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Improving the Prevention and Control of Hazardous Substance Exposures: A Randomized Controlled Trial in Manufacturing Worksites

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Background *New measures of exposure prevention (EP) activity were used to evaluate the effectiveness of a 16-month management-focused intervention addressing hazardous substance exposures in manufacturing work settings.*

Methods *EP efforts were assessed using a rating scheme developed for this study. The rating scheme yields a set of measures of exposure potential and protection, which are combined into an overall EP summary rating. A randomized, controlled design was used to assess intervention effectiveness. Fifteen large manufacturing worksites completed the 16-month intervention and follow-up assessments. Analyses were conducted on the 107 production processes assessed at both baseline and final.*

Results *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, worker-focused). A mixed model analysis of variance showed greater improvement in EP ratings in intervention versus controls, but the difference in improvement was moderate and statistically non-significant.*

Conclusions *This study has demonstrated that EP efforts in the manufacturing sector can be systematically assessed across the full range of hazardous substances in use, and that such assessments can serve both needs assessment and effectiveness evaluation functions. Findings suggest that more sustained or intense management-focused intervention would significantly improve EP activity in manufacturing settings.* Am. J. Ind. Med. 48:282–292, 2005. *© 2005 Wiley-Liss, Inc.*

KEY WORDS: intervention research; intervention effectiveness research; experimental design; evaluation; upstream prevention; hazardous substances; precautionary principle

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BACKGROUND

NIOSH identified ‘intervention effectiveness research’ as a National Occupational Research Agenda (NORA) priority area in 1996, recognizing the need for expanded research efforts on how best to translate occupational safety and health (OSH) knowledge into exposure prevention (EP) and control in the workplace [NIOSH, 1996]. Yet, there is still a dearth of theoretically based and rigorously evaluated intervention studies in the OSH literature. There continues to be a particular shortage of intervention studies targeting occupational disease and associated exposures, although the situation is somewhat better for workplace safety interventions [Shannon, 1998; Shannon et al., 1999; Goldenhar et al., 2001; Robson et al., 2001]. Given the relative contributions of disease versus traumatic injury to the burden of work-related mortality and morbidity (as high as 10 to 1) [Leigh et al., 1997], intervention studies targeting occupational disease are a particularly high research priority.

The challenges to conducting such studies go part of the way toward explaining the shortage of them. Challenges include distinguishing work-related from other contributions to multi-factorial disease outcomes and the long latency from initial exposure to manifestation of many work-related diseases. Where sufficient epidemiologic evidence is available, these challenges can be met by using exposure metrics as proxies for disease outcomes [LaMontagne et al., 2002]. While quantitative exposure or dose assessment is the most objective way to assess the effectiveness of hazardous substance interventions, complementary methods are also needed. Quantitative exposure assessment may be feasible where one or only a few contaminants are being addressed, such as in the recent Minnesota Wood Dust Study [Brosseau et al., 2002; Lazovich et al., 2002], but is not feasible when addressing numerous contaminants. In addition, needs assessment and intervention tailoring need to take pre-existing prevention and control efforts into account. Quantitative exposure measurements, however, do not provide information on existing control measures, nor do they point to upstream source-focused prevention and control alternatives. Statistical power considerations are also an issue. When evaluating change at the level of the work process or worksite, it is often necessary to include multiple worksites in intervention and comparison groups in order to have sufficient power to detect intervention-related change. In such cases, the need for assessing intervention effectiveness across differing sets of substances by process or worksite poses further feasibility challenges to using quantitative exposure assessment.

We faced these challenges in evaluating the effectiveness of the Wellworks-2 intervention to improve the prevention and control of hazardous substance exposures in manufacturing worksites. Wellworks-2 is a randomized, controlled workplace intervention trial targeting the reduction of lifestyle and occupational health risks in blue-collar workers in the manufacturing sector. The primary hypothesis was that workers would be more likely to make lifestyle behavior changes if occupational health risks were addressed simultaneously [Sorensen et al., 2002]. Thus, Wellworks-2 as a whole addressed both health promotion (smoking cessation) and occupational health: sites received an integrated intervention containing both aspects; control sites received a ‘standard care’ health promotion-only intervention.

A secondary hypothesis in the Wellworks-2 trial was that integrated intervention sites would show greater improvements in the prevention and control of hazardous substance exposures in comparison to non-OSH intervention controls. We developed an EP rating scheme to assess the degree of upstream prevention being applied to a given manufacturing process at baseline, to identify intervention needs, and to evaluate intervention effectiveness at follow-up. Wellworks-2 presented a rare opportunity to include this new EP outcome measure in a study using a randomized controlled design. Because this is the first use of such a measure, Wellworks-2 is best described in the language of clinical trials as a Phase II Methods Development study with respect to these EP outcomes [Greenwald and Cullen, 1984; Flay, 1986].

A previous report described the EP rating scheme we developed for needs assessment and effectiveness evaluation in the Wellworks-2 trial, including its theoretical basis, piloting, refinements, inter-rater reliability, and pre-intervention field performance [LaMontagne et al., 2003]. The EP rating scheme assesses the degree of upstream prevention efforts observable in a given process or similar exposure group, providing a complement to quantitative exposure measures. Our goal was to develop a method that could be applied with modest expense by OSH researchers and other groups engaged in workplace prevention and control efforts (e.g., independent OSH professionals, company, or union OSH staff).

The Wellworks-2 OSH intervention was designed around a three-level social ecological framework [McLeroy et al., 1988], with specific intervention activities at the level of the worker (e.g., OSH training and education), the organization (e.g., management consultation on OSH), and the physical work environment (e.g., tailored efforts to improve the prevention and control of hazardous substance exposures) [Sorensen et al., 2002; LaMontagne et al., 2004, 2003; Hunt et al., 2005]. Each level contributes to reduction in hazardous exposures and associated adverse health outcomes (Fig. 1). This report presents the effectiveness evaluation of the physical work environment intervention (shaded in Fig. 1), using the EP measures developed for this purpose.

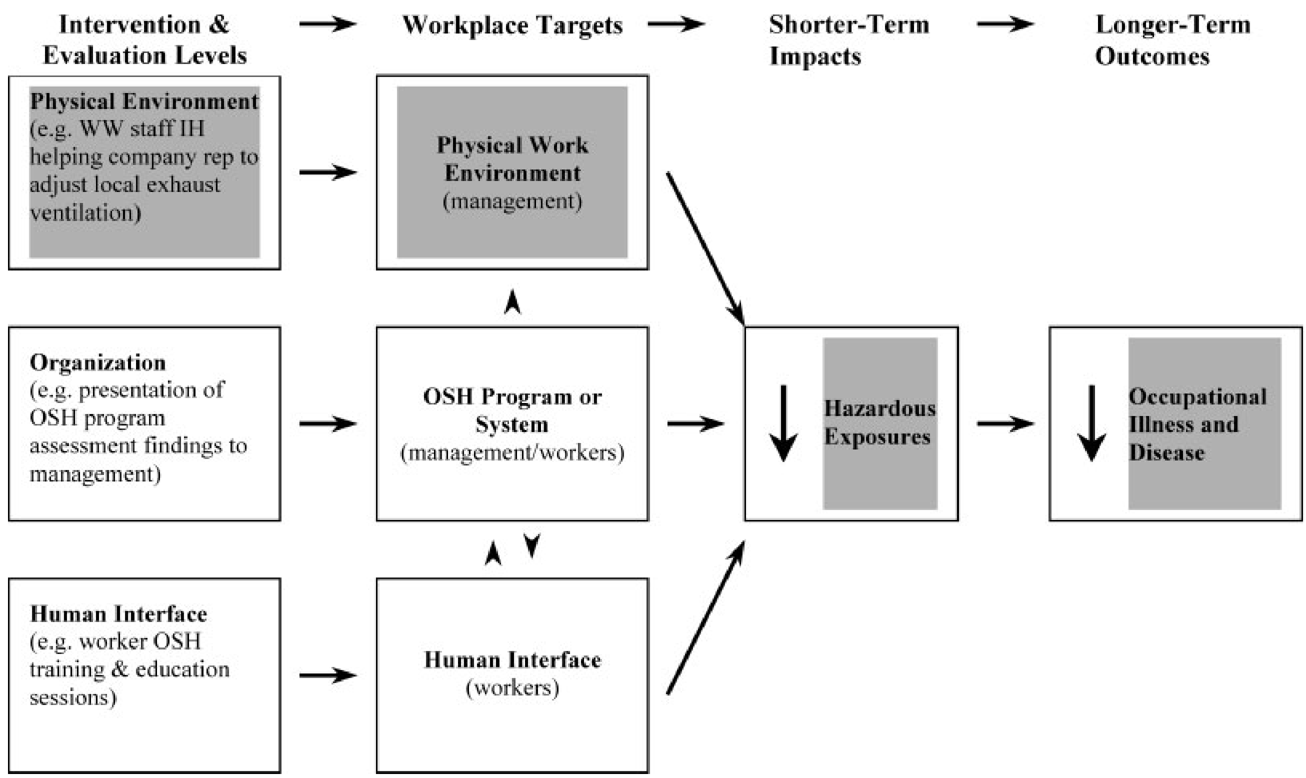

FIGURE 1. Wellworks-2 Intervention Model.

METHODS

Study Design and Population

The Wellworks-2 study used a randomized, controlled design with the worksite as the unit of assignment and intervention [Sorensen et al., 2002]. After baseline assessments, worksites were randomly assigned to one of two conditions: worksite health promotion integrated with occupational health protection (HP+) and worksite health promotion only (HP). The HP-only condition is described as a non-intervention control in this report because OSH was not addressed at all by the Wellworks-2 intervention in control worksites.

Health behavior changes (smoking and dietary habits) were the primary outcomes of this study, and accordingly, Wellworks-2 was powered to detect statistically significant and meaningful changes in health behaviors with the worksite as the unit of randomization and analysis [Sorensen et al., 2002]. Hence, power and sample sizes were not determined with respect to EP outcomes. The results of this report present the first intervention effect size estimates for the EP outcomes used, thus providing precedent for EP outcome-based power and sample size calculations in future studies.

The principal selection criteria for Wellworks-2 study sites were (a) manufacturing industry worksites employing between 400 and 2,000 workers, (b) probable use of hazardous substances, and (c) turnover rate $<20\%$ [Sorensen et al., 2002]. Further details on recruitment, company characteristics, and employee demographics are presented elsewhere [Sorensen et al., 2002; LaMontagne et al., 2003, 2004]. The types of manufacturing conducted at the participating worksites included adhesives, food products, high technology, jewelry, motor controls, paper products, newspapers, abrasive products, automobile parts, and metal fabrication.

Fifteen sites completed the intervention and final assessments (seven HP+ integrated intervention sites and eight HP control sites). Two sites dropped out after baseline assessments, one due to a plant closure and the other due to inadequate participation in baseline employee surveys and intervention planning. The Wellworks-2 protocol (selection/recruitment, evaluation instruments, and intervention procedures) was reviewed and approved by the Dana-Farber Cancer Institute's Institutional Review Board.

Intervention Methods

Intervention duration was 16 months at each site. Wellworks-2 encouraged companies to adopt a pro-active, upstream, source-focused preventive approach, going beyond compliance with legal standards set by OSHA [Sorensen et al., 2002; LaMontagne et al., 2003]. Management was targeted as the primary channel for improving the physical work environment because management has both primary control over—and primary responsibility for—providing a safe and healthy work environment. Operationally, the Wellworks-2 management intervention was conducted primarily through contacts with middle and upper management, led by a Wellworks-2 staff industrial hygienist.

Detailed explanations of justification for management focus of intervention, intervention needs assessment, site-specific intervention tailoring, intervention process, and intervention process evaluation have been presented previously [LaMontagne et al., 2004; Hunt et al., 2005]. In brief, management consultations (intervention) focused on achieving improvements in the physical work environment through a systematic approach to managing OSH (emphasizing the importance of OSH program elements of management commitment and employee participation, hazard analysis, hazard prevention and control, and training and education [LaMontagne et al., 2004]), and specifically applying a hierarchy of controls approach to hazardous substance issues. Accordingly, in order of descending preference, recommendations were made to management and OSH Committees for materials and process substitution (upstream), engineering or process controls, and intervention at the level of the worker (downstream).

The following intervention anecdotes illustrate the Wellworks-2 approach concretely. At one site where a silica-containing buffing compound was used, the Wellworks-2 industrial hygienist educated managers about the hazards of silica and the availability of safer alternatives. Management responded by substituting a non-silica containing buffing compound. At another site, the industrial hygienist identified the use of compressed air to clean up a mix residue as the reason for wide distribution of dust. After obtaining management support, the industrial hygienist adapted an existing local exhaust ventilation to include a vacuum cleanup system for the mix residue. Thus in addition to identifying and recommending concrete changes to reduce exposures to hazardous substances, Wellworks-2 provided on-going technical support in implementing recommendations.

Data Collection

Details of data collection have been presented previously [LaMontagne et al., 2003, 2004]. In brief, each production *department* at each site was briefly assessed by walk-through to identify all production *processes* and to gain a general sense of OSH in the *department* (typically required 10–15 min). This served to identify within each *department* the production area or work *process* where hazardous substance exposures were most likely, and where exposures were anticipated to be qualitatively similar (similar exposure groups). Where there was more than one *process* in a given *department*, the industrial hygienist chose the *process* of greatest concern within each *department* for rating, as judged by the use of hazardous materials with low occupational exposure limits and the amounts of such materials used, the number of workers potentially exposed, and the manner in which contaminants were generated and the presence or absence of control measures. At baseline, this yielded a comprehensive and systematically prioritized assessment of hazardous substance exposure concerns for each worksite, as well as specific guidance for addressing them. An identical data collection process was repeated at the final visit.

All baseline EP and control assessments were conducted by one Wellworks-2 staff industrial hygienist (M.L.). Because this industrial hygienist was subsequently involved in intervention delivery, all post-intervention assessments were administered by a second staff industrial hygienist (R.Y.) in order to avoid bias. To make baseline and final assessment methods comparable, both of these industrial hygienists were involved in the development of the EP rating method, a detailed protocol for its administration, and an assessment of inter-rater reliability [LaMontagne et al., 2003].

Walk-through assessments were guided by the person most responsible for OSH at each site. These included OSH managers or other specifically OSH-responsible persons (including occupational health nurses at 2 sites) where available (14 sites at baseline; 13 at final), and with human resource or personnel directors at other sites (1 site at baseline; 2 sites at final). The same site representative guided walk-through assessments at baseline and final at 9 of the sites.

Measures

The theoretical basis, checklist of yes/no indicator variables, and measures constituting our EP Rating scheme, have been previously described in detail [LaMontagne et al., 2003]. Briefly, the further upstream from exposure one aims in practicing occupational hygiene, the more likely one is to achieve the preferred goal of EP versus control. We devised our EP rating scheme in line with these principles, applying a simplified ‘‘hierarchy of controls’’ [OTA, 1985] to express a gradient of upstream (*materials* correspond with *source* of the hazard) versus midstream (*process* corresponds with *path* between source and worker) versus downstream (*human interface* corresponds with the level of the worker as the *receiver* of exposure) preventive efforts (Table I). This was combined with an examination of the balance between exposure potential and exposure protection at each of these three levels. The resulting potential and protection matrix, expressed as a 2×3 table, allows both a horizontal (balance

TABLE I. Hazardous Substance Exposure Prevention Ratings: Potential/Protection Matrix Rating Frequencies at Baseline ($N = 131$)

	Potential			Protection		
	Rating	N	%	Rating	N	%
Materials	High: ≥4 points	26	19.8	Material potential not used for EP ratings: covered by OSH program measures		
	Moderate: 2–3	54	41.2			
	Low: 0–1	51	38.9			
Process	High: ≥6 points	24	18.3	High: ≥4 points	51	38.9
	Moderate: 3–5	55	42.0	Moderate: 2–3	36	27.5
	Low: 0–2	52	39.7	Low: 0–1	44	33.6
Human interface	High: ≥5 points	6	4.6	High: ≥ 4 points	55	42.0
	Moderate: 3–4	28	21.4	Moderate: 2–3	64	48.8
	Low: 0–2	97	74.0	Low: 0–1	12	9.2

of potential and protection at each level) and a vertical (degree to which those efforts are focused upstream) assessment of EP. Six sets of (yes/no) indicator variables were developed to assess exposure potential and protection at the material, process, and human interface levels (full list detailed previously [LaMontagne et al., 2003]).

An ordinal score for each cell in the potential and protection matrix was computed as described previously [LaMontagne et al., 2003]. Ordinal scores were then categorized as representing low, moderate, or high potential or protection, such that each cell is weighted equally despite the varying numbers of indicators contributing to each of the six ordinal scores (Table I).

Next, we computed an overall EP summary rating of the degree of upstream EP effort for each area/process assessed. This overall EP rating made use of 5 of the 6 cells in the potential/protection matrix. The material protection cell was excluded because of substantial overlap with our parallel organization-level assessment of OSH programs (described in a separate report [LaMontagne et al., 2004]). Overall EP summary ratings ranged from 1 (best, minimal intervention—if any—needed) to 6 (worst, extensive intervention needed urgently), as detailed in Table II. In short, this EP rating scheme cascades downstream in terms of proximity of preventive efforts to the source of the hazard. Accordingly, materials are considered first, followed by process, and finally by human interface. Similarly, at each level (materials, process, human interface), low potential was judged as more desirable than high protection.

Inter-rater reliability of EP ratings was assessed at baseline (with the same two industrial hygienists who conducted baseline and final assessments) [LaMontagne et al., 2003]. The percent agreement of the area EP summary ratings (6-point scale) was excellent (85%) in the 13 processes assessed in duplicate, and the weighted kappa statistic indicated excellent inter-rater reliability (0.84, with a lower 95% confidence limit of 0.67).

Statistical Analysis

Two types of analyses of baseline to final changes were conducted on the cohort of 107 processes assessed at both time points: descriptive analyses for change *within* each condition/arm separately, and then for a difference in change *between* intervention and control arms. Accordingly, we first conducted a descriptive analysis of changes from baseline to final of the five potential/protection ratings and the EP summary ratings using pairwise crossclassification of the baseline and final ratings *within each arm*. We report the two-sided *P*-value for a descriptive test of symmetry comparing the baseline and final frequency distributions. This provides a test of change from baseline to final within each intervention arm, ignoring clustering of production processes within worksites (ranged from 2 to 14 processes assessed per site at final) and differences between arms.

To explore the difference in change *between intervention versus control arms*, we conducted two sets of analyses. First, we computed a summary change score for each measure in each process assessed at both baseline and final. If the rating improved from baseline to final or had the best score at baseline and remained at that score at final, the department was coded as 1 = better/best. If the rating did not improve or got worse, it was coded as 0 = same/worse. This helps to account for ceiling effects among those processes that were rated favorably at baseline. We cross-tabulated this change score with intervention condition and again, for descriptive purposes, we report the *P*-value for the test of no association between change and intervention condition.

Finally, to test the primary evaluation hypothesis of no difference in change between the intervention conditions, we used a mixed model analysis of variance on the change in EP summary ratings from baseline to final. We included intervention condition as a fixed effect and in order to control for clustering of processes/departments within worksites, and worksite was included as a random effect.

TABLE II. Overall Hazardous Substance Exposure Prevention Ratings: Definition, Intervention Recommendations, and Observed Relative Frequencies at Baseline (Intervention and Control Sites Combined)

Rating	Definition: explanation	Intervention recommendations in order of preference	%
1	*Material potential low:* Because the materials used have low inherent toxicity, process potential and human interface are of minimal concern	Minimal	39
2	*Material potential medium or high, but process potential low:* because there is limited potential for exposure from the process in question, then there is minimal potential for worker exposure at the human interface	Reduce material potential Improve engineering controls	25
3	*Material potential medium or high, process potential medium or high, but engineering controls high:* material and process potential are significant or of concern, but well-addressed by permanent exposure controls	Reduce material potential Reduce process potential	16
4	*Material potential medium or high, process potential medium or high, engineering controls low or medium, but human interface low:* material and process potential significant or of concern, but offset by low potential for exposure at the human interface	Reduce material potential Reduce process potential Improve engineering controls	10
5	*Material potential medium or high, process potential medium or high, engineering controls low or medium, human interface medium or high, but PPE high:* material and process potential significant, and matched with inadequate permanent exposure controls and an over-reliance on control at the worker through PPE	Reduce material potential Reduce process potential Improve engineering controls Reduce human interface potential Rely less on PPE	5
6	*All potentials medium or high, and engineering controls and PPE low or medium:* exposure potential likely to be inadequately matched by protective measures	Reduce material potential Reduce process potential Improve engineering controls Reduce human interface potential Rely on PPE only as a temporary stopgap measure	5
Total:			100%

RESULTS

Production Processes Assessed at Baseline and Final

We assessed 131 processes in the 17 large manufacturing sites participating in the study at baseline. Two sites dropped out after baseline assessments, removing 8 processes from follow-up. A total of 107 processes were assessed both at baseline and final. A wide variety of hazardous substances were captured in rated processes, including several carcinogens (e.g., cadmium, methylene chloride, silica, metal-working fluids), irritants (e.g., acids, nickel compounds), asthmagens (e.g., epoxies, formaldehyde), and reproductive hazards (e.g., lead, arsenic, solvents).

There were 16 production processes assessed at baseline that were no longer present or assessable at final. In the intervention condition, 9 processes were lost from 7 sites; those 9 processes had Summary EP ratings ranging from 1—4, with a median of 2 and a mean of 2.4. In the control condition, 7 processes were lost from 8 sites; those 7 processes had Summary EP ratings ranging from 1—6, with a median of 2 and a mean of 2.3. Thus, there was no evidence of a differential loss of higher hazard processes from the intervention condition (which—if it had occurred—could have been construed as a favorable effect of the intervention).

Time Trend Analyses: Change Within Each Intervention Condition

Baseline distributions of EP sub-scale and overall summary ratings were similar between 57 production areas assessed in the intervention condition and the 50 areas similarly assessed in the control condition (Table III). The

TABLE III. Tests of Change in Relative Frequency Distributions of Hazardous Substance Exposure Prevention Ratings From Baseline to Final Within Intervention Conditions (n = 107 Manufacturing Processes)

		HP + (n = 57)			HP only (n = 50)		
		Baseline (%)	Final (%)	*P*-value*	Baseline (%)	Final (%)	*P*-value*
Material potential	Low	40	49	0.21	38	40	0.26
	Medium	44	37		34	38	
	High	16	14		38	22	
Process Potential	Low	37	44	0.28	46	52	0.73
	Medium	47	44		34	28	
	High	16	12		20	20	
Process protection	Low	21	23	0.01	46	36	0.02
	Medium	33	16		18	10	
	High	46	61		36	54	
Human interface potential	Low	75	84	0.17	70	78	0.26
	Medium	25	16		20	12	
	High	0	0		10	10	
Human interface protection	Low	7	11	0.60	8	2	0.27
	Medium	46	40		52	46	
	High	47	49		40	52	
Overall EP rating	1	40	49	0.81	38	40	0.93
	2	21	21		30	30	
	3	18	23		16	26	
	4	9	7		12	2	
	5	9	0		0	0	
	6	4	0		4	2	

**Note*: Two-sided *P*-value for test of symmetry between baseline and final distributions.

results of tests of change over the intervention period within each intervention condition are presented in Table III. This test considers the fact that the before and after measures are paired by production process, but not the clustering of processes/departments by worksite. There was a significant improvement (shift towards 'high' ratings) in process protection (engineering controls) in manufacturing processes in both conditions, but no significant change in the other four potential and protection sub-scale ratings. Although most baseline to final distribution shifts were not statistically significant, the general pattern of shifts in EP ratings in both conditions is in OSH-favorable directions. That is, there was a baseline to final shift towards ''low'' ratings for the three measures of exposure potential, and a shift towards ''high'' for the two measures of protection. A slight difference in the pattern of change between intervention and control can be observed in the material potential and human interface protection (personal protective equipment) ratings. After the significant shift in process protection, the next most marked favorable shift in the intervention condition was in material potential: an increase of 9% in areas rated ''low'' versus a 2% increase in controls. This pattern is reversed in at the human interface protection level, where there was a marked shift towards ''high'' in the controls (from 40% at baseline to 50% at final) versus a split shift in the intervention condition (a movement in both directions away from ''medium'').

Table III (bottom row) also shows that although there was a greater shift toward favorable ratings among production processes in intervention versus control groups, neither shift was statistically significant. In the intervention condition, there were seven production areas/processes with a 5 or 6 (poor) overall EP rating at baseline, all of which improved (note that Table III presents percentages rather than absolute numbers to facilitate cross-comparison). Two of them had a score of 1 at final, 4 had a score of 3, and 1 had a score of 4. In the control condition, there were two processes with a score of 6 at baseline and they both improved: one had a score of 2 and the other a score of 3 at final. Nevertheless there was one process in the control condition that went from a score of 2 at baseline to a score of 6 at final. In the intervention condition, the number of processes with the best overall EP rating increased from 23 to 28 at final, while in the control condition, the number increased from 19 to 20.

Experimental Analysis: Comparing Change Between Intervention and Controls

Table IV shows the frequencies and percentages of the dichotomous change summaries (1 = better/best, 0 = same/worse) in the two intervention conditions. There was a slightly greater shift towards 'better/best' in intervention versus control processes for three of the five potential and protection sub-scales as well as the overall EP rating. However, there were no statistically significant differences between conditions in improvement in any of the measures (Table IV, far right column results of tests of change between conditions).

To definitively test the primary evaluation hypothesis, we computed the mixed model analysis of variance for the overall EP summary rating, adjusting for the clustering of processes/departments within worksites. We computed a mixed effects analysis of variance on the change in summary EP score from baseline to final. Processes in the control condition had an average improvement of 0.20 points in the EP summary rating, while processes in the intervention condition had an average improvement of 0.46 points. The *P*-value for the difference in improvement was 0.19. Thus while there was greater movement upstream in prevention efforts in the intervention versus control groups, the difference in improvement between intervention and controls was moderate and statistically non-significant.

TABLE IV. Tests of Change in Hazardous Substance Exposure Prevention Ratings From Baseline to Final Between Intervention Conditions (n = 107 Manufacturing Processes)

	HP + (n = 57)		HP (n = 50)		
	n	%	n	%	*P*-value*
Material potential					0.62
Better/best	29	51	23	46	
Same/worse	28	49	27	54	
Process potential					0.39
Better/best	26	46	27	54	
Same/worse	31	54	23	46	
Process protection					0.47
Better/best	37	65	29	58	
Same/worse	20	35	21	42	
Human interface potential					0.41
Better/best	48	84	39	78	
Same/worse	9	16	11	22	
Human interface protection					0.73
Better/best	30	53	28	56	
Same/worse	27	47	22	44	
Overall EP rating					0.36
Better/best	36	63	27	54	
Same/worse	21	37	23	46	

**Note*: Two-sided *P*-value for comparison of frequency or mean.

DISCUSSION

Our findings have demonstrated that EP efforts in the manufacturing sector can be systematically assessed across the full range of hazardous substances in use, and that such assessments can serve both needs assessment and effectiveness evaluation functions.

Effectiveness Evaluation Findings

The Wellworks-2 intervention resulted in slightly greater but not statistically significant improvements in EP ratings in intervention versus control sites. These findings suggest that increasing the intensity or duration of our management-focused intervention could result in significant improvements in EP. This possibility is supported by the significant improvement in management commitment to OSH observed in the parallel organization-level evaluation of the intervention (middle level in Fig. 1) [LaMontagne et al., 2004]. Taken together, these findings suggests that it takes at least 16 months of sustained intervention to begin to affect how OSH is managed in large manufacturing sites, and that changes in the work environment and work processes would take longer.

These findings provide useful guidelines for designing future interventions of this sort. Reviews of international trends in OSH intervention initiatives have identified an over-emphasis on changing workers, neglecting the parallel needs to change managers, organizations, and work environments [Quinlan, 1999; Frick et al., 2000; Shannon et al., 2001]. The Wellworks-2 results provide further support for refocusing intervention efforts on the management, organizational, and physical environmental levels, as well as insights on combined intervention strategies that can be used to achieve this goal.

This suggestion of positive intervention-related change is strengthened by a rigorous experimental design as well as a conservative analysis approach. In addition, detailed review of the results indicates that the patterns of change were consistent with the intervention objectives emphasizing upstream strategies. Notable differences in this regard are the greater improvement in material potential (∼use reduction and substitution, upstream) in intervention versus controls, and—by contrast—the greater increase in human interface protection (~personal protective equipment, downstream) in the control versus intervention groups. Both changes contribute to improvement in overall EP ratings, but material improvements contribute more strongly because they are further upstream. There was a significant improvement in process protection (engineering controls) within each intervention condition. This may have been due to an intervention-independent secular trend, participation in the Wellworks-2 trial independent of intervention condition assigned, or some combination of both. In the overall EP summary ratings, the intervention-independent positive changes in controls offset the greater degree of improvement within the intervention group, accounting for the net result of a moderate and statistically non-significant difference in improvement between intervention versus controls.

The change pattern observed in controls is consistent with those observed in other studies. A review of a clinic-based industrial hygienist's recommendations in 206 consultations found that companies were most likely to take up recommendations for administrative interventions, followed by personal protective equipment, engineering controls and training, and—least likely—material substitution [Bracker et al., 1999]. Similarly, a recent critical literature review of industrial hygiene intervention recommendations also found a greater emphasis in practice on exposure control in the path between source and worker or at the worker level, rather than on the source [Roelofs et al., 2003]. The Wellworks-2 intervention emphasized intervention at the source, and showed corresponding patterns of change in the intervention group as described above.

Other recent trends in theory and practice strengthen the case for refocusing upstream. For example, the precautionary principle in OSH holds the ultimate goal of optimal environmental as well as occupational health through sustainable production practices [Anonymous, 2004; Quinn et al., 1998; Kriebel et al., 2001] In addition, the shift away from exposure limit-based regulation towards solutions-based strategies provides an opportunity to refocus upstream. The UK COSHH Essentials (Control of Substances Hazardous to Health) is an example of such new regulatory approaches [HSE, 2003]. The COSHH Essentials approach, however, while focusing on exposure reduction appears to not adequately address substitution. Our EP rating scheme recognizes exposure reduction as a valuable achievement, but more strongly emphasizes and values upstream solutions.

The EP rating method used has several strengths. First, it captures the degree of upstream prevention applied to hazardous substance exposures in general. This overcomes the feasibility challenges of evaluating intervention effectiveness for a variety of hazardous substances, particularly when the variety of substances differs across production processes, worksites, and intervention conditions. Further strengths include the linking of needs assessment, intervention recommendations, and effectiveness evaluation for each process assessed.

Our results must also be qualified by certain limitations. With respect to generalizability, our findings likely overestimate the degree of upstream EP in the large manufacturing sector as a whole. Participating companies had to voluntarily agree to participate in the trial; thus the sample would be enriched for sites that are receptive to OSH intervention have relatively good OSH conditions, or both. While this strengthens the argument that there is a need for improvements in EP efforts in the manufacturing sector, it suggests that our effectiveness evaluation findings may be less generalizable to sites with poor OSH conditions. Generalization of findings from our sample to smaller manufacturing worksites, to other industries, and to other states and countries is limited further still.

The EP ratings were based directly on the hierarchy of controls and have been previously shown to have good to excellent inter-rater reliability and reasonable discriminatory power in the large manufacturing sector [LaMontagne et al., 2003]. Further, the current results showed secular change patterns in controls that were consistent with expectations of prevalent practice as well as intervention-related change patterns that were consistent with intervention objectives. These points support the face validity of the EP ratings. However, the EP ratings have not been directly validated against airborne-contaminant concentrations or other established hazardous substance exposure metrics. Validation was not feasible in the present study because of the developmental stage of the instrument, technical and economic feasibility constraints, and concerns about site recruitment [LaMontagne et al., 2003]. Requests to conduct extensive exposure monitoring in the recruitment phase would be likely to further bias the sample of participating companies toward those with relatively good exposure control programs.

Validation could be conducted by sampling to obtain multiple exposure measurements for selected hazardous substances in various production processes, and then summarizing by process for each agent (e.g., mean workshift Time-Weighted Average in ppm for a solvent for each process). Summary measures for a range of agents could be transformed to percent of a chosen set of occupational exposure limits (OELs), averaged into an overall percent OEL across the range of agents present in a given production process, paired with corresponding EP ratings, and analyzed using standard correlation methods. We considered requesting previously collected exposure monitoring data to attempt this. The anticipated paucity of sampling data, however, turned out to be the reality: routine monitoring was reported for only 19 of the 131 areas assessed at baseline. This demonstrates a prevalent gap in workplace exposure assessment practice that might be addressed in part through the adoption of more prevention-focused alternatives such as the approach described in this report.

Integrating HP and Health Promotion in Wellworks-2

The work-environment intervention described in this study was complemented by parallel OSH management intervention as well as intervention activities at the level of the worker, as described in detail elsewhere [Sorensen et al., 2002; LaMontagne et al., 2004; Hunt et al., 2005]. Thus any intervention-related differences would be attributable to the whole of the intervention, and not strictly to its work-environment-focused aspects. The integration of OSH with health promotion may have also played an important role—particularly the common focus on management to address both organisational and physical environmental issues relevant to worker health. Integration in Wellworks-2 has been shown to improve health behavior outcomes in blue-collar workers (twofold greater smoking quit rates in intervention versus controls [Sorensen et al., 2002]) and may be an inducement to management to improve OSH efforts. Workplace health promotion and HP can be mutually reinforcing, promising benefits in both areas by more widespread implementation of integrated approaches [Landrigan et al., 1995; Heaney and Goldenhar, 1996; Sorensen, 2000; LaMontagne and Christiani, 2002; Quinn, 2003; LaMontagne, 2004].

Conclusions and Future Directions

EP efforts in the manufacturing sector can be systematically assessed across the full range of hazardous substances in use, and such assessments can serve both needs assessment and effectiveness evaluation functions. Effectiveness evaluation findings suggest that more sustained or intense management-focused intervention would improve EP efforts. These findings should help to justify investment in subsequent studies of this sort with longer or more intense interventions, larger sample sizes, combined quantitative and qualitative assessment methods, and embedded validation of EP ratings against established exposure metrics.

AUTHORS' CONTRIBUTIONS

A.D.L. participated in the design of the study, led the development of the occupational health evaluation methods, contributed to statistical analysis, and wrote the paper. A.M.S. participated in the design and methods development aspects of the study, and conducted the statistical analysis. R.A.Y. and M.L. participated in design and methods development and conducted data collection in the field. G.S. conceived of the study, participated in design and methods development, and was Principal Investigator of the overall Wellworks-2 project. All authors read and approved the final manuscript.

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