

Evaluation of the IMPACT Blood Pressure Program

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To evaluate the incremental effectiveness of a work-site blood pressure control program, we conducted a randomized, controlled trial at four work sites with established health promotion programs. Workers with blood pressures of 140/90 mm Hg or higher were eligible. Eighty subjects were assigned to receive a referral to a community physician, monthly 10-minute work-site counseling sessions including blood pressure readings, and personalized mailings, whereas 79 control subjects received only a physician referral. Results for 74 intervention and 71 control subjects were obtained after 1 year. As compared with control subjects, intervention subjects experienced average declines of 8.5/3.9 mm Hg. Adjusted for age, sex, and baseline blood pressure, the decreases were 7.6 mm Hg for systolic and 2.4 mm Hg for diastolic blood pressure. These results suggest that counseling of high-risk persons and personalized mailing programs can have an incremental benefit in controlling blood pressure.

Although the number of US adults with hypertension (defined as systolic blood pressure [SBP] ≥ 140 and/or diastolic blood pressure [DBP] ≥ 90 and/or taking blood pressure medication) has fallen from an estimated 58 million in 1976 to 1980¹ to 50 million in 1988 to 1991,² an estimated 51% of such adults remain untreated.²

High blood pressure (HBP) is a recognized cause of stroke, myocardial infarction, and other cardiovascular diseases,² with life expectancy related in a continuous, graded, and independent manner to both SBP and DBP.³ Blood pressure control is effective in reducing the incidence of disability and death from these causes.⁴ Pharmacologic therapy is the mainstay of treatment for persistent blood pressure elevations. However, various nonpharmacological approaches, including weight reduction, limitation of alcohol intake, salt restriction, exercise, and maintenance of adequate dietary potassium, calcium, and magnesium, are of demonstrated value, particularly in the control of mild HBP.²

Work-site health promotion and disease prevention programs offer a valuable opportunity to improve blood pressure control in working adults. Results from evaluations of work-site-based hypertension control programs have been mixed. Several work-site hypertension control programs and more comprehensive programs with HBP control components have reported significant reductions in systolic and diastolic blood pressure in persons with elevated SBP and/or DBP^{5,6} for the overall group of participants.^{7,8} However, only one of these programs⁵ randomized subjects to conditions and used a randomized control group. A study of one HBP work-site program found a bene-

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fit:cost ratio of 1.89 to 2.72 based on differences in adjusted claims paid for those in the study versus control groups.⁹

The US Department of Health and Human Services *Healthy People 2000: National Health Promotion and Disease Prevention Objectives* set the goal of blood pressure and/or cholesterol control programs available at 50% of US work sites with 50 or more employees.¹⁰ The 1992 National Survey of Worksite Health Promotion Activities found that 29% of such work sites offered HBP activities as compared with 16% in the 1985 survey. Although three quarters (72%) of these work sites offering blood pressure readings in 1992 referred workers with high readings to a physician, only 39% offered follow-up services or tracking.¹¹ There is a need to evaluate the effectiveness of large-scale, potentially widely disseminable work-site-based blood pressure control programs. The purpose of the present study is to evaluate one such program.

Methods

Subjects were recruited from five work sites selected based upon the presence of an on-site health promotion program coordinated by Johnson & Johnson Health Management, Inc, an offer of blood pressure screening (usually as part of the administration of a health risk assessment), management interest, and agreement to follow study protocols covering recruitment of subjects and delivery of the study intervention. Four sites met all criteria and were included in the study. Populations from which subjects were drawn thus had access to a comprehensive work-site-based health promotion/disease prevention program covering, at a minimum, fitness, blood pressure, smoking cessation, nutrition, and weight control for at least 2 years before this study. Industries represented by sites selected were automobile manufacturing, defense contracting, medical products, and other light manufacturing. Sites were one each in California, Florida, Georgia, and Texas. The work site populations included both white collar and blue collar groups.

Employees with SBP readings of 140 mm Hg or higher and/or DBP readings of 90 mm Hg or higher obtained during a work-site screening were invited to have measurements retaken to determine eligibility for inclusion in the study. Those whose measured SBP and/or DBP exceeded these screening levels were eligible and received information on the nature of the study intervention, the study design, and had any additional questions answered before being asked to sign a consent form.

All eligible employees were also referred to their physician or given an appropriate referral if they indicated no usual source of primary health care. Subjects signing the consent form were randomized, using a table of random numbers at a central coordinating office remote from all sites, into approximately equal numbers to treatment and control groups. All study subjects completed questionnaires covering basic demographic information and medication use at baseline and 1-year follow-up.

Subjects randomized to the IMPACT intervention group received monthly 10-minute individual sessions at the work site with a counselor that included assessment of current behaviors, readiness to change, and perceived vulnerability for negative effects due to the risk factor using validated instruments according to predetermined protocols. Also assessed were the degree to which prior goals were reached and reasons for not reaching them, compliance with any physician-prescribed medication, and goal setting for the next month. In addition, the monthly package mailed to the home address contained a personalized cover letter, information on blood pressure including behavioral challenges (among these were limiting salty snacks to one per week, walking 20 minutes three times per week, and limiting alcohol consumption to no more than one drink per day).

Incentives such as coupons toward athletic equipment were offered upon meeting each challenge. In addition, participants received priority enrollment in relevant programming offered as part of the overall work-site health promotion program. Sites were

required to offer annually at least six classes or demonstrations (such as a display of common foods with test tubes of salt to indicate the salt content of each) related to blood pressure control during the study period.

Counselors were either registered nurses, nutritionists, or health educators with a minimum of 3 years experience in counseling for this risk area in comparable settings and who had successfully completed a 16-hour IMPACT training program including review of relevant literature, practice in effective counseling techniques, role playing, use of materials, and quality assurance efforts. Counselors were supervised by the on-site program coordinator, and conformance with protocol was monitored centrally through review of notes in standardized form from all counseling sessions and participant reports of satisfaction with counselors and content of sessions.

Blood pressure measurements at baseline and at the 1-year follow-up were collected using a DINAMAP[®] PLUS VITAL SIGNS MONITOR automated blood pressure device which has been shown to meet the standards for accuracy set by the Association for the Advancement of Medical Instrumentation/American National Standards Institute (Critikon, Inc, unpublished data). Three measurements were collected for each worker in the sitting position using the right arm. Employees were asked to sit quietly for 5 minutes before the initial measurements and for 2 minutes before each of the subsequent measurements. Baseline and follow-up blood pressures were each defined as the average of the final two readings.

SBP and DBP changes over baseline for treatment subjects were compared with corresponding changes for control subjects. Adjustments of systolic and diastolic change scores for age, sex, and baseline blood pressure were accomplished using a regression model.

Results

The size of initial intervention and control groups and follow-up numbers and rates are provided in Table

TABLE 1
Follow-up of Enrolled Groups

	Intervention Group	Control Group	Both Groups
Number enrolled	80	79	159
Number followed	74	71	145
Percent followed	93%	90%	91%

1. Reasons for loss to follow up include left the company, remained with the company but moved out of area, and refused to return for follow-up blood pressure determination despite at least two written and two telephone or person-to-person attempts.

Baseline characteristics of the final study groups are provided in Table 2. No intergroup differences are striking, with the possible exception of a higher percentage of the intervention group taking blood pressure medication.

Table 3 lists changes in SBP and DBP observed in each group together with crude and adjusted intergroup differences and associated 95% confidence intervals. Both SBP and DBP decreased to a greater extent in the treatment group than in the control group. A statistically significant ($\alpha = .05$) difference between groups remained for SBP, but not DBP, after adjustment for age, sex, and baseline blood pressure.

Among subjects not initially taking blood pressure medication, a significantly greater proportion in the treatment group (13/49) started taking medication than in the control group (5/52) ($P = .03$).

TABLE 2
Description of Study Groups

	Intervention Group	Control Group
N	74	71
Percent female	14%	18%
Mean age (y)	45.8	47.9
Percent taking blood pressure medication	34%	27%
Baseline systolic blood pressure (mm Hg)	149.0	146.9
Baseline diastolic blood pressure (mm Hg)	91.6	88.2

Discussion

The results of implementation of IMPACT for blood pressure control suggest that rescreening, followed by counseling of high-risk persons and personalized mailing programs can have an incremental benefit in reducing cardiovascular risk over a 1-year period when superimposed upon a comprehensive health promotion program offered to the entire work-site population. IMPACT was developed in response to demand from employers for programs that better targeted those at highest risk. Some of these employers expressed the concern that their programs already in place spent equal dollars on each employee regardless of risk, while a majority of their health benefit costs were expended on a small percentage of the work force and their dependents, presumably including those at high risk for cardiovascular diseases.

This work-site study differs from previous published reports of work-site-based blood pressure control activities in that a broad-based work-site health promotion program was in place for at least 2 years before implementation of IMPACT at each of the five sites. At all IMPACT sites, the preexisting program in all cases in-

cluded blood pressure screening and at least referral of all those with elevated readings (using the same criteria as this study) to their physicians. Therefore, all of those identified as eligible for IMPACT had been referred previously to their physician. Preexisting programs may account in part for the relatively low average elevations in both SBP and DBP in the eligible population, and may have contributed to relatively small effect size, including lack of significance for DBP. Another reason for the small change scores may be that employees were all identified based on results of previous screenings and then re-screened, reducing regression to the mean effects.

For middle-aged workers, who comprised the bulk of the study population, SBP relates strongly to risk. Stamler et al³ have argued, in contrast to earlier views, that SBP is a more important predictor of major cardiovascular outcomes than is DBP. They cite results from the Chicago Heart Association Detection Project in Industry showing that men aged 35 to 64 were 4.07 times more likely to die of coronary heart disease if their blood pressure was 140 to 159/<80, as were those with blood pressures <140/<80, but showed nonsignificant increases in risk as compared with those with the same SBP, but DBP 80 to 99.³ Therefore, the significant reductions observed in SBP achieved the majority of the potential reduction in population risk of blood pressure-related cardiovascular disease.

Comparison of these results to other work-site interventions is complicated by different definitions of the

TABLE 3
Mean Blood Pressure Changes

	Systolic Blood Pressure (mm Hg)	Diastolic Blood Pressure (mm Hg)
Intervention group	-10.9	-5.6
Control group	-2.4	-1.7
Crude difference (95% confidence interval)	8.5 (4.3-12.7)	3.9 (0.8-7.0)
Adjusted* difference (95% confidence interval)	7.6 (3.7-11.6)	2.4 (-0.4-5.3)

* Adjusted for age, sex, and baseline blood pressure.

at risk population. A quasiexperimental design testing four models at four randomly selected plants over 3 years used 160/95 as cutoff points for defining HBP. That study showed that a follow-up counseling component and a menu approach to health improvement classes were associated with a higher percentage of those under control ($\leq 140/90$) at 3 year follow-up than screening alone or screening coupled with health improvement classes.⁵ Using a telephone and mail intervention, a research team at Stanford conducted the Stanford Coronary Risk Intervention Program (SCRIP), focused on slowing the progression of coronary artery disease.¹² Although reductions in DBP and SBP were not significant, results did indicate an improvement in low-density lipoprotein, high-density lipoprotein, triglycerides, cholesterol, weight, and exercise capacity.

Use of a highly accurate and precise automatic blood pressure measurement device minimized measurement bias in a study where observing blindly by those performing manual measurements would have presented significant logistical difficulties.

All but one of the work-site counselors for blood pressure were nurses. Although all received identical training and used a structured, detailed protocol, review of counselor notes and monthly challenge results revealed that nurses concentrated more on confirming physician visits and compliance with medication, whereas nutritionists focused more on nutritional requirements. An interactive

software management tool that could guide counselors to cover all required areas and choose appropriate challenges could increase consistency and improve results.

Longer follow-up is required to determine the trends in compliance. If the intervention is not continued in some form, recidivism is likely. In the study at Ford, a significant blood pressure reduction in the treated group compared with the control group observed at the end of the intervention period vanished in a follow-up 4 years after the program was discontinued.¹³

Future studies should determine effect sizes of continuing the same intervention for a longer period and of maintenance interventions, possibly modulating the intervention frequency and intensity based on such individual characteristics as previous compliance history and perceived ability to follow regimen.

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