

Design and Conduct of Occupational Injury Intervention Studies: A Review of Evaluation Strategies

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Occupational injuries continue to exact a great toll on American workers and their employers—the physical and financial costs are enormous. However, in the current political climate, few employers or regulatory agencies will implement injury prevention interventions without specific evidence of their effectiveness. This paper reviews the literature on the design, conduct, and evaluation of occupational injury interventions. Our review suggests that randomized controlled trials are rare and also notes that the quasi-experimental studies in the literature often use the weakest designs. We recommend a hierarchical approach to evaluating occupational injury interventions—beginning with qualitative studies, following up with simple quasi-experimental designs using historical controls, continuing with more elaborate quasi-experimental designs comparing different firms' experience, and, when necessary, implementing randomized controlled trials. Am. J. Ind. Med. 32:164-179, 1997. © 1997 Wiley-Liss, Inc.

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INTRODUCTION

Occupational injuries continue to exact a great toll on American workers and their employers. Each day about 20

American workers die from work-related injuries [Bureau of Labor Statistics, 1995]. Many more suffer temporary and permanent disabilities. The costs are enormous. However, in the current political climate, few employers or regulatory agencies will implement injury prevention interventions without specific evidence of their effectiveness. This paper reviews the literature on the design, conduct, and evaluation of occupational injury interventions, focusing on the difficulties in carrying out convincing studies. We discuss primarily single worksite interventions, although we also consider interventions with a larger scope. The studies we examined emphasized primary prevention—interventions aimed at preventing the initial injury—rather than secondary prevention or rehabilitation. Finally, we examine acute traumatic injuries as well as work-related musculoskeletal disorders. Many of the issues concerning the design and conduct of intervention studies are similar for both types of injury outcomes, yet we have tried to also point out the methodological differences between the two conditions.

INTERVENTIONS

Occupational injury interventions may be categorized as engineering interventions, targeting the physical work

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TABLE I. Engineering Intervention Evaluations: Type, Design, Population, and Results for Identified Studies

Author	Intervention	Design (length)	Population (setting)	Results									
Goldwater et al. [1989]	Needle recap device	Pre-post (33 mo)	70 venipuncturists (hospital)	Significant decrease from 1 stick in 3,175 venipunctures to 1 in 16,067 for users and 1 in 4,006 for nonusers									
Kerstein [1982]	Visible tent stakes	Pre-post (4 wk)	6,000 reservists (military camps)	Decrease from 56 injuries in 4,800 reservists to 6 in 6,000									
Loomis et al. [1982]	Ground proximity warning system	Pre-post (10 yr)	Pilots (aircrafts)	Significant decrease from 17 to 2 crashes									
Mohr et al. [1989]	Power makeup equipment	Pre-post (5 yr)	Drillers (offshore drilling units)	Significant decrease from 38 to 23 injuries									
Wigglesworth et al. [1991]	Railroad barriers	Pre-post control (19 yr)	Train drivers/motorists (railroad crossings)	Fatalities: <table border="1" style="display: inline-table; vertical-align: middle;"> <thead> <tr> <th></th> <th>Pre</th> <th>Post</th> </tr> </thead> <tbody> <tr> <td>With barriers</td> <td>61</td> <td>2</td> </tr> <tr> <td>Without barriers</td> <td>13</td> <td>10</td> </tr> </tbody> </table>		Pre	Post	With barriers	61	2	Without barriers	13	10
	Pre	Post											
With barriers	61	2											
Without barriers	13	10											

environment; administrative interventions, focusing on procedures and policies; and personal interventions, addressing worker behavior, education, and training. To examine the emerging consensus that effective injury prevention programs employ a combination of approaches [National Agenda for Injury Control, 1992; National Committee for Injury Prevention and Control, 1989], we include a fourth category—multiple interventions. Starting with the NIOSHTIC and PSYCHINFO databases, we searched the occupational safety and health literature for articles that reported on the results of a specific intervention project. We identified 38 reports (Tables I–IV) and eight reviews that covered an additional 208 studies targeting occupational injury interventions [Amandus et al., 1985; Goldenhar and Schulte, 1994; Goldenhar and Schulte, 1996; Habes et al., 1994; Johnston et al., 1994a,b; McAfee et al., 1989; NIOSH Back Belt Working Group, 1994; Sulzer-Azaroff et al., 1994].

Engineering Interventions

Engineering interventions have targeted hazards associated both with acute traumatic injury and with work-related musculoskeletal disorders. In the area of acute traumatic injury, interventions have included needle-sheathing phlebotomy/venipuncture devices [Billiet et al., 1991; Goldwater et al., 1989] and sharps containers [Kraskinski et al., 1987; Ribner et al., 1987; Sellick et al., 1991; Makofsky et al., 1993; Burken et al., 1994] to prevent needle stick injuries; environmental designs of convenience stores to reduce robbery risk associated with homicides [Amandus, 1995]; petroleum drilling equipment designed to reduce tongs-related injury [Mohr et al., 1989]; and ground proximity and minimum safe altitude warning devices to prevent aircraft crashes [Loomis et al., 1982].

In the area of work-related musculoskeletal disorders, interventions have included patient transfer devices [Garg, 1992], adjustable work stations [Lutz et al., 1987; Westgaard

and Aaras, 1985], work station redesign [Drury et al., 1984], tool redesign [Miller et al., 1971; Armstrong et al., 1982; Knowlton et al., 1983], new factory design [Parenmark et al., 1993], and back belts [NIOSH, 1994]. Habes and Grant [1993] identified 15 studies that demonstrated the effectiveness of engineering controls for reducing exposure to ergonomic risk factors, and Goldenhar et al [1994] include four engineering studies targeting musculoskeletal and cumulative trauma disorders.

Administrative Interventions

Administrative interventions primarily consist of organizational strategies targeting work practices and policies. This category includes participative management, improved housekeeping practices, modified work loads and paces [Behrens et al., 1984; Bilette, 1987], pay rate [Sundstrom-Frisk, 1984], as well as laws and regulations [Springfeldt et al., 1987]. Most of the administrative studies reviewed used performance management techniques, which included worker involvement and empowerment in addition to a variety of behavioral strategies, such as goal setting, monitoring, and feedback of work behaviors [Carter and Menckel, 1990; Menckel and Carter 1985; Fiedler 1987; Harms-Ringdahl, 1987; Painter et al., 1986; Wood 1987; Saari, 1989]. Sulzer-Azaroff et al. [1994] reviewed 44 studies and concluded that this administrative management technique positively influences safety behavior and decreases accident rates. McAfee et al. [1989] reached the same conclusion in their review of 24 studies using feedback/positive reinforcement. In addition, citations and fines for violations of OSHA standards can be considered administrative interventions [Robertson and Keeve, 1983]. Nelson et al. [1996] found a significant reduction in workers' compensation claim rates in construction companies that have been inspected and cited compared to those companies that have not been inspected and cited.

TABLE II. Administrative Intervention Evaluations: Type, Design, Population, and Results for Identified Studies

Reference	Intervention	Design (length)	Population (setting)	Results		
				Accidents	Pre	Post
Carter et al. [1990]	Accident investigation and review groups	Pre-post (2 yr)	900 production workers (manufacturing plants)	Co. 1	19	18
				Co. 2	34	23
				Co. 3	102	87
				Co. 4	52	45
Conway et al. [1995]	State law re: training and equipment	Post only (4 yr)	Alaska fishing industry (fishing vessels)	Decrease in case fatality rates from 24% to 2%, while number of vessels lost and people at risk remained relatively constant		
Cooper et al. [1994]	Goal setting and feedback	Pre-post (20 wk)	540 production workers (manufacturing plant)	Significant increase in safety performance from 52% to 70%; decrease in total accidents from 6.33 to 3.88/wk and targeted accidents from 3.3 to 0.56/wk		
Kjellen [1983]	Worker participation	Post only (18 mo)	1,300 production workers (manufacturing plants)	Countermeasures developed for 34 of 82 safety risks; 90% of group members judged this approach made possible or accelerated countermeasures		
Makofsky et al. [1993]	Relocate needle boxes; change slot	Pre-post (6 mo)	Health care workers (hospital)	Decrease in recapped needles from 33% to 27% and 27 to 18 for wards with relocated boxes; no effect for ward with slot change		
Menckel et al. [1983]	Accident investigation and near accident reporting group	Pre-post (6 yr)	300 workers (manufacturing plant)	Nonsignificant decrease in accidents and significant reduction in accident severity and days absent per accident		
Painter et al. [1986]	Participatory safety and hazard program	Pre-post (4 yr)	300+ loggers (logging company)	Decrease in accidents by 75% and workers' comp costs by 62%		
Pasmore et al. [1982]	Participatory action research	Pre-post (9 yr)	335 production workers (manufacturing plant)	Decrease in soreness injuries		
Springfeldt et al. [1987]	Law requiring ROPS	Pre-post (20 yr)	Farmers (farms)	Decrease in annual fatality rates from 12 to 1 per 100,000 farmers		
Sundstrom-Frisk [1984]	Time-based wages vs piece-rate	Pre-post (40 mo)	422 cutters (forestry industry)	Decrease in accidents from 119 to 84 per million work hours		
Wood [1987]	Medical management program	Time series (3 yr)	Health care workers (hospital)	Significant decrease in back injury claims from 7.1% to 1.7%		

Some companies have attempted to reduce musculoskeletal disorders by selecting workers on the basis of their strength. Since there are few evaluations of these interventions and, since these interventions raise difficult issues related to the Americans with Disabilities Act, we will not discuss them further.

Personal Interventions

We found only a few peer-reviewed evaluations of personal protective equipment, mostly evaluations of seat belt use [Johnston et al., 1994]. However, we did find evaluations of other types of personal protective equipment

TABLE III. Personal Intervention Evaluations: Type, Design, Population, and Results for Identified Studies

Reference	Intervention	Design (length)	Population (setting)	Results
Baker [1993]	Education and training	Pre-post	96 farm wives (classroom)	Increased knowledge, attitudes, and self-reported behaviors regarding farm safety
Burken et al. [1994]	Education and feedback	Pre-post (18 mo)	Healthcare workers (hospital)	Significant decrease in sharps recovery rates from 8.9 to 4.1 and 4.4 per 100,000 lb laundry
Donchin et al. [1990]	Exercise and training	Pre-post control (1 yr)	140 health care workers (hospital)	Significant decrease in length of duration of low back pain episodes for exercise group (mean = 4.5) compared to back school (mean = 7.3) and control (mean = 7.4)
Fiedler [1987]	Management training	Pre-post (6 yr)	Supervisors (mine)	Decrease in citations by 80% and decrease in accidents from approximately 10–3 per 200,000 hours
Garrett et al. [1993]	Protective eyewear	Pre-post (2 wk)	100 health care workers (hospital)	No statistically significant difference in use for 4 of 5 eyewear types; statistically significant decrease in use for one type
Hilyer et al. [1990]	Flexibility training	Pre-post control (30 mo)	469 firefighters (fire station)	Statistically significant increase in flexibility; lower injury rates (19.1 compared to 23.9 per 100 workers)
McKenna [1981]	First-aid training	Pre-post control (2 yr)	98 production workers (chemical factory)	Decrease in accidents from 164 to 138; increase in accidents from 101 to 120 in control group
Perkins [1995]	Training	Post only (4 yr)	Fishermen and skippers (fishing industry)	Documented fatalities during study period did not include any trained graduates
Schwab [1994]	Media safety education messages	Pre-post (24 mo)	Farmers (Iowa counties)	Significant increase in self-reported farm safety behavior and hazard awareness
Streff et al. [1993]	Pledge to wear safety eyewear	Pre-post (24 wk)	51 machinists (electronics co)	Significant increase in eyewear use between base-line and intervention with return to baseline levels at follow-up
Wood [1987]	Back training program	Pre-post-control (1 yr)	Health care workers (hospital)	No difference in back claims between training and control group

including safety glasses [Streff et al., 1993, Garrett, 1993], and back belts [NIOSH, 1994]. We found a larger literature evaluating worker education and training. A recent review of training effectiveness [Johnston et al., 1994] indicated that only 41 of 198 studies (21%) quantitatively assessed the relationship between training and outcome; 38 of these 41 (93%) studies measured changes in work behavior and only 8 of the 41 measured effectiveness through injury or lost workday rates. Education and training were examined in 13 studies targeting either acute traumatic injury or work-related musculoskeletal disorders [Goldenhar and Schulte,

1994], safety performance [Peterson, 1984], or global reports of injuries [McKenna et al., 1981; Sanborn et al., 1988]. Educational strategies have resulted in moderate increases in seat belt use [Johnston et al., 1994] but have been less successful in reducing rates of low back pain [Snook et al., 1978, 1988].

Multiple Interventions

Although most peer-reviewed evaluations of injury prevention interventions focus primarily on a single intervention type (engineering, administrative, or personal), in

TABLE IV. Multiple Factor Intervention Evaluations: Type, Design, Population, and Results for Identified Studies

Reference	Intervention	Design (length)	Population (setting)	Results
Gjessing et al. [1994]	Participatory ergonomics and training	Pre-post	2,400 production workers (meatpacking plants)	Plant 1: decreased CTDs Plant 2: significant decrease in lost time incidence rates Plant 3: increased CTD symptoms and decreased satisfaction with team effectiveness
Harms-Ringdahl [1987]	Safety analysis design	Pre-post (7 yr)	30 production workers (paper mill)	Decrease in accidents by 56% and in days absent due to accidents by 75%
Kuorinka et al. [1995]	Ergonomic improvements and physical training	Pre-post-control (1 yr)	340 production workers (manufacturing plant)	Physical training had a preventive effect on new neck/shoulder disorders compared to ergonomics and control group
Lowery et al. [1988]	Engineer design, emergency protection system, training, safety procedures	Pre-post (7 yr)	3,200 production workers (offshore oil and gas platforms)	Low accident rates despite increased man-hours
Mazerolle [1987]	Teams to assess/treat CTDs and ergonomic interventions	Pre-post (10 mo)	Production workers (electronics plant)	No new cases of CTD four months postintervention compared to 16 cases for prior 12 mo
Moore [1994]	Participatory ergonomics	Pre-post (69 mo)	Drill crews (offshore drilling units)	CTDs decreased from 1.8 to 0.4 incidents per year
Sanborn et al. [1988]	Design/placement of needle boxes and education	Pre-post (1 yr)	Health care workers (hospital)	Nonsignificant decrease of needles from 24 to 16
Sawney et al. [1992]	Safety team, education and training, PPE	Pre-post (1 yr)	Production employees (manufacturing plant)	Decrease in OSHA incidence rates by 67%; decrease in lost work-days by 50%
Wickstrom et al. [1993]	Participatory ergonomics and education	Pre-post (7 yr)	Sheet metal workers (manufacturing plant)	Decrease in average sick leave from 3.2 to 1.9 per person-year
Parenmark et al. [1993]	Engineering interventions and administrative controls	Post only (12 mo)	Production workers, manufacturing plant	Decrease in average sick leave rate by 5% points
O'Hara et al. [1976]	Engineering interventions and administrative controls	Pre-post (2 yr)	350+ cash register operators, supermarket firm	Decrease in muscle fatigue of arms, hands and lower back pain; no change in muscle fatigue of neck, shoulders, and upper back

practice, many interventions are multifactorial. For example, the implementation of engineering controls may require training and behavioral changes to be effective. Four reports combined intervention types to impact injuries [Harms-Ringdahl, 1987; Lowery et al., 1988; Sawney et al., 1992], and eight studies targeted musculoskeletal disorders [Gjessing, 1994; Kuorinka et al., 1995; Mazerolle, 1987; Moore, 1994; O'Hara et al., 1976; Parenmark et al., 1993; Silverstein et al., 1994; Wickstrom et al., 1993]. For example, Parenmark et al. [1993] reported reduced sick leave, turnover leave and turnover, and increased productivity when engineering improvements, work organization, and training were introduced into the design of a new factory and the workers were transferred into the new facility. Silverstein et

al. [1994] evaluated the prevalence of musculoskeletal disorders in data entry operators before and after workstation improvements, work organization improvements, and participatory planning were implemented. Finally, O'Hara et al [1976] evaluated the effects of reducing musculoskeletal load in cashiers by changes in engineering, work organization, and administrative controls.

STUDY POPULATIONS

The choice of a workforce and an organization in which to evaluate an intervention will define many aspects of the evaluation. For example, current labor law may restrict the type of labor-management committee structure in nonunion

organizations. Any intervention that seeks employee input into the redesign of hazardous work tasks will be structured differently in union and nonunion organizations. The size of the employer may determine whether a given intervention would be successful or not because of different levels of engineering expertise in small or large organizations. Thus, researchers must consider how the type of workforce and organization will influence a specific intervention. The type of industry also may have unintended effect on the success of a specific intervention. For example, industries that have been undergoing rapid gains in productivity and shrinkage of workforces may only have workers with long durations of employment. Interventions aimed at less experienced or younger workers would simply not work in these high seniority industries. On the other hand, these industries may present unique opportunities in the future as older workers retire and new workers replace them.

The choice of organization also influences the variables that can be considered in evaluating an intervention. For example, if one studies only a single organization, one cannot study the influence of different levels of top management commitment because there will be no variation within the organization. Similarly, the autonomy of an employee to structure work tasks may vary substantially in different enterprises. Engineering interventions would likely be least influenced by the choice of organization, whereas administrative interventions would be most influenced by this choice.

Ideally, the evaluation of the intervention should be conducted in a work force and an organization that represents the environment in which the intervention, if successful, would be most widely implemented. The type of work force chosen for the evaluation of intervention can strongly influence the generalizability or applicability of the results. For example, many control programs to reduce work-related musculoskeletal disorders envision creating “ergonomic teams” with representatives from the in-plant medical provider, maintenance, production workers, engineering staff, and others. How applicable is this approach to a small business where one person carries out multiple duties? Before beginning the intervention evaluation, the researcher should learn as much as possible about the site to be studied.

Finally, in defining the study population for evaluating an occupational injury intervention, we must remember that the American workplace is contested terrain—a wide variety of stakeholders have often conflicting interests in what happens on the shop floor. Without the support of these stakeholders, the intervention is likely to fail and the evaluation will be impossible. Often, there are conflicts in workplaces between the workers and management over issues of wages, productivity, and control of the work process. If these two primary stakeholders do not support an evaluation, it will not likely succeed. Approaches to obtaining the consent of the workers will differ in union and

nonunion environments. In both cases, the researchers will have to be sensitive to a wide variety of worker concerns. Special attention must also be given to the first line supervisors. Caught between management and the workforce, they may have their own interests in the outcome of the intervention. In addition, regulatory agencies such as the Occupational Safety and Health Administration (OSHA), governmental researchers in the National Institute for Occupational Safety and Health (NIOSH), workers’ compensation insurers, and the manufacturers of production equipment may all have a stake in the outcome of the evaluation. These external organizations may also exert some degree of control over the data or over work process factors that can facilitate or hinder the course of the evaluation. At the outset of an intervention evaluation, the researchers must negotiate the support of all these key stakeholders and work with them to assure their continued support as the project progresses. These negotiations are often the most difficult part of the evaluation.

DESIGN ISSUES

Randomized Controlled Trials

The randomized controlled trial has been the standard of proof in medical and behavioral intervention studies for the last half-century, yet very few have been done in the field of occupational injury prevention. For example, a recent literature search (MEDLINE 1966–1993) found only seven randomized controlled trials of worksite back pain prevention programs, out of 64 reviewed with original data [Lahad et al., 1994]. This paucity of randomized controlled trials has many reasons—historical, social, and political, as well as methodological. The methodological reasons often interact with the social and political context of the intervention. For example, how does one randomize behavioral change or ergonomic interventions within a group of workers who interact, know what the others are doing, and are in labor disputes with management over safety issues? The methodological issues inherent in field studies are widely recognized and have been reviewed in a number of publications, notably Cook and Campbell’s classic text (1979) on quasi-experimental designs. We will focus here on the most problematic methodological impediments to research involving trials of primary prevention interventions.

Cook and Campbell list obstacles to conducting randomized experiments in field settings. The key challenges to randomized controlled trials in this environment can be summarized as number and choice of units for randomization, study group contamination, compensatory treatment in the control unit, and population turnover. We will discuss each below.

The number and choice of units for randomization reflect several converging issues. The first is one of statistical power. Occupational injuries, and even the most common musculoskeletal disorders such as low back pain or upper extremity syndromes, are fairly rare events, statistically speaking. Each year only about two percent of the U.S. workforce will have a compensable low back injury, although the rate may be three or four times higher in selected subgroups. Statistical power for comparisons of injury rates depends primarily on the number of injuries in two samples (the numerators). In a study of Boston Postal Workers, Liang and Daltroy (personal communication) calculated that reduction of injuries by 25% would take 6 or 7 years follow-up of 3,800 workers (1,900 per study group) to achieve power of 80%, with α set at 0.05. While various methods have been proposed to enhance statistical power (e.g., using survival analyses, or measuring a more common interim outcome such as behavior or self-report of pain), measurement of the true outcome of interest, injury rates, generally requires very large samples or long follow-up times or both. Training, maintenance, and collection of data on such a scale are larger tasks than most businesses are willing to undertake in the name of research.

While few companies have enough employees to even enter into a trial, another issue is the choice of unit for randomization. Most interventions affect more than one individual. Many ergonomic changes (e.g., installing new equipment, or modifying the work process) cannot be assigned to individuals but must be assigned to all workers at a redesigned workstation. Ergonomic changes may even be incompatible with old equipment or procedures, so that old and new features cannot exist simultaneously in a plant. Many behaviors also affect more than one individual, such as workers helping each other in heavy lifts, supervisor reinforcement, and so on. The development of new group norms may be a key to changing individual behavior. Thus, the appropriate unit of intervention may be all those who work in a physical plant or cooperative work unit. The pooling of workers into job, administrative, or political units, while perhaps optimizing an intervention's effectiveness, tends to further reduce statistical power. Finding multiple sites or independent work units, willing to be randomized and similar enough to provide balanced comparisons, may be a significant logistic and political challenge.

Study group contamination and population turnover are frequent and related possibilities within companies, as study subjects may come and go and or transfer from one unit to another during the course of several years. If one is following individual comparison workers, they may also change jobs or have experiences with different equipment and behaviors. Comparison workers may even receive educational interventions in the name of safety training that expose them to the experimental study condition. One may

counter this to some extent by training comparison workers who move into an experimental unit (if the intervention is a behavioral one) or by counting person-years of exposure within a group or ergonomically identified location. With the first strategy, the intervention group is maintained at full strength, while the control group is gradually contaminated by infiltration of trained workers and supervisors; this is better than contamination of both groups. With the second strategy, one counts injuries against the unit or location in which they occurred. While the person-year strategy makes it statistically easy to handle worker turnover and transfers, it makes the assumption that the hazard is essentially instantaneous, in a sense that the worker's body has no memory for previous abuse, an assumption that is not likely, as we discuss below.

Compensatory treatment in the control unit is also a frequent problem in this kind of study, for two reasons. First, if the intervention appears desirable, control units (or individual control subjects) may balk at their assignment, or even exact some kind of treatment as the price of being in a trial. Their treatment, whether by happenstance or design, then drifts from the control condition originally planned. Control subjects may seek out their own treatment to make up for the lack they perceive. Often this is done without the evaluator's knowledge, jeopardizing correct interpretation of study results. Second, companies often perceive economic pressure to solve the injury problem now, rather than later. Thus, many types of interventions, generated by supervisors, company administrators, medical officers, or headquarters in some far-off state, may be proposed and applied to the problem in the hopes that something might work. Most companies will not stand still while waiting for the experiment to work. When companies take such an activist approach to reducing occupational injuries, randomized trials may be the strongest way to truly evaluate the effectiveness of specific interventions. The observable effect of the intervention must be able to rise above the noise created by all the other efforts and historical changes (plant equipment, changing labor force) that may affect the injury problem.

Quasi-Experimental Studies

Although randomized controlled trials provide the best evidence of intervention effectiveness, under some circumstances, it is neither necessary nor ethical to carry out a randomized controlled trial. For example, no one would suggest such a trial to prove the efficacy of penicillin to treat pneumococcal pneumonia. Similarly, in occupational injury prevention, when there is clear evidence that an intervention is effective based on quasi-experimental studies (e.g., the use of rollover protection structures to prevent fatal tractor rollover injuries), a randomized trial would be neither necessary nor ethical. Moreover, in some cases, randomiza-

tion is impossible or impractical in field studies and alternative methods must be sought.

In a quasi-experimental intervention study, the comparison group provides an estimate of what the injury incidence would be without the intervention [Rothman, 1986]. While the comparison group does not need to be exactly like the intervention group, they should be similar on factors related to the injury incidence. Restriction or matching in the selection of controls often offers a reasonable alternative to randomization to assure the similarity of the intervention and comparison groups. With restriction, one selects only control subjects with specific characteristics. For example, if the intervention group contained only men or only workers with greater than ten years seniority, then only men or workers with greater than ten years seniority would be chosen as controls. With matching, each control subject is matched to a specific intervention subject on selected characteristics. An alternative to restriction and matching in the selection of the comparison group is to control confounding in the analysis of the results. Confounding occurs when the effect of an intervention is distorted by the presence in the intervention or comparison group of a causal risk factor for the type of injury under study. Confounding can be controlled in the analysis of the data either by using multivariate analysis—using modeling to separate the effect of the causal risk factors from the intervention—or by using a stratified analysis (evaluating the intervention within each stratum of the causal risk factor). If the researcher has a good understanding of the risk factors for injury, the appropriate use of restriction, matching, or the control of confounding in the analysis will insure a convincing quasi-experimental evaluation of an intervention [Rossi and Freeman, 1993]. Wherever possible, the treatment group and the equivalently constructed control group should be identified prior to implementation of the intervention so that baseline measures may be taken (*ex ante* quasi-experiments). *Ex post* quasi-experiments tend to use statistical controls. If the criteria for selection of “treatment subjects” are fully known and uncorrelated with the outcomes, the design may approximate a randomized controlled trial.

An alternative to using contemporaneous controls is the use of historical controls—comparing the injury rates in a single group before and after the intervention. Often, we use historical controls when evaluating a full coverage intervention (e.g., implementing a mandatory seat belt regulation) in a pre/post mode. This design assumes that the only change that occurs is the intervention itself. If researchers cannot find ways to validate this assumption, the interpretation of the results will be compromised. Historical controls can range from single pre/post measurements to more powerful multiple interrupted time-series measurements. Usually, historical controls are less robust than contemporaneous controls [Cook and Campbell, 1979].

Measurement Issues

When we try to prevent work-related musculoskeletal disorders, the validity of evaluations is threatened by measurement issues—including long latency period, multifactorial etiology, and compliance with recommendations.

Long latency period and multifactorial etiology of work-related musculoskeletal disorders significantly challenge intervention research in several ways. First, the long latency of many occupational musculoskeletal disorders means that an intervention may need to be in place for years to demonstrate an impact. Second, subjects may move in and out of situations with different degrees of risk, making it difficult to ascribe symptoms, when they become reportable, to a particular occupational exposure. Further, this becomes confounded by the fact that many people perform tasks that put them at risk outside of work. For instance, sedentary lifestyle and poor posture may contribute to back problems equally at home as on the job. If an intervention does not reach out to most exposures and settings, its impact may be at best diluted, and at worst obscured.

In evaluating interventions to reduce occupational musculoskeletal disorders, we must remember that the injury may be the final common pathway for multiple etiologies, acting alone or in concert. The time when a chronic condition of gradual onset actually becomes reported may be a function of social, economic, and chance variables as much as of the intensity of the discomfort or disability at the moment. It is notable that risk factors for low back problems include both physical activities (lifting, twisting) and labor-saving solutions (sitting for extended periods, especially at machines designed to do the work replacing the physical activity). Other research [Keyserling et al., 1980] suggests that the fit between worker and task may be important, implicitly calling for a detailed study of physiology and individual-level interactions. For certain exposures, the dose-response curve may be U shaped, with both high and low levels of exposure associated with higher injury rates and with intermediate levels of exposure associated with the lowest injury rates. Thus, the solution may not be substitution of one regular activity or posture for another, but a more radical restructuring of the work process, which allows workers to change tasks frequently, so as not to create work-related musculoskeletal disorders. Interventions involving the radical restructuring of the work process might necessitate randomizing entire plants if the work process changes were plant-wide.

Compliance with recommendations constitutes a challenge to the interpretation of results in any intervention study, whether controlled or not. Essentially, one wants to know to what extent the recommended intervention took place, whether it was changes in lifting behaviors, tool-handling, or postures, or, even the installation and correct use of new equipment. Numerous educational interventions

[Daltroy et al., 1993; Green and Kreuter, 1990] have shown that changes in knowledge and skills do not necessarily equate to changes in behavior, especially if the behavior is not properly reinforced in the work environment where it is to be carried out. Even installation of new equipment and procedures often leaves much leeway. Equipment might be incompletely or inadequately installed, operators poorly trained, and so on. Stories of overloaded motorized vehicles and conveyor belts being pushed by hand are all too common in many worksites.

Assessment of occupational behaviors presents a number of challenges. First, the behavior may be unobservable. For example, behaviors done off-site may influence back or upper extremity health. Second, harmful or benign behaviors may look so similar that they cannot be reliably distinguished in the work setting. Third, workers who know they are being observed may alter their behavior to appear at their best. Finally, so many behaviors may be involved in the etiology of injuries that selecting and sampling types of actions within workers and work settings may be highly problematic. Nevertheless, we need some measure of behavior to be able to interpret the effect or lack of effect of a workplace intervention. Self-report by questionnaire, supplemented by regular observation by a trained observer may work best together. When using questionnaires, researchers should always remember that workers may perceive the admission of an “unsafe” behavior as a form of self-incrimination with the potential of punitive actions. Thus, the credibility of these reports must be carefully weighed. Guarantees of anonymity and abstinence from punitive measures may help to correct for an unwillingness to participate in such surveys.

OUTCOMES

Together with study design, the specification of an outcome and the definition of outcome measures are the most important factors in carrying out an evaluation of an occupational injury intervention. We can use a variety of outcomes including measures of injury as well as a series of intermediate outcomes. In any case, we need to have a clear conceptual model of how the intervention will prevent injuries in order to define the appropriate outcome measures. We need to understand precisely what type of injuries we are trying to prevent and how our intervention will prevent them.

Measuring Injury Outcomes

Ideally, we would like to use injury rates as the outcome measure for our intervention evaluations. Since the goal of the intervention is to prevent injuries, measuring a reduction in injuries will be the most convincing demonstration of the intervention’s effectiveness. However, concerns about sam-

ple size and power (mentioned above) may lead us to consider alternative, intermediate outcome measures.

In occupational health, we can separate injuries into two broad classes: acute traumatic injuries and work-related musculoskeletal disorders. For the most part, acute traumatic injuries are disruptions of the body’s physiology caused abruptly by a transfer of energy. Usually, this involves a transfer of kinetic energy as in falls causing fractures, gunshot wounds causing penetrating trauma, butcher’s knives causing amputations or lacerations, or machinery causing crush injuries. However, acute traumatic occupational injuries may also be caused by heat (burns in fast food restaurants), chemical energy (acid burns in chemical plants) or radiation (overexposures in nuclear plants). On the other hand, work-related musculoskeletal disorders are painful musculoskeletal conditions that are believed to be related to repetitive motions, awkward postures, and overuse of the musculoskeletal system in the workplace. These would include both industrial back pain, the most common of occupational injuries, as well as musculoskeletal disorders of the upper extremities including work-related nerve entrapments, muscle-tendon disorders, and vibration syndromes.

Sometimes, we cannot easily distinguish acute traumatic injury from work-related musculoskeletal disorders. For example, can we clinically distinguish low back pain of acute onset after lifting a 50 pound package from low back pain of gradual onset after years of heavy lifting? Still, when we discuss evaluating occupational injury interventions, it is useful to keep this distinction in mind because of the methodological implications it has in the definition of outcome measures.

Acute Traumatic Injury

In defining the outcome measure for an intervention to prevent acute traumatic injuries, we must keep clear in our minds a model of how the injuries are caused and how the interventions prevent them. Ideally, the outcome measure should include only the type of injuries that can be prevented by the intervention. Thus, an engineering change to prevent workers’ hands from getting caught in a machine should be evaluated using only hand crush injuries and amputations as the outcome variables, but a broader intervention aimed at changing the entire safety culture of a large organization would need to consider a wider variety of traumatic injuries as potential outcome variables.

When used as outcome measures, acute traumatic injuries may be classified in several ways. First, they may be grouped by pathophysiologic diagnosis. Usually, the damage done to the body is clearly defined—a fractured fibula, a severed tendon, or a scratched cornea. These diagnoses can be classified using the International Classification of Diseases—N-Codes [U.S. Department of Health and Human Services, 1989], which permit comparisons of similar inju-

ries from different worksites, cities, or nations. Used routinely in medical facilities around the world, these codes are easily obtained from the medical records. To the extent that an intervention is aimed at a single type of injury, the N-Codes are a useful means of classifying injuries.

However, often, interventions attempt to alter the circumstances that caused the injury—the fall, the vehicular crash, the gunshot fired during a robbery. In fact, a single mechanism of injury can cause a wide variety of physiologic damage. A fall may cause a fractured fibula, ruptured tendon, or closed head injury. When interventions are directed at the circumstances of the injury, a second classification of outcomes, the International Classification of Diseases—E-Codes [U.S. Department of Health and Human Services, 1989], is useful. These codes classify the external cause of injury, the mechanism through which the injury occurred. Unfortunately, the E-codes are less likely to be available on existing medical records. Even when available, or when they are coded by the researchers, the E-codes may not provide sufficient detail on the mechanism of the occupational injury, leading to the use of specialized coding systems in specific industries such as agriculture [Murphy et al., 1993; Langley, 1996].

In addition, injury outcomes may be classified by the severity of the injury. Often, the risk factors for fatal and severe injuries differ from those for less severe injuries. For example, older workers tend to have the highest rates of fatal injuries, but lower rates of less severe injuries [Zwerling et al., 1996]. In the injury literature, a variety of scales are available for categorizing injury severity. For epidemiological purposes, the Abbreviated Injury Scale (AIS) [Committee on Injury Scaling, 1980] is most commonly used. The AIS is usually coded from the medical record based upon a detailed estimation of the seriousness of the injury to each organ system. However, the AIS can also be coded from the ICD—N-Codes using a computerized algorithm [MacKenzie et al., 1989]. Because the AIS is designed to classify severe trauma, it may not be adequate in occupational settings where the overwhelming majority of the injuries will fall in the least severe category.

Instead, occupational injury epidemiologists often use the length of disability as a surrogate measure of severity. This surrogate has the advantage of being closely related to the costs in lost wages that result from an injury. Thus, it has strong face validity with policy makers. However, it may be related to a variety of factors other than the anatomical damage caused by the injury. For example, the same injury may keep a police officer away from work much longer than a school teacher. The availability of limited duty, as well as the demands of the job, and the worker's motivation to return to work will impact on the number of days out of work.

Additional classifications of occupational injuries can be based upon the American National Standard Method of

Recording Basic Facts Relating to the Nature and Occurrence of Work Injuries. Sponsored by the National Safety Council and the Association of Casualty and Surety Companies and approved by the American National Standards Institute, standard Z16.2 classifies occupational injuries according to the nature of the injury, the part of the body affected, the source of the injury and the type of accident or exposure [American National Standards Institute, 1989]. A major advantage of classifications built on ANSI standard Z16.2 is the availability of data—this standard is widely used to classify injuries in industry and by state workers' compensation plans.

Work-Related Musculoskeletal Disorders

Defining appropriate outcome variables is even more difficult in the realm of work-related musculoskeletal disorders. For acute traumatic injury, the pathophysiology of the trauma is usually clear; however, for work-related musculoskeletal disorders, this is often not the case. For some conditions such as a herniated lumbar disk with radiculopathy or carpal tunnel syndrome, the anatomic damage is well defined and can be objectively measured with MRIs and nerve conduction studies. However, many work-related musculoskeletal disorders fall into more amorphous categories, such as industrial low back pain and industrial hand pain. For these, there is no clear anatomic correlate for the symptoms and no objective way to define the condition or measure its severity. Thus, we are dependent on the worker's self-report to define the outcome variable. But considerable evidence suggests that social factors such as worker job satisfaction and norms concerning reporting injuries, the cultural role of pain, medical-legal criteria for injury compensation, concern about job loss, and fear of surgery all play a significant role in the reporting of work-related musculoskeletal disorders. In addition, there are some incentives to employers not to record workers' injury reports. These incentives are not constant and may well increase when management is trying to intervene to control a perceived injury problem. The elasticity of injury claims in response to a variety of psychological, worksite, administrative, legal, medical, and economic influences is another reason why the randomized controlled trial is important in the evaluation of injury prevention interventions. While quasi-experimental studies can select control and intervention groups that are similar on many of these possible confounding variables, such control of confounding is surer in a randomized controlled trial.

Defining injury severity is also more difficult for work-related musculoskeletal disorders than for acute traumatic injuries. The Abbreviated Injury Scale and the other injury severity scales are of little use because almost all of these injuries fall within the least severe category, even

though some of them lead to long-term disability and chronic pain. Given that physical examination is not reliable in defining the severity of these conditions, we are often left to rely on the length of disability or on the need for treatment such as surgery as a surrogate measure of severity. However, even more than in the case of acute traumatic injuries, these surrogates for the severity of work-related musculoskeletal disorders are easily influenced by post-injury factors, such as the quality and availability of medical care, job satisfaction, economic incentives to return to work, and the availability of modified work assignments.

Intermediate Outcomes

In evaluating occupational injury interventions, the strongest outcome measure is the final outcome—a reduction in the rate of the targeted injuries. However, in a number of situations we use intermediate outcomes—measurable events along the causal pathway from the intervention to the injury outcome. At times, we use intermediate outcomes, alongside the final injury outcome, to demonstrate that the reduction in injury rate takes place through the proposed mechanism. But often, we use intermediate outcome measures as the sole outcome measure in the evaluation of an intervention. The intermediate outcome may be chosen as the primary outcome measure in an evaluation because it is closer to, and more directly affected by, the intervention. Moreover, the intermediate outcome may be more frequent and thus more easily measured than the final outcome. Since injuries are relatively rare events, evaluations using injury outcomes require large populations to generate sufficient statistical power to evaluate interventions. More frequent intermediate outcomes may decrease the size of the population needed for the evaluation.

A recent review of the efficacy of training for occupational injury control [Johnston et al., 1994] illustrates the use of intermediate outcomes in the evaluation of injury prevention interventions. Implicit in most occupational safety training is a conceptual model that occupational injuries can be prevented by changing the workers' knowledge about safety, their attitudes towards safety, and their behaviors in the performance of their jobs. Johnston and her colleagues [1994] identified 198 descriptions of training programs to prevent occupational injuries. As summarized above, only 8 of these used a measure of injury rates as an outcome measure. More than 80% of these quantitative evaluations used only intermediate outcomes, usually safety behavior at the worksite. The intermediate outcomes of knowledge, attitudes and behaviors are more commonly used because changes in them are more easily measured, while injuries are rarer events requiring larger study populations. However, since the goal of safety training is injury prevention, changes in these intermediate outcomes are only significant to the extent that these changes in knowledge, attitudes and

behaviors have been associated with changes in injury rates. Although safety trainers believe strongly in this connection, empirical evidence for it is rare.

Similarly, the intermediate outcome of changes in exposure is often used to evaluate interventions aimed at preventing work-related musculoskeletal disorders. There is a widespread consensus among researchers in the field that industrial back pain, hand pain, and shoulder pain are related to heavy lifting, bending and twisting, forceful hand motions, working overhead, and working in awkward positions [Hagberg, 1994; Castorina and Deyo, 1994; Cherniack, 1994; Armstrong, 1994; Brisson et al., 1992; Keyserling and Armstrong, 1992]. If we accept this paradigm, we can evaluate worksite interventions using self-reported or observed workplace exposures as an outcome measure. It will be easier, less costly, and faster to measure changes in the amount of repetitive lifting, bending and twisting, than it would be to observe changes in the rarer incidence of medical symptoms. However, not all researchers and clinicians accept the ergonomic model of work-related musculoskeletal disorders. Some argue instead that musculoskeletal pain is an expected part of life and has only become "work-related" through the impact of our disability compensation programs [Hadler, 1991].

The above examples emphasize that the utility of intermediate outcomes depends on the acceptance of a causal model. If there is general acceptance of a model explaining how an intervention would reduce the injury rate, then we can use intermediate outcomes along this causal chain to measure the efficacy of the intervention. But if there is not widespread agreement on the causal chain, intermediate outcomes will not be convincing. Conversely, a study providing data both on the injury outcome as well as on the intermediate outcomes can be used as evidence to support a particular causal model.

Validity and Reliability of Outcome Measures

In addition to defining the outcomes of interest, we must specify a method for obtaining that information. Principally, we must choose between using data from existing sources or collecting new data specifically for research purposes. Existing data sources may include payroll, safety, benefits, administrative, or medical records maintained by the company; insurance and membership records maintained by the union; OSHA 200 logs; or other NIOSH or OSHA data systems. These existing records are less expensive to use because someone other than the researcher paid for their collection. However, they may be considered proprietary information by the group that collected them and they come with a variety of confidentiality concerns as well. Moreover, they were collected for some business purpose other than research and may not contain the precise information needed to evaluate the intervention. Collecting new data specifically

for research purposes may provide the exact outcome data needed, in the precise format required. However, it is likely to be more costly and the company and union are less likely to be willing to pay for collecting those data if there is an alternate, extant source, albeit an imperfect one. The choice is sometimes not easy, and mixed data collection systems may be the best solution [Sorock et al., 1997].

NONHEALTH OUTCOMES

In considering the evaluation of workplace interventions, we should consider other outcomes in addition to the prevention of injury. The actual costs of the intervention, the impact on workplace productivity, the acceptability to workers and managers, and similar factors must also be assessed. These factors may play a role not only in the evaluation of the intervention but also in the later acceptance and implementation of that intervention in similar work settings. Documentation of these factors as part of the evaluation of the intervention may help in developing a plan for increasing the adoption of that intervention throughout the industry. In fact, many interventions enjoy widespread implementation not because of their actual effectiveness but rather due to these other factors such as their acceptability to workplace managers and employees.

Economic Factors

The costs of an intervention may influence the later adoption of that intervention in industry. Full documentation and evaluation of those costs are important but are often overlooked in the evaluation of workplace interventions [Haddix et al., 1996]. These costs include not only the direct costs of buying and using the intervention but also additional labor, equipment, and maintenance costs associated with the use of the intervention. Labor costs should also consider the need for additional training necessary to use the intervention. Some of these costs may be immediate while others may be delayed or continued over a long period of time (e.g., training of new employees). At the same time, the total costs of an injury must be considered as well [Oxenburgh, 1991]: the loss of production after the injury due to shutdown of the process, the administrative costs associated with the care of the injured employee, the costs of training a replacement worker, the repair of damaged equipment, and the costs associated with gradually returning the injured employee to work.

Effects on productivity also need to be considered as potential costs. These effects may be difficult to measure particularly during the initial evaluation of an intervention, since not only the intervention but also the evaluation itself may interfere with production. In addition, the productivity of some types of jobs may be hard to assess. For example, the production of some technical tasks is difficult to assess.

In other types of work, production may be quite variable (e.g., construction) and therefore difficult to evaluate in a short time period.

The costs of evaluating an intervention must also be considered when selecting or recruiting sites for evaluating an intervention. These evaluation costs may be considerable, and the burdens of collecting additional information needed for evaluation may be more disruptive and costly than those entailed by the actual intervention.

Other Workplace Factors

In addition to the effectiveness of an intervention and the costs, other workplace factors often play a role in the initial evaluation and eventual adoption of an intervention. Some industries may be very reluctant to change the pattern of work in order to adopt an intervention. For example, workers may resist the use of uncomfortable personal protective equipment. They may also be reluctant to adopt a change that could increase productivity and thus in the long run reduce the amount of labor required for a particular task. Conversely, they may resist changes that may temporarily decrease productivity, particularly if they are working piece rate. Management may resist adopting a change that reduces their control of the work environment by delegating some of that control to their employees.

The traditional ways that work is organized in a complex work environment may be difficult to change in order to introduce an intervention. For example, construction sites are organized by craft (e.g., pipefitters, carpenters). An intervention for one group may affect the work of another craft or could require a redefinition of work assignments on the job site. This type of change can be very difficult to implement.

These types of factors may impede both the initial evaluation of an intervention as well as the ultimate adoption of that intervention throughout the industry. The documentation of the reasons for resistance during the initial introduction may be helpful for developing a plan for overcoming resistance to more widespread implementation.

RECOMMENDATIONS

In spite of the difficulties in doing occupational injury intervention evaluations, such evaluations are essential to efforts to limit the toll that occupational injuries take in the workplace [Rosenstock, 1996]. A number of strategies to improve the quality of intervention evaluations should be explored.

Use of Qualitative Methods

We need to make wider use of qualitative research methods, such as interviewing, observation, and focus

groups to provide a better understanding of how interventions operate in the work environment [Needleman and Needleman, 1996]. Either alone or in conjunction with quantitative methods [Ferguson and Scharf, 1996], a variety of qualitative techniques will provide an understanding of the factors that facilitate or hinder adoption of interventions. Qualitative research methods [Denzin et al., 1994] can address the important questions of how to implement interventions, to determine the resources needed to maximize factors that facilitate the probability of success, and to identify the full range of intervention effects. In addition, the new paradigm of action research [Israel et al., 1989] has a role to play in evaluation research. In this paradigm, the researcher, instead of being just an objective observer, would participate with workers and management in the design of the intervention, the definition of appropriate outcome measures, the redesign of the intervention in response to new experience, and the final evaluation of the intervention. This participatory and collaborative approach could provide a model for researchers to use in the face of the uncertainties of the changing workplace [Silverstein, 1992].

Improving Quasi-Experimental Studies

Quasi-experimental studies can be improved in several ways. We can identify controls with similar exposure to causal risk factors as the intervention subjects, by using restriction or matching prior to the introduction of the intervention. For causal risk factors on which the control and intervention subjects may differ, we can measure these both before and after the intervention, which will allow for control of confounding in the analysis. Generally, such contemporaneous controls will be more convincing than historical controls in a pre/post evaluation of the treatment group alone. Given the dynamic nature of market economies, of public policy, and of workplace culture, most pre/post evaluations will be confounded by unexpected changes in the workplace. Changing levels of production, corporate leadership, workers' compensation systems, and corporate safety strategies will all make it difficult to draw conclusions using historical controls.

Identifying a critical set of variables that should be recorded in all intervention studies will allow aggregation of data from a number of smaller studies. For example, if different research groups were interested in assessing the effectiveness of knee pads in reducing bursitis or knee pain in kneeling work, they could agree to include duration, frequency, and intensity of kneeling activities, type and duration of knee pad use, age, gender, weight and prior injury history. Insurance carriers could work with clients to collect and maintain consistent records of key descriptive variables, interventions, and duration. This would facilitate the acquisition of information across workplaces and indus-

tries, thereby increasing the power to detect the effectiveness of common types of interventions. In exchange for access to these data by researchers, companies would be able to compare their experience with that of others.

The implementation of surveillance systems within and across companies with exposure and outcome variables, as well as denominator data, would greatly increase our ability to identify treatment and statistical control groups for quasi-experimental intervention evaluation studies. Linking health and safety data to production engineering and personnel data would make surveillance system maintenance easier and more accessible to relevant staff [Sorock et al., 1997]. Personnel data might include linked identifier, age, gender, job seniority date, shift, job, department, time on job, hours worked (overtime). Engineering data might include production rate, tool and equipment use, parts handled, relevant work station characteristics. Health data might include prior injuries, current symptoms, diagnosis, nature, type, and body location (ANSI Z16.2 or ICD-9), disposition, restriction, lost time, and return-to-work date. Accessibility and confidentiality of individual identifying information will require careful planning.

A Hierarchical Approach

A hierarchical approach to evaluating occupational injury interventions might be the most cost-effective way to address these problems. Qualitative techniques could be used to define the options. Simple quasi-experimental designs using historical controls could provide a first assessment of whether the intervention had any promise. This might be followed by more elaborate quasi-experimental designs comparing different firms that instituted the intervention at different times with some that did not implement it at all. Finally, the most promising interventions could undergo randomized controlled studies. Similarly, we might begin by measuring intermediate outcome variables that are more common, and thus less costly to measure. If the results using intermediate outcomes were promising, we could proceed with more costly studies using injury outcomes.

Even using these cost-effective approaches, we realize that intervention evaluations are often costly. However, if there is a consensus that these evaluations are important to show which interventions are needed to reduce the toll of occupational injuries, then we must identify the resources to fund this type of intervention research.

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