The Vermont Worksite Wellness Project:* Design, Implementation, Midterm Biometric Findings

* CDC R01 DP000108 "Worksites overweight/obesity control/prevention trial" (04/01/2005 – 09/29/2007), R.H. Ross, P.I.

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A. Problem-Substantive

- Two-thirds of U.S. adults, including working adults, are now overweight (BMI ≥ 25) or obese (BMI ≥30).
- As a result, they are at elevated risk for diseases and conditions, including hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, and osteoarthritis (U.S. Surgeon General 2001, U.S. CDC 2006).
- In the workplace, these are known to increase absenteeism, decrease productivity, and increase health and disability insurance premiums.

A. Problem-Technical

- The problem with the long list of worksite health promotion/disease prevention interventions conducted/reported by at NIH PubMed since 1982 is that most are <u>single-barreled</u>, based on the <u>individual</u> Health Risk Assessment (iHRA) or the <u>environmental</u> Health Risk Assessment (eHRA) approach to reducing employee behavioral health risk factors.
- Most companies that currently employ worksite wellness programming offer iHRA-type interventions, which are based on a singularly <u>psychological</u> view of health determinants. The psychological view tends to ignore well-observed <u>proximal</u> (organizational and institutional) and <u>distal</u> (community and societal) determinants as these too converge on the workplace (Amick et al. 1995, Kawachi et al. 1999, Tarlov and St. Peter 2000).

B. Background-"Individual" approach

- Employers wanting to reduce employee behavioral health risk factors have long had variations on the <u>individual</u> Health Risk Assessment (iHRA) approach to turn to.
- The iHRA approach links individual health risk assessment to individuallevel health risk-reduction programming, employing individual health risk screening and risk-reduction coaching as the platform for delivering <u>tailored health services</u> (e.g. targeting healthy diet, physical activity, stress reduction, smoking cessation) to sub-sets of employees identified according to risk, e.g. poor diet, physical inactivity, unmitigated stress, tobacco addiction (**Table 1**).
- Recent Medline search (19 Jan 07: health promotion, worksite/workplace, trail/control/randomized): most interventions conducted and reported since 1982 have been iHRA-type (see Muto and Yanauchi 2001, Proper et al. 2003, Elliot et al. 2004, Purath et al. 2004, Proper et al. 2004, Aldana et al. 2005, Elliot et al. 2007 for some more recent).

Table 1. the iHRA approach to worksite wellness		Approaches			
		Assessments/Screenings	Awareness raisers	Specific interventions	
Mechan- isms	Self- guided, e.g.	personal health risk assessment (HRA), stage readiness	tailored HRA report with recs on how to maintain or improve nutrition, weight, exercise, stress, smoking; newsletters	nutrition (weight watchers at work), well points program with raffle	
	One-on- one, e.g.	blood pressure, blood sugar (glucose) and cholesterol, bone density, facial skin, body comp, fitness tests (flex, cardio, endurance, strength)	post-assessment customized report, one-on-one consultation to ensure full understanding of results, increase health awareness	around nutrition, weight, exercise, stress, smoking, back care, men's/women's cancer education, osteoporosis, diabetes and asthma management, CAD, CHF	
	Group- mediated, e.g.	"group" HRAs, "friendly competitions"	study groups for fitness, smoking cessation, stress management	support groups for fitness, smoking cessation, stress management	

B. Background-"Environmental" approach

- An alternative <u>environmental</u> Health Risk Assessment (eHRA) approach has more recently emerged.
- The eHRA approach links environmental health risk assessment to environment-level health risk-reduction programming, employing building/worksite asset screening and asset-improvement coaching as the platform for delivering <u>altered worksite settings</u> (targeting physical, informational, nutritional, grounds, neighboring, policy, educational environments) to all employees alike independent of risk (**Table 2**).
- Same Medline search: growing number of eHRA-type employee risk factor reduction interventions is now being conducted and reported (see Basen-Engquist et al. 1998, Emmons at al. 1999, Biener et al. 1999, Simpson et al. 2000, Beresford et al. 2001, Pegus et al. 2002, Oldenburg et al. 2002, Sorenson et al. 2002, 2003, 2004, Linnan et al. 2005).
 - NB: Seeking no less than the iHRA approach to reduce employee behavioral health risk. factors, the eHRA approach must be considered no less "behavioral."

Table 2. the eHRAapproach to worksitewellness		Approaches			
		Communications	Regulations	Facilities	
Mechan- isms (on-site only, see separate table for off-site apps and mechs)	Encourage- ments, e.g.	signs, posters, notices on bulletin boards re: healthy diet, exercise, stress, smoking, alcohol	company smoking ban; incentives, flextime for bike to work, regular exercise, lunch walk	stairways climber- friendly: visible, carpeted, painted, decorated, utilities covered	
	Options/ Pro- scriptions, e.g.	signs posted at elevators re: stair-climbing, in cafeterias re: healthy choices	healthy food and drinks modeled at company events	healthy in cafeteria, lunchrooms, vending machines; no cigarette machines, alcohol served	
	Enablers. e.g.	company endorsement of walk/bike to work, regular exercise, lunchtime walk, classes on diet, weight, exercise, stress, smoking, back care, men's/women's cancer, osteoporosis, diabetes and asthma management, CAD, CHF	company allowances for bike to work, at work exercise, lunchtime walking, work-time exercise or health education, flextime for exercise	fitness facilities: showers and changing rooms for walkers, bikers to work; seasonal volleyball, basketball courts; grassy space for exercise; run/walk groups, yoga, tai chi, relaxation, swimming, dance classes	

B. Background-"Integrated" approach

- Now, cost-driven by rising insurance premiums and observed ROIs in the range of \$3-6:1, employers are urged to adopt comprehensive risk factor reduction programs (Matson Koffman et al. 2005) built on four (4) elements:
 - 1. screening, health risk assessments, and referrals.
 - 2. environmental supports for behavioral change, e.g., access to healthy food choices.
 - 3. financial and other incentives.
 - corporate policies that support healthy lifestyles, e.g., tobacco-free policies.

C. Significance-in the Nation

- Estimates based on the 1998 Medical Expenditure Panel Survey (MEPS) and 1996 and 1997 National Health Interview Surveys (NHIS) put aggregate 1998 cost attributable to adult overweight (BMI 25–29.9) and obesity (BMI 30>) at 9.1 percent of total U.S. medical expenditures: <u>\$51.5 billion</u> using MEPS data and <u>\$78.5 billion</u> (\$92.6 billion in 2002 dollars) using 1998 National Health Accounts (NHA) data which add nursing home expenditures costs to the estimates.
- Half of these costs were paid by Medicaid and Medicare (Finkelstein, Fiebelkorn et al. 2003). Because of the high costs of obesity, and the fact that the majority of these costs are financed by taxpayers, there is a clear motivation for <u>government</u> to try to reduce these costs (Finkelstein, Ruhm et al. 2005).

C. Significance-in the Workplace (1)

- Overweight and obesity ranks foremost, along with physical inactivity and smoking, among personal risk factors associated with work-related injury, disability, and related compensation claims (Kostova and Koleva 2001, Fransen et al. 2002, Arena et al. 2006, Long et al. 2006).
- Cost of obesity to U.S. business already in 1994 was estimated at <u>\$12.7 billion</u> (CPI-adjusted 2006: <u>\$17 billion</u>): 2.6 billion due to mild (BMI=25-28.9), \$10.1 billion due to moderate to severe (BMI ≥29 kg/m2) obesity. <u>Health insurance</u> expenditures constituted <u>\$7.7 billion</u> of that total and paid sick leave, life insurance, and disability insurance, respectively, \$2.4 billion, \$1.8 billion, and \$800 million, of the same (Thompson et al. 1998).

C. Significance-in the Workplace (2)

- Association between obesity, health care costs, and absenteeism is progressive: above the low point (BMI 25 to 27) additional health risks, short-term disability, absence due to illness, medical claims and health care costs steadily rise.
- Mean annual health care costs for "at risks" (men BMI ≥27.8, women BMI ≥27.3) was <u>\$2,274 versus \$1,499</u> for the "not at risks;" major differences in costs were observed for employees 45 > years old, particularly among women (Burton et al. 1998, 1999).
- Annual costs (medical expenditures, absenteeism) attributable to overweight and to three categories of obesity (grades I, II, and III) among full-time employed men and women range from \$175 per year for overweight male employees to \$2,485 per year for grade-II obese female employees. Annually, the cost of obesity alone at a firm with 1000 employees (looking only at medical costs and absenteeism, not at obesityrelated cost associated with disability, reduced productivity) is estimated at \$285,000 (Finkelstein, Fiebelkorn et al. 2005, Schmier et al. 2006)

C. Significance-Small Firms (1)

- **Small firms** (U.S. SBA 2006) (< 500 employees)
 - employ fully <u>half</u> of all private sector employees.
 - pay >45% of <u>total payroll</u>.
 - □ generate 60-80% of <u>net new jobs</u>.
 - create >50% of non-farm private GDP.
 - supply >23% of total value <u>federal prime contracts</u>.
 - produce 13-14 times more <u>patents per employee</u> than large firms, patents twice as likely to be among 1% most cited.
 - employ 41% of <u>high tech workers</u>, e.g. scientists, engineers, computer workers.

C. Significance-Small Firms (2)

- Small firms are those where for cost considerations employee <u>wellness program delivery capacity</u> can be
 - more readily <u>generated</u>, e.g. by an on-site program delivery (PD) team composed of motivated, qualified employees
 - than <u>bought</u> in the form of full- or part-time professionals, e.g. in the exercise or nutrition sciences.

D. Project Design

The Vermont Worksite Wellness Project is a

- <u>thirty-month</u> (04/01/2005-09/29/2007), <u>four-arm</u> (3 test, 1 control), <u>small employer</u> (51-249 employees), <u>cluster randomized control trial</u> sponsored by the <u>CDC</u>, conducted at the <u>University of Vermont</u> in partnership with <u>Blue Cross Blue Shield of Vermont</u>, with seven (7) employers per arm (n=28), 957 active participants at study start.
 - an "active" participant is defined as an employee 1) who had signed the consent form, 2) whose clinical (e.g. lipids and glucose) and baseline paper survey data had been taken, 3) who had not either withdrawn from the study or been withdrawn due to his/her a) having left the employer, b) having missed more than one consecutive post-Baseline outcomes collection, or c) employer having left the study.
- Aim: to compare <u>relative effectiveness</u>-compared to no programming at all--of <u>three</u> distinct program <u>approaches</u> to promoting healthy behaviors at worksite.

D. Project Design-Rationale

- RCT: The <u>Cluster</u>-randomized control trial is strongest possible design (Hulley SB & Cummings R et al. 2001) for assessing the relative effectiveness—compared to the Standard worksite wellness/SWW (no programming, screening only)—of the three Standard-plus Worksite wellness/SpWW (screening plus programming) models under study: Individual per se (Ips), Environmental per se (Eps), Integrated environmental-individual (Iei).
- Randomization: Compared to purposive forms of assignment, random assignment of employers to study arms stands the better chance of eliminating bias due to influence of <u>unmeasured confounders</u>. Making randomly assigned employers the unit of analysis permits generalization to the <u>institutional level of analysis</u>. Randomizing at baseline from a pool of the unexposed—SWW model employers—permits the most unbiased and practical test possible of the impact of implementing each of three distinct SpWW models.

E. Subjects and Sites

- Project sites: Blue Cross and Blue Shield of Vermont (BCBSVT) small employers (51-249 employees) that at study start had adopted no *deliberate* OO/CP program nor *collaborative* program delivery components were randomly ranked 1-n and in that order were invited to participate in the study so as to reach seven (7) employer per four (4) project arms.
 - Stratified blocked randomization was used to ensure that a balanced number of urban-to-rural, smaller-to-larger (<90, 90> employees), type-diversified (by NAICS sector) sites were accrued to each arm.
- Project subjects: the full- and part- (no less than 50% fte) time BCBSVT or other insured employees twenty-one (21) years of age or older of employers so assigned were eligible to participate in the study.
 - □ Test site employees were, Control site employees were not, exposed to one of the three SpWW Interventions.
 - Exposure variously lasted from 18 23 months (October 21, '05 September 28, '07) according to accrual date.

F. Timetable-PreTest period

- Phased accrual of sites: due to phased accrual, the <u>Pre-Test</u> (April '05-April '06) and <u>Test</u> (October '05-September '07) periods overlapped. Test site test periods ranged from 18-23 months, depending on date of accrual.
- Pre-Test period (April '05-April '06) tasks: the P.I., Project Manager, and Project Clinician variously enrolled employers (21 test, 8 control sites); explained protocol and instructed sites in study roles/responsibilities; <u>constituted</u> each site's Program delivery (PD) team; <u>established</u> data reporting, collection, storage, management modalities; finalized study forms, including survey instruments and data sheets; settled study logistics with each site's front office (management, cost centers, human resources); detailed PD team protocol management responsibilities; led deliberations concerning exactly which program components will be adopted; explained information systems that would track project protocol implementation; drafted final agreements counter-signed by company CEO; assembled potential employee participants, explained study, invited participation, and guided those who agreed in completing the consent form and baseline paper survey; <u>collected</u> baseline clinical outcomes measures.

F. Timetable-Test period

- Test period (October '05-September '07): the P.I., Project Manager, and Project Clinician variously <u>managed</u> program delivery (PD) teams' implementation of agreements covering on- and off-site programming according to Test arm (Ips, Eps, Iei); <u>conducted</u> Outcomes collection Clinics in four (4) iterations (Baseline and 3 Follow-up) at Test and Control sites at which both clinical and paper survey outcomes were collected; <u>assessed</u> employer success implementing programs and employer evaluations of content and process of project programming.
- Outcomes collection Clinics were conducted
 - □ Baseline: October 21, '05 April 26, '06
 - □ 1st follow-up: April 27 September 14, '06
 - □ 2nd follow-up: January 2 February 22, '07
 - □ 3rd follow-up: July 26 September 28, '07

G. Protocol

- Control arm: Standard Worksite Wellness (SWW) or Screening only/No programming.
- Test arms: Standard <u>plus</u> Worksite Wellness (SpWW) or screening plus three (3) distinct <u>program</u> <u>approaches</u> to Worksite Wellness
 - "Tailored Health Services": the "Individual per se" (Ips)
 - "Altered Worksite Settings": the "Environmental per se" (Ips)
 - □ Integrated environmental + individual (Iei)

G. Protocol-the Ips intervention

- The Ips intervention links an <u>individual</u> health risk assessment (iHRA) to <u>individual-level</u> health risk-reduction programming, employing <u>individual</u> health risk screening and risk-reduction coaching as the platform for delivering <u>tailored health services</u> (e.g. targeting healthy diet, physical activity, stress reduction, smoking cessation) to <u>sub-sets of employees</u> identified according to risk, e.g. poor diet, physical inactivity, unmitigated stress, tobacco addiction. Core of the Ips is:
 - □ <u>Quality Health SurveyTM</u>: stage-based, scientifically validated assessments and reports that together assess the presence of the most costly behavioral risks and empower the participant to begin and maintain a healthier lifestyle.
 - Quality Health ProgramsTM: an integrated evidence-based behavior change program that provides individualized, stage-matched interactive multiple behavior change interventions; dynamically tailored on 14 Transtheoretical (stages of change) variables for each participant to assist them in continuing the process of Changing for Good.

G. Protocol-the Eps intervention

- The Eps intervention links an <u>environmental</u> health risk assessment (eHRA) to <u>environment-level</u> health risk-reduction programming, employing building/worksite asset screening and asset-improvement coaching as the platform for delivering <u>altered worksite settings</u> (targeting physical, informational, nutritional, grounds, neighboring, policy, educational environments) to all employees alike independent of risk (next slide). Core of the Eps is:
 - the "Checklist for Health Promotion Environments at Worksites": Oldenburg B, Sallis JF, Harris D, Owen N. Checklist of Health Promotion Environments at Worksites (CHEW): Development and measurement characteristics. *Am J Health Promot.* 2002 May-Jun;16(5):288-99
 - Seven (7) settings: physical, nutritional, informational, grounds, neighboring, policy, educational.

G. Protocol-the "Facilitator"

- **Facilitator**: Each intervention alike (Ips, Eps, Iei) featured a <u>distinct</u> program approach to modifying behavioral health risk factors known to contribute to weight gain and maintenance but one <u>common</u> facilitator:
 - Program delivery (PD) teams were composed of 2-4 member participants who covered four (4) distinct "Go-to" Assignments (30-60 minutes a week burden) and met weekly or bi-weekly (roundtable) to report, discuss, solve, propose, and plan. Assignments included the Go-to person for the QHS (or the CHEW), Go-to person for the Pedometer club, Go-to person for the Buddy system, Go-to person for Outcomes collection
- **PD teams** worked <u>hand-in-glove</u> with the Research team in the pre-Test and Test periods to design and implement the intervention.

G. Protocol-the "Translators" (1)

- **Translators:** Each intervention alike (Ips, Eps, Iei) featured a <u>distinct</u> program approach to modifying behavioral health risk factors known to contribute to weight gain and maintenance but two <u>common</u> translators:
 - □ **Pedometer clubs** promoted daily individual or group walking and, by means of six-week Walking logs, daily/weekly step-counting/building.
 - Buddy systems promoted formation of "buddy groups" of two-tofive (2-5) participants who committed to regular shared activity around modifying one or more of four behavioral health risk factors (physical inactivity, unhealthy diet, unmitigated stress, tobacco addiction)
- **PD Teams** worked <u>hand-in-glove</u> with the Research team in Test period to distribute and collect six-week Walking logs and facilitate, monitor, and evaluate Buddy groups.

G. Protocol-the "Translators" (2)

- Translators: While each intervention alike (Ips, Eps, Iei) featured Pedometer clubs and Buddy systems, the <u>manner</u> in which PD teams promoted these <u>differed</u> according to <u>distinct</u> nature of the intervention:
 - □ the Ips promoted activity always by <u>individual</u> means, involving personalized, <u>face-to-face</u> invitations and encouragements.
 - the Eps promoted activity always by <u>environmental</u> means, involving <u>socially marketed</u> invitations and encouragements.
 - the Iei promoted activity always by a combination of <u>individual and</u> <u>environmental</u> means.
- Analogy: By analogy with a device trial, two distinct <u>delivery systems</u>—respectively <u>individual and environmental</u>—were employed alone (Ips, Eps) or in combination (Iei) to deliver two common program translators, Pedometer club and Buddy system. A walking program, after all, is consistent with, and regularly attached to, Ips- and Eps-type interventions alike. It is on *how* they are delivered that the distinction arises.

H. Hypotheses

- Primary predictions were that, independent of employer (e.g. urban-to-rural, smaller-to-larger, NAICS sector) characteristics,
 - h:1. among Study sites, Test site/SpWW employers will report significantly more positive outcomes than Control site/SWW employers.
 - h:2. among Test sites, Iei employers will report significantly more positive outcomes than Ips or Eps employers.
 - h:3. between Ips and Eps employers, no more or less positive outcomes will be observed.

I. Measures-Clinical

- Clinician-reported
 - **BMI**: overweight/obesity = BMI 25 + /30 +.
 - waist circumference: overweight = WC >35 (women), >40 (men).
 - lipids: total, HDL, LDL, triglycerides.
 - **glucose**: blood sugar.
 - blood pressure.

I. Measures-Functional

Participant-reported

- □ **Physical, mental health status**: SF-12 Health survey—physical and mental component summary scales (Ware J Jr et al. 1996).
- Work limitations: WLQ-8 Work Limitations Questionnaire percent of work time when tasks are difficult to perform: time, physical, mental, and output demands (Amick BC et al. 2000, Lerner DJ et al. 2001, Lerner D et al. 2003, 2003).
- Work performance: World Health Organization Health and Work Performance Questionnaire/WHO HPQ—health problems and treatment, absenteeism, critical incidents (Kessler RC et al. 2003, 2004).

I. Measures-Productivity

Participant-reported

□ WLQ-8, weighted as a productivity measure.

• WHO HPQ "presenteeism."

I. Measures-Cost

- Employer- and insurer-reported
 - Medical and Pharmaceutical claims
 - Cost effectiveness analysis (CEA) based on Clinical outcomes
 - Health related cost estimate (1-WLQ = percent productivity loss or gain x 2080 X fte x hourly).

I. Measures-CEA

- cost of each intervention program (plus related short-term costs): 1) variable (personnel and materials) and 2) fixed (facilities and space, capital equipment and real estate, administrative staff and support, volunteer time, donated goods and services)
 - direct costs estimated using: 1. direct health-care costs, regardless of diagnoses, from medical and pharmacy claims and 2. costs, also derived from claims data, that reasonably could be expected to be influenced by weight-loss within a 3-year time period, e.g. drugs and visits related to hypertension, hyperlipidemia, diabetes.
 - indirect costs measured in terms of lost productivity, with estimates of hourly wages used in conjunction with the number of hours lost from work (absenteeism) as well as reduced productivity (presenteeism).
- effectiveness of each intervention program: percent reduction in BMI.
- cost-effectiveness: program incremental cost divided by incremental effectiveness, i.e., additional cost per point improvement in BMI.

J. Findings-Baseline to 1st Follow-up

Table 3. Changes in Clinician-reported Outcomes: Test and Control Arms: 647 active participants (6-7 employers per arm) distributed (Iei) 158/24%, Ips 165/26%), Eps 179/28%), Control/SWW 145/22%.

	Integrated IEI	Individual IPS	Environm't EPS	Control SWW
BMI	-0.3	-0.22	-0.05	-0.21
Waist Circ	-1.83	-1.75	-2.28	-0.65
Weight	-1.56	-1.01	-1.68	-0.52
LDL	-15.09	-7.34	-9.56	-9.32
Cholesterol	-28.04	-17.76	-22.77	-21.32
Glucose	-4.24	-1.78	-0.31	-3.76
Blood Press	-8.41	-6.93	-10.49	-5.27



J. Findings-Baseline to 1st Follow-up



J. Findings-Baseline to 1st Follow-up

- <u>Clinician-reported</u> outcomes reported in **Table 3** show unit <u>declines</u> in all biometrics across all four Study arms, indicating that Program (IEI, IPS, EPS) and No-Program (SWW/Screening only) protocols alike improved participants' clinical health status. Cumulative rankings indicate that the:
 - □ <u>strongest</u> effect (ranked 7/7 in 1st or 2nd place) occurred in IEI arm where participants were exposed to both EPS and IPS programming.
 - <u>next strongest</u> effect (ranked 5/7 in 1st or 2nd place) occurred in EPS arm where participants were exposed to environmental programming alone: to altered worksite settings targeting physical, informational, nutritional, grounds, neighboring, policy, educational environments.
 - weakest effect occurred not in the No-Program SWW (ranked 2/7 in 1st or 2nd place) where participants were exposed to screening only but in the IPS arm (ranked 1/7 in 1st or 2nd place) where participants were exposed to individual programming alone: to tailored health services targeting healthy diet, physical activity, stress reduction, smoking cessation.
- Among Program protocols, the IEI and EPS register strongest, the IPS registers weakest, weaker even than the No-Program SWW.

J. Findings-Baseline to 2nd Follow-up

Table 4. Changes in Clinician-reported Outcomes: Test and Control Arms: 553 active participants (6-7 employers per arm) distributed (Iei) 117/21%, Ips 145/26%), Eps 160/29%), Control/SWW 131/24%.

	Integrated IEI	Individual IPS	Environm't EPS	Control SWW
BMI	0.21	0.4	0.16	0.24
Waist Circ	-2.32	-1.15	-2.24	-0.82
Weight	0.53	0.52	0.13	1.53
LDL	-3.69	-2.92	-5.53	-2.34
Cholesterol	-7.66	0.23	-9.89	-2.14
Glucose	8.6	4.62	10.38	4.68
Blood Press	-4.36	-1.96	-5.46	-0.59

J. Findings-Baseline to 2nd Follow-up





J. Findings-Baseline to 2nd Follow-up (1)

- <u>Clinician-reported</u> outcomes reported in **Table 4** show unit <u>declines</u> in four of seven biometrics (excepting BMI, weight, glucose) across all four Study arms. Program (IEI, IPS, EPS) and No-Program (SWW/Screening only) protocols alike improved participants' clinical health status along Waist circumference, LDL, Cholesterol, and Blood pressure. Cumulative rankings on these four dimensions indicate that the:
 - strongest effect (ranked 3/4 in 1st, 1/4 in 2nd place) occurred in EPS arm where participants were exposed to environmental programming alone.
 - <u>next strongest</u> effect (ranked 1/4 in 1st, 3/4 in 2nd place) occurred in IEI arm where participants were exposed to both EPS and IPS programming.
 - weakest effect occurred in the No-Program SWW (ranked 1/4 in 3rd, 3/4 in 4th place) where participants were exposed to screening only; the <u>next weakest</u> was IPS (ranked 3/4 in 3rd, 1/4 in 4th place) where participants were exposed to individual programming alone.
- Among Program protocols, the EPS and IEI again register strongest, the IPS and SWW again register weakest.

J. Findings-Baseline to 2nd Follow-up (2)

- That the <u>clinician-reported</u> outcomes reported in **Table 4** show unit <u>increases</u> in three of seven biometrics (BMI, weight, glucose) across all four Study arms may be due to seasonal factors,
 - specifically to the fact that the 2nd Follow-up Outcomes collection Clinics were conducted during the post-holiday Winter months, January 2 – February 22, '07, when adults on average tend to be less active and eat less healthily than in the warmer months, April 27 – September 14, '06, when the 1st Follow-up Outcomes collection Clinics were conducted.
- The seasonality factor may be gauged (though not "proven") when data from the 3rd Follow-up Outcomes collection Clinics, conducted over the Summer months, July 26 – September 28, '07, are reported.

K. Conclusion-Test to Control Arms

- Baseline to 1st and 2nd Follow-up, among all four Study arms, that Control arm (screening only) participants improved right along with (though usually at < rate than) Test arm participants is notable and arguably a result of
 - the knowledge they too gained at the Outcomes collection Clinics from receiving lipids, glucose, BMI, waist circ, BP profiles <u>and</u> interpretative brochure.
 - the awareness they too acquired during the consent process (when study was explained to them) and from consent form (where reason for the study was given and each of four study arms described) of the magnitude of the current U.S. overweight/obesity epidemic.
 - the exposure they too have had since study start to national print and visual media for which the current overweight/obesity epidemic among U.S. adults (and children) is "front page" news.

K. Conclusion-among Test Arms

- Baseline to 1st and 2nd Follow-up, among Test arms, that "Integrated" (IEI) and "Environmental" (EPS) arm participants improved consistently and significantly more than "Individual" (IPS) arm participants is equally notable and arguably a result:
 - in the case of the IEI, of a "double whammy" individual-plusenvironmental effect whereby participants were exposed both to individual (IPS) and to environmental (EPS) programming.
 - in the case of the EPS, of an "all employees alike" blanket effect whereby participants were exposed to alterations in up to seven (7) worksite settings, including changes in physical, informational, and nutritional environments, which they could not avoid in the way that they could avoid internet-accessed individual programming (merely by choosing not to "log-on").

L. Discussion-Implications

CDC says ...

DO NOT hide CANDLE under BUSHEL

□ DISSEMINATE, IMPLEMENT.

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M. Literature Cited

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