevention ratings (mean EP Rating by site) in comparison to OSH program scores by site. No relationship was observed, but further analyses will be conducted adjusting for randomization block. Experimental analyses of changes in EP ratings between intervention and controls showed that patterns of improvement within the intervention condition were consistent with the intervention emphasis on upstream or source-focused intervention; whereas patterns in controls were consistent with prevalent practice (more downstream). A mixed model analysis of variance showed greater improvement in EP ratings in intervention versus controls, but the effect was moderate and statistically non-significant.[8] Analyses comparing individual level employee self-reports with OSH program measures have yet to be conducted (specific aim 3), but experimental analyses of changes in employee reports of OSH working conditions showed no significant intervention-related changes.

In the Small Business study, analyses of the relationship between the SBEI and OSH program measures are in progress. The SBEI measures have only recently been completed. We anticipate completion of analyses and reporting on these results in the near future (specific aim 2). Individual level employee self-reports of working conditions were greatly reduced in the pre-testing of survey instruments, rendering assessment of specific aim 3 in the Small Business trial infeasible. This was largely because pre-testing indicated the need for the survey instruments to be translated into and administered in-person in English, Spanish, Portuguese and Vietnamese.

Specific Aim 4: Determine the impacts of WellWorks interventions on OSH program measures using experimental designs in large and small manufacturing worksites

We accomplished this aim. Detailed scientific reporting on this aim is embodied in one peer-reviewed publication included in Appendix A and another report that is in preparation and will be submitted to a peer-reviewed journal:

- LaMontagne A, Youngstrom R, Lewiton M, Stoddard A, McLellan D, Wallace L, Barbeau E, and Sorensen G. Assessing and intervening on OSH programs: effectiveness evaluation of the WellWorks-2 intervention in 15 manufacturing worksites. *Occup Environ Med* 2004; 61: 651-660.
- Barbeau E, Roelofs C, Youngstrom R, Stoddard A, Sorensen G, LaMontagne AD. Intervention effects on OSH programs in small businesses and related measurement concerns. (in preparation).

In summary, in the WellWorks-2 study we assessed whether a management-focused integrated occupational health and health promotion intervention resulted in greater improvement in OSH programs compared to health promotion-only intervention. As described above under specific aim 1, we developed and used an OSH program assessment instrument based on the U.S. Occupational Safety and Health Administration's 1995 Program Evaluation Profile. Seventeen large manufacturing worksites were assessed at baseline; 15 sites completed the 16-month intervention and follow-up assessments. A randomized, controlled design was used to assess intervention effectiveness (eight integrated versus seven control sites), with changes in essential element and overall program scores compared between intervention and control sites using mixed model analysis of variance. We found that integrated intervention sites showed greater improvements than controls in the four program elements and in overall program scores, with significantly greater improvements in 'management commitment and employee participation'. Despite a small sample size, we have demonstrated that sustained management-focused intervention can result in improvement in these OSH program measures. These findings strengthen the accumulating evidence of the need for management-focused intervention to improve OSH programs.

In the Small Business study, we likewise used a randomized control trial design to assess whether a management-focused intervention to improve the OSH program was effective, but instead, compared to a minimal intervention control. We observed that the total OSH program score improved by four points (out of 100) for the intervention sites, and decreased by four points in the control condition sites, suggesting an intervention effect (table below). This difference by intervention condition, however, was not statistically significant. Qualitative

findings suggest that the baseline program scores may have been inflated owing to social desirability introduced in the interview process. We are now conducting additional analyses on manager surveys of OSH programs to assess this potential source of bias in our data.

Small Business Trial: Mean Change from Baseline to Final (weighted scores), by Intervention Condition

Program Elements	*Intervention (n=12)*	*Control (n=12)*	*p-value*
Management commitment	1.5	1.25	.79
Employee Participation	-.25	-1.5	.20
Hazard Identification	-.083	-.333	.66
Hazard Prevention and Control	.333	-.167	.35
Training and Education	.75	-.833	.04
Total Program Score	3.56	-4.025	.22

Conclusions

From the WellWorks-2 study, we conclude that the OSH program assessment method used is (1) broadly applicable to manufacturing work settings, and (2) suggests needs for improvement in OSH programs in most such worksites. In the intervention effectiveness evaluation, despite a small sample size, we demonstrated that sustained management-focused intervention can result in improvement in these OSH program measures. These findings strengthen the accumulating evidence of the need for management-focused intervention to improve OSH programs in large manufacturing worksites.

From the Small Business study, we conclude that small manufacturing businesses (in the range of 100 employees) were able to mount comprehensive programs; however, they may rely on outside resources for this task. Being small may not be a barrier to meeting the requirements of an OSHA program management rule. Importantly, quantitative OSH program assessment methods should be complemented by qualitative in small to medium-sized companies. From the effectiveness evaluation, we conclude that more intense and/or longer intervention is required to significantly improve OSH programs in small to medium-size manufacturing settings.

Publications

As detailed below, a number of peer-reviewed publications have been published, are under review, or are in preparation. In addition, study results have been presented at numerous national and international conferences over the last four years. Future publications and research presentations will be reported to NIOSH.

Peer-reviewed publications

Barbeau E, Roelofs C, Youngstrom R, Stoddard A, Sorensen G, LaMontagne A. Intervention effects on OSH programs in small businesses and related measurement concerns. (in preparation).

LaMontagne AD, Stoddard AM, Youngstrom RA, Lewiton M, Klar JM, Sorensen G. Improving the prevention and control of hazardous substance exposures: A randomized controlled trial in manufacturing worksites. (in review).

LaMontagne AD, Stoddard AM, Youngstrom RA, Lewiton M, and Sorensen G (2004): Improving the prevention and control of hazardous substance exposures: a randomized controlled trial in manufacturing worksites (abstract). *Occ Env Medicine* 61:e26 (http://oem.bmjjournals.com/cgi/content/extract/61/11/e26).

Barbeau E, Roelofs C, Youngstrom R, Stoddard A, Sorensen G, LaMontagne A. Assessment of occupational safety and health programs in small businesses. *Am J Ind Med* 2004; 45: 371-379.

Barbeau E, Wallace L, Lederman R, Lightman N, Stoddard A, Sorensen G. Recruiting small manufacturing worksites that employ multi-ethnic, low-wage workers to a cancer prevention research trial. *Prev Chronic Dis* 2004; 1(3): 1-9.

LaMontagne A, Youngstrom R, Lewiton M, Stoddard A, McLellan D, Wallace L, Barbeau E, and Sorensen G. Assessing and intervening on OSH programs: effectiveness evaluation of the WellWorks-2 intervention in 15 manufacturing worksites. *Occup Environ Med* 2004; 61: 651-660.

LaMontagne A, Youngstrom R, Lewiton M, Stoddard A, Perry M, Klar JM, Christiani DC, Sorensen G. An exposure prevention rating method for intervention needs assessment and effectiveness evaluation. *Appl Occup Env Hygiene* 2003; 18: 523-534.

National and International Research Presentations

Oct 2004	US Centers for Disease Control/NIOSH STEPS TO A HEALTHIER WORKFORCE SYMPOSIUM, Washington. Oral presentation on "The WellWorks-2 integrated OSH and workplace health promotion trial: OSH effectiveness evaluation results," by LaMontagne, Stoddard, Youngstrom, et al.
Oct 2004	EpiCOH, INTERNATIONAL CONGRESS ON OCCUPATIONAL HEALTH EPIDEMIOLOGY CONFERENCE, Melbourne. Oral presentation on "Improving the Prevention and Control of Hazardous Substance Exposures: A Randomized Controlled Trial in Manufacturing Worksites," LaMontagne, Stoddard, Youngstrom, et al.
April 2004	WORLD HEALTH PROMOTION CONFERENCE 2004, Melbourne. Invited oral presentation on "WellWorks and beyond: Lessons from integrated health promotion and health protection intervention trials in the US," by LaMontagne, Sorensen, Hunt, et al.

Dec 2003 — 21th ANNUAL MEETING OF THE AUSTRALIAN INSTITUTE OF OCCUPATIONAL HYGIENE, Adelaide, SA, Australia. Oral presentation on "An Assessment of OSH Management in Small/Medium Manufacturing Enterprises", Barbeau E, Roelofs C, Youngstrom RA, et al (presented by LaMontagne AD).

Nov 2002 — AMERICAN PUBLIC HEALTH ASSOCIATION ANNUAL MEETING, Philadelphia, PA, USA. Oral presentation entitled "Occupational safety and health programs in Massachusetts small businesses," Roelofs CR, Barbeau EM, Sorensen GC, Stoddard AM, and LaMontagne AD (abstract #43862).

March 2001 — WORKCONGRESS5: INTERNATIONAL CONGRESS on WORK INJURY PREVENTION, REHABILITATION, and COMPENSATION, Adelaide, South Australia. Oral presentation on "Assessing OHS Management Systems: WellWorks-2 Strategies and Results", by LaMontagne et al. See www.workcongress5.org.

Nov 2000 — AMERICAN PUBLIC HEALTH ASSOCIATION ANNUAL MEETING, Boston, MA, USA. Oral presentation on "Assessing OSH Programs and Chemical Hazards: WellWorks-2 Strategies and Results", by LaMontagne et al.

Oct 2000 — 12th NATIONAL HEALTH PROMOTION CONFERENCE, Melbourne, Australia. Invited oral presentation on "Integrating Health Promotion and Health Protection: Possible Synergies" in Leadership Forum on Promoting Work and Health, by LaMontagne et al.

Inclusion of Gender and Minority Study Subjects

Eligibility for inclusion in the study was based on employment at participating worksites. No research subjects were excluded from WellWorks-2 or from the Small Business study on the basis of race, gender, ethnicity, sexual preference, or any other individual characteristic. In fact, the Small Business study targeted companies that employ multi-ethnic, low-wage employees in an attempt to address the under-representation of minority subjects and communities in occupational health research.[6]

Inclusion of Children

Children were neither eligible for nor included in this study.

Materials Available For Other Investigators

OSH program and Exposure Prevention rating instruments are available to other investigators on request.

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4. Occupational Safety and Health Administration. OSHA Instructions CPL 2.110, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, DC, 1995.
5. LaMontagne, A.D., Youngstrom, R.A., Lewiton, M., Stoddard, A.M., McLellan, D., Wallace, L.M., Barbeau, E., Sorensen, G. Assessing and intervening on OSH programs: Effectiveness evaluation of the WellWorks-2 intervention in fifteen manufacturing worksites. *Occupational and Environmental Medicine* 2004; 61: 651-660.
6. Barbeau, E., Roelofs, C., Youngstrom, R., Sorensen, G., Stoddard, A.M., LaMontagne, A.D. Assessment of occupational safety and health programs in small businesses. *American Journal of Industrial Medicine* 2004; 45: 371-379.
7. Hunt, M.K., Lederman, R., Stoddard, A.M., LaMontagne, A.D., McLellan, D., Combe, C., Barbeau, E., Sorensen, G. Process evaluation of an integrated health promotion/occupational health model in WellWorks-2. *Health Education and Behavior* in press;
8. LaMontagne, A.D., Stoddard, A.M., Youngstrom, R.A., Lewiton, M., Klar, J.M., Sorensen, G. Improving the prevention and control of hazardous substance exposures: A randomized controlled trial in manufacturing worksites. in review;

Appendix A

LaMontagne AD, Youngstrom RA, Lewiton M, Stoddard AM, McLellan D, Wallace L, Barbeau E, Sorensen G [2004]. Assessing and intervening on OSH programmes: effectiveness evaluation of the Wellworks-2 intervention in 15 manufacturing worksites Occup Environ Med 2004 Aug; 61(8):651-660.
http://oem.bmjjournals.com/cgi/content/abstract/61/8/651

Barbeau E, Roelofs C, Youngstrom R, Sorensen G, Stoddard A, LaMontagne AD [2004]. Assessment of occupational safety and health programs in small businesses Am J Ind Med 2004 Apr; 45(4):371-379.
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