Personal Exposure Monitoring Wearing Protocol Compliance: An Initial Assessment of Quantitative Measurement

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Keywords: personal monitoring, quantitative protocol compliance

Running title: Exposure monitoring compliance

Abstract

Personal exposure sampling provides the most accurate and representative assessment of exposure to a pollutant, but only if measures are implemented to minimize exposure misclassification and reduce confounders that may cause misinterpretation of the collected data. Poor compliance with personal sampler wearing protocols can create positive or negative biases in the reported exposure concentrations, depending on proximity of the participant or the personal sampler to the pollutant source when the monitor was not worn as instructed.

This paper presents an initial quantitative examination of personal exposure monitor wearing protocol compliance during a longitudinal particulate matter personal exposure monitoring study of senior citizens of compromise health in North Carolina. Wearing compliance varied between participants due to gender or employment status, but not longitudinally or between cohorts. A minimum waking wearing compliance threshold, 0.4 for this study of senior citizens, is suggested to define when personal exposure measurements are representative of a participant's exposure. The ability to define a minimum threshold indicates data weighting techniques may be used to estimate a participant's exposure assuming perfect protocol compliance.

Introduction

Quantification of an individual's exposure to particulate matter (PM) is critical for understanding its effects on their health. Many epidemiologic studies have shown short-term and long-term exposures to ambient PM adversely affects human health and that the increase in the level of exposure is significantly associated with increase in prevalence of mortality (Schwartz, 2003) and morbidity (Zanobetti and Schwartz, 2003). PM-health effects were found most consistently in young children who are still under physical development and have physiological differences from adults and in senior citizens who are likely to have pre-existing health conditions.

Ambient PM concentrations measured by a centrally located sampler as a surrogate of personal exposure have been used in epidemiological studies to show increases in mortality or morbidity with incremental increases in PM concentration (Dockery et al., 1993). However, the level of representativeness of this exposure surrogate approach is sometimes difficult to define compared to true breathing zone assessments (Rodes and Thornburg, 2004).

Stationary samplers located indoors and outdoors to monitor home environments are another approach. For health compromised participants, the local indoor and outdoor exposure measures are expected to provide a more representative assessment of their exposure and a correspondingly stronger association to adverse health effects than would regional sampling. An individual's PM exposure varies according to the presence of nearby outdoor and indoor sources, residential air exchange rate, and fraction of time spent indoors, outdoors, or other indoor environments (Williams et al., 2000a; Rodes et al., 2001; Thornburg et al., 2004; McBride et al., 2007; Williams et al., 2009; Rodes et al., 2010;). This location-time approach relies heavily on

the accuracy of the participants' time-activity diary to apportion exposure between indoor and outdoor aerosols. However, this method may miss exposures to sources not being explicitly monitored, such as office, school, or automobile (Wallace and Williams, 2005; Wallace et al., 2006). Additionally, indoor and outdoor measurements miss the "personal cloud", the particulate matter exposures that results from personal activities magnified by their proximity to the source (Rodes et al., 2004). The National Academy of Science designated this bias as "exposure misclassification error" and recommended research was needed to address the development of robust linkages between exposures and health outcomes (NRC, 2004).

Personal, breathing zone exposure monitoring is another approach that when applied correctly captures PM exposures in all environments and removes all sampling ambiguities. Various studies have taken different approaches to examine personal PM exposure levels for comparison with outdoor and/or indoor air monitoring data (Janssen et al., 1998; Adgate et al., 2002; Liu et al., 2003; Turpin et al., 2007; Williams et al., 2003a; Williams et al., 2009). Personal exposure monitors collect real-time and time integrated measurements of acute and chronic exposure, respectively. Time-activity diaries are useful for categorizing the immediate environments where exposure occurred and sources of PM, but they do not provide an accurate and representative assessment of exposure.

Personal sampling provides the most accurate and representative assessment of PM exposure, but only if measures are implemented to minimize exposure misclassification and minimize data misinterpretation. Rodes et al. (2010) showed that personal monitor wearing protocol compliance violations reduced the accuracy and representativeness of the personal exposure measurements obtained during a general population study in Detroit, MI. The

corresponding associations between the biased PM exposures and adverse health outcomes could have been weakened if this had not been accounted for in the analysis (Brook et al., 2010). This situation leads to exposure misclassification; the inadvertent attribution of a health effect (or absence of a health effect) to a PM concentration and its chemical speciation that is not representative of their actual exposure.

"Wearing compliance" is defined here as how well a participant wears the personal sampler in accordance with the sampling protocol. This definition is not to be confused with other forms of "compliance" monitoring such as monitoring to determine compliance with regulatory standards (e.g., Chow and Watson, 2008) or respiratory testing protocol compliance (e.g., Delfino et al., 2006). If the participant fails to wear the personal sampler properly for significant time intervals, then the measured concentrations may be artificially low or high and yield exposure misclassification. Conclusions drawn under the assumption that the PM samples represent their actual exposure might represent an entirely different exposure scenario.

Participant compliance with study protocols is easily measured by monitoring the movement of the sampler with an embedded sensor. The rationale is that the movement of the monitor and the signal that is recorded are correlated to the participant's movements, with the sensor recording a signal indistinguishable from background signal noise if there is not any movement because the monitor is not being worn. Commercially available 1-, 2-, and 3-axis accelerometer packages, such as the Actical® (Mini Mitter, Bend OR) or HOBO Pendant G (Onset Computer Corp., Bourne MA), or an embedded, bare 3-axis accelerometer chip (e.g., Oki L8950, Tokyo Japan) on a circuit board is one approach to monitor compliance using a small, low power system. Another method uses a co-planar capacitance plates connected to a capacitive

sensor in a data logger to detect proximity to the participant's body (Pellizzari et al, 1995; Lawless, 2003). Ideally, any sensor used should provide a signal proportional to the participant's activity level.

Wearing compliance with regard to personal exposure sampling has generally received little attention. Ebelt et al. (2000) used time-activity diaries to verify personal sampler use and found that on average, the samplers were worn for 63 percent of the protocol time. They attributed the non-compliance to the burden of the samplers, even though they described the participants as "highly committed". Delfino et al. (2004, 2006) addressed protocol wearing compliance for specific, technically difficult personal exposure measurements. This research noted the impact of personal monitoring burden on exposure data representativeness, but did not quantitatively account for poor wearing compliance in the data analysis. In the RIOPA study, relatively low-burden small passive samplers were used, but wearing protocol compliance of the samplers was not monitored (Liu et al, 2006; Liu et al, 2007).

This paper presents the first quantitative examination of protocol wearing compliance during a PM personal exposure monitoring study. The influence of protocol compliance on the representativeness of the collected exposure data is discussed. The definition of protocol compliance is refined to consider the events that have the largest impact on a participant's PM exposure. How compliance is measured and the procedures for analyzing compliance data are also presented.

Methods

Personal exposure sampler *wearing protocol compliance* is the fraction of time that the sampler is worn compared to the time it should have been worn. If a participant follows the

protocol and keeps the sampler in their bedroom while sleeping, this period is always considered to be fully compliant. We found participants almost always complied with this portion of the study protocol. Therefore, it is useful to define *waking wearing compliance* as the fraction of time the participant follows the personal exposure monitor sampling protocol while awake. The benefit is that waking wearing compliance maximizes the range (highest to lowest) of compliance measurements for the most compliant and least compliant participants. The amplified range increases the ability to detect statistically significant differences between participants and across longitudinal sampling sessions. Similarly, the term *mass wearing compliance* describes the fraction of time the sampler was worn while the PM concentration was within one of several, user-defined mass concentration ranges. This definition considers whether the sampler was worn during peak concentration events that possibly contributed to a substantial portion of the exposure over an entire sampling period.

Waking and mass wearing compliance were assessed as part of the U.S. EPA's RTP Particulate Matter Panel Study (Williams et al., 2003a, 2003b). Determination of wearing compliance was performed for subjects completing all four seasons of the monitoring campaign (n=26). Data from five consecutive monitoring days, with daily in-home visits to download personal PM sampler data logger data, retrieve $PM_{2.5}$ personal filter samples, and download real-time, personal nephelometer were recovered. The personal PM sampler consisted of a two-channel, battery-powered sampling system that contained a data logger to monitor personal activity, battery voltage, air temperature, and pump pressure in both channels (Lawless, 2003). The activity monitor used was based on the co-planar capacitance plates approach. $PM_{2.5}$ PEM (Personal Environmental Monitor, MSP, Inc.) inlets collected a Teflon filter for gravimetric mass

and PM speciation analysis, and a quartz filter for EC (elemental carbon) and OC (organic carbon) analysis. A passive mode MIE personalDataRAM nephelometer (Thermo Fisher Model pDR-1000 uncorrected for aerosol or relative humidity influences and a HOBO H8 (Onset Computer Corporation) measured PM concentration and temperature-relative humidity, respectively (Howard-Reed et al, 2000; Wallace et al., 2006). Participants wore a specially constructed vest that held the PEM inlets near the breathing zone and the nephelometer at waist level. The vest was made of light blue or light gray nylon, weighed 2.5 kg, and pump noise was less than 40 dB. Williams et al. (2003a) provides additional details. The study protocol asked participants to wear the vest at all times, except when sleeping, bathing, or riding in an automobile. In these instances, the vest was to be kept in the same room or within the automobile passenger compartment. Participants were not informed that their compliance with study protocols was being monitored.

Waking and mass wearing compliance was calculated from the personal PM sampler logger and nephelometer data. The capacitance sensor movement, data logger temperature, and nephelometer concentration and temperature data were loaded into a Visual Basic program that displayed the traces graphically on a common time scale (Figure 1). The analyst first considered the activity signal (top panel), then the logger pump temperature (second panel), and finally the nephelometer temperature (fourth panel) in deciding whether the sampler was being worn at any time and sleep periods and establishing data inclusion points. The program then calculated the cumulative time contained within the start and end of the waking compliant interval during the 5 days of data collection per individual and summarily the waking wearing compliance and mass wearing compliance. The mass wearing compliance ranges selected were 10-20 $\mu g/m^3$, 20-30

μg/m^3, 30-50 μg/m^3, 50-100 μg/m^3, and greater than 100 μg/m^3. These ranges were based on the distribution of PM concentrations measured with the nephelometer.

Effects of study subjects and monitoring conditions on the waking and mass wearing compliance were investigated using a general linear model (SAS v9.1.3, Cary NC). The type of cohort, season, gender, occupation, PM level, and all interactions of these variables were initially included in the model as independent variables. A second model substituted participant identification number for cohort. To identify a meaningful subset of predictors, non-significant or auto-correlating variables were removed stepwise from the model. The significance of the effect was tested at the 5% level.

Results

Table 1 presents the calculated waking wearing compliance across all seasons for each participant. Table 2 shows the average waking or mass wearing compliance, the average standard deviation in the wearing compliance measurement, and the coefficient of variation (CV) for all participants and seasons calculated by three independent analysts. Coefficients of variation from 0.21 to 0.28 across the waking and mass wearing compliance assessments provided evidence the three analysts interpreted wearing compliance values from the data logger and nephelometer traces similarly. The consistency in the CVs between the different measures of wearing compliance indicated measurement error did not vary as a function of PM concentration.

The statistical analysis results for the two linear models are shown in Table 3. Independent variables in the first model were Cohort, Gender, Occupation, Season, and PM concentration ranges used to define mass wearing compliance. PM concentration range, Gender, and Occupation were statistically significant. Figure 2 shows the increase in wearing compliance

as the real-time PM concentration exposure increases. A slight difference in wearing compliance between the two study cohorts might be evident (Figure 3), but the fewer number of participants in the defibrillator cohort cautions against this interpretation. The second model examined differences between individual Participants (ID), Season, PM concentration ranges, ID-Season interaction, and ID-PM range interaction. Wearing compliance values varied between participants and PM concentration range. As with the first model, seasonal variation in wearing compliance was not evident. However, the significant ID-Season interaction (p-value < 0.0001) indicated individual participants exhibited seasonal variations in their wearing compliance. The ID-PM range interaction was not significant.

Discussion

The statistical insignificance of cohort on waking and mass wearing compliance was important. Since participant recruitment for the study used a convenience cohort approach with specific inclusion criteria (Williams et al., 2003a), a difference in wearing compliance between the cardiac defibrillator and hypertensive cohorts was expected. We theorized the defibrillator cohort would be more compliant because of their more compromised health status and their overall enthusiasm as participants in the research. The general trend does show that compliance with study protocols might be related to the participant's interest in the study, characterized by health status where all of the defibrillator cohort had an average waking wearing compliance $\geq$ than 0.63 (Figure 4).

Each participant had a profound impact on their waking and mass wearing compliance, with men wearing having higher waking compliance than women (0.66 vs. 0.57) and retired

participants having higher waking compliance than those that worked outside the home (0.61 vs. 0.56). However, it appears that individual decisions determined the participant's wearing compliance level more than general participant characteristics because the average values ranged from 0.33 to 0.93. The almost significant participant-mass wearing compliance interaction term also confirmed that participants tended to wear the sampling vest when exposed to elevated PM concentrations. Common participant decisions that caused poor wearing compliance and biased exposure levels included leaving the vest in another room while inside the house, leaving the vest inside when outside of the home, and leaving the vest inside the car after arriving at their destination. Such protocol violations could have caused positive or negative biases in exposure levels covering several orders of magnitude.

Closer examination of the data in Table 1 shows the 26 participants fell into four groups. Two groups showed either continual increase (6 participants) or decrease (4 participants) in wearing compliance. The other two groups had either stable wearing compliance with less than ±0.07 variation in the average during the study (6 participants), or showed a cyclical increase/decrease pattern between seasons (10 participants). Participants cited numerous reasons for not wearing the sampling vest used in the study. Personal comfort was one common reason. Another explanation was embarrassment. Some participants felt embarrassed by the questions and stares received while wearing the vest in public. Sometimes an employer would not allow the vest to be worn at work. Other reasons were also cited.

The concept of mass wearing compliance should identify whether a participant is wearing the personal exposure monitor according to study protocols when their exposure to PM or other pollutants occurs. A fully waking wearing compliant participant will also be mass wearing

compliant at all PM concentration levels. If the minimum mass concentration is 10 :g/m^3 or higher, the lowest mass wearing compliance is the same as waking wearing compliance. It is also true that a participant may be poorly waking wearing compliant, yet be wearing the sampler during every significant PM exposure, whether by choice or by chance. Measured concentrations of 100 :g/m^3 and above are almost always associated with proximity to a PM source (Wallace et al., 2006). As a result, mass wearing compliance at 100 :g/m^3 or higher is usually 1.0.

The maximum, 75%, median, and 25% mass wearing compliance values of the distributions increased steadily with increasing concentration thresholds. Mass wearing compliance quartiles for each concentration threshold exceeded the waking wearing compliance only for concentrations above 30 :g/m^3. This suggests that the highest values of personal concentration occurred during waking hours and that the participants were present. Comparison of each participant's nephelometer concentration traces with their time-activity diaries for potential PM generating activities such as cooking confirmed this conclusion (Rea et al., 2001; Wallace et al., 2006).

Quantitative assessment of personal exposure monitor wearing compliance should be more useful than evaluation of recruitment and retention efforts or exploring sociological differences between participants. One goal of personal sampler wearing compliance monitoring is reducing exposure misclassification which results from noncompliant personal samples providing unrepresentative exposure data. Such exposure estimates do not represent the participant's true exposure and weaken the statistical relationship between exposure and any health effect determination. Zhao et al. (2007) used monitor wearing compliance monitoring to arbitrarily set a minimum threshold of 75% waking wearing compliance for defining personal

samples as representative of the participant's exposure. Rodes et al. (2010) and Brook et al. (2010) used a slightly lower waking wearing compliance value (60%) as being acceptable to increase the sample size included in their statistical analysis.

Figure 5 plots the weekly average personal-to-indoor $PM_{2.5}$ ratio for all participants across all four seasons as a means to develop a minimum compliance threshold. The scatter in the data might represent poor personal monitor wearing compliance. Other explanations might be concentration differences between personal and indoor monitors due to proximity to the source (Wallace et al., 2006), and significant exposures in other microenvironments. Initial analysis of all data did not provide a statistically significant linear regression (p-value = 0.14). Removal of the eight data with the lowest waking wearing compliance (hollow symbols) was necessary before the remaining data (filled symbols) showed a statistically significant regression (p-value = 0.018). This analysis suggested a minimum waking wearing compliance threshold of 0.4 could be considered representative of the participant's exposure. This value is less than the value of 0.6 suggested by Rodes et al. (2010) and necessary for a statistically significant relationship between $PM_{2.5}$ exposure and cardiovascular effects (Brook et al., 2011) in the DEARS cohort. A plausible explanation for the difference is that DEARS enrolled a general population cohort while this cohort consisted of health compromised senior citizens. If a minimum, cohort specific threshold can be established, it becomes possible to weight personal exposure concentrations to provide an estimate of what the participant's exposure might have been with perfect waking compliance. Although not conducted in this analysis because all data were not available, the determination of the minimum waking wearing compliance threshold should consider time-activity diary and questionnaire information that identify time spent in various microenvironments and participant

activities. This approach has the potential to be of value in determining the amount of useable exposure data collected for health studies and therefore reduce exposure misclassification.

Conclusions

This paper presented a quantitative examination of personal exposure protocol compliance. Waking wearing and mass wearing compliance were established. Wearing compliance varied between participants. Differences in wearing compliance between cohorts of different health status were not statistically significant. Participant fatigue with personal exposure monitor wearing protocols over the longitudinal study was not evident.

One area of improvement is development of automated methods for calculating compliance from activity sensor and other data. Application of signal processing algorithms to combine activity sensor, temperature, and real-time PM concentration data should be explored. Real-time signal processing of accelerometer and nephelometer data could also provide an estimate of inhaled dose when calibrated for specific individuals; the result being a robust clinical tool for identifying exposure events that trigger acute respiratory attacks.

Compliance estimations have potential value in significantly reducing exposure misclassification. A wearing compliance threshold will allow estimation of a participant's exposure assuming perfect protocol compliance, allow accurate identification of the most exposed portion of the population, and strengthen the statistical relationship between exposure and adverse health outcome. We suggest a combination of personal to indoor ratios and questionnaire data be used to develop a minimum waking wearing compliance threshold. For this cohort, a threshold of 0.4 was representative of the participant's exposure. However, compliance thresholds are most likely cohort specific and need to be determined for each research study.

Acknowledgments

The U.S. Environmental Protection Agency, through its Office of Research and Development partially funded the research described here through Contract 68-D-99-021 (RTI International), EP-D-04-065 and EP-D-68-00-206 (Alion Science and Technology), and EP-D-04-068 (Battelle Columbus Laboratories). Mention of Trade names or commercial products does not constitute an endorsement or recommendation for use. Carry Croghan and Carvin Stevens of the US EPA are acknowledged for their assistance in data validation.

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Figure 1. Example of data logger and MIE data traces superimposed by the Visual Basic program for waking and mass compliance determination. The analyst uses the activity signal (top panel), data logger temperature (second panel), the MIE concentration trace (third panel) and MIE temperature (fourth panel) to decide whether the sampler was being worn at any time. Waking wearing compliant or non-compliant intervals identified by the analyst are marked. The time period when the participant is asleep is not included in the waking wearing compliance calculation.

Figure 2. Waking and mass compliance distributions across all participants and all seasons. Quartiles, minimum, and maximum values are shown.

Figure 3. Waking and mass compliance distributions by cohort. The hypertensive cohort compliance distribution trended lower, but the difference was not statistically significant. Quartiles, minimum, and maximum values are shown.

Figure 4. Four-season average, maximum, and minimum waking compliance values by participant cohort (HT = hypertensive, CD = cardiac defibrillator), gender (F = female, M = male), and employment status (E = Employed, R = retired).

Figure 5. Personal-Indoor PM2.5 ratio as a function of participant waking compliance. Hollow symbols represent data omitted from the linear regression analysis to identify the minimum threshold of 0.4 that identifies representative personal exposure data.

Figure 1.

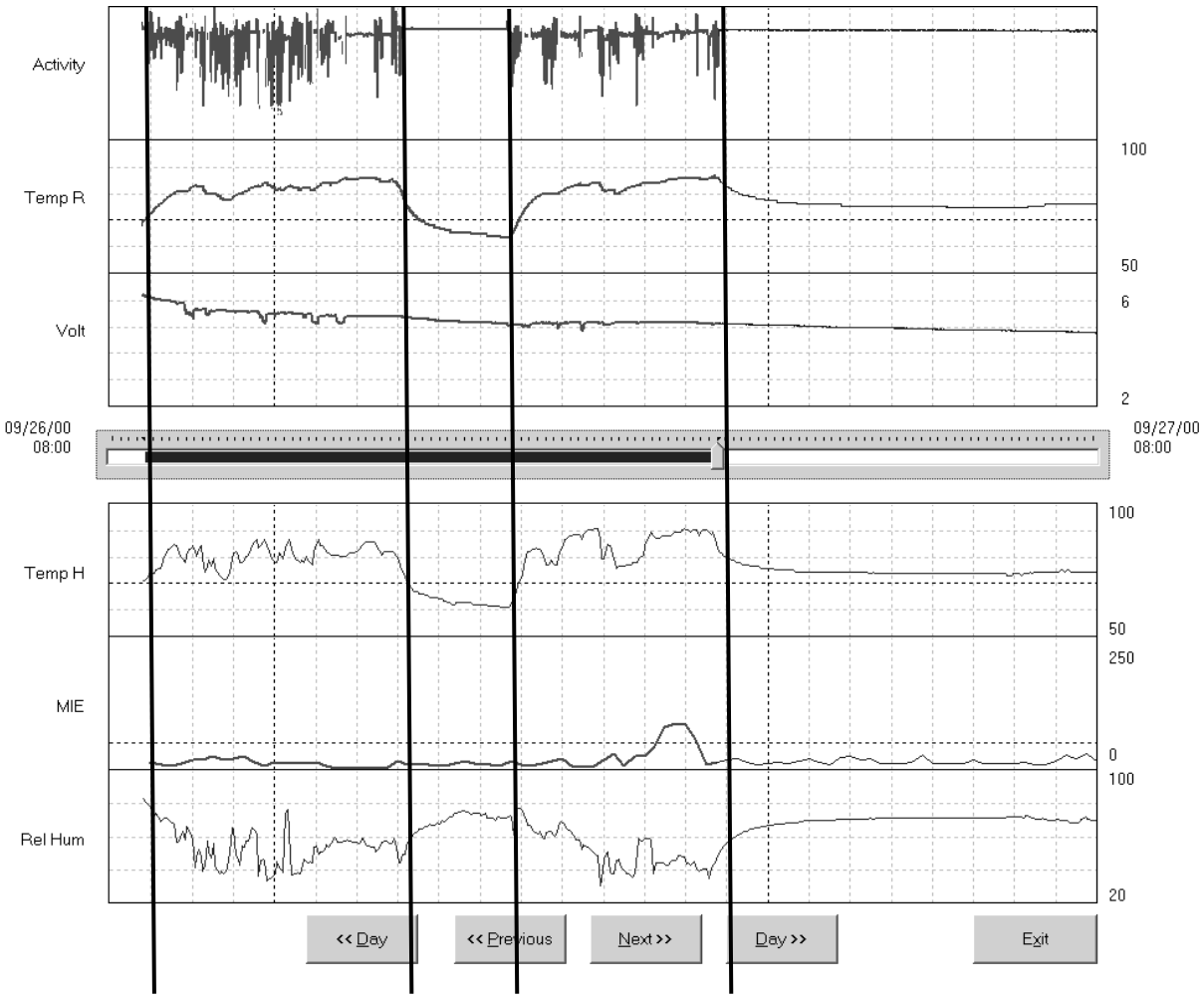
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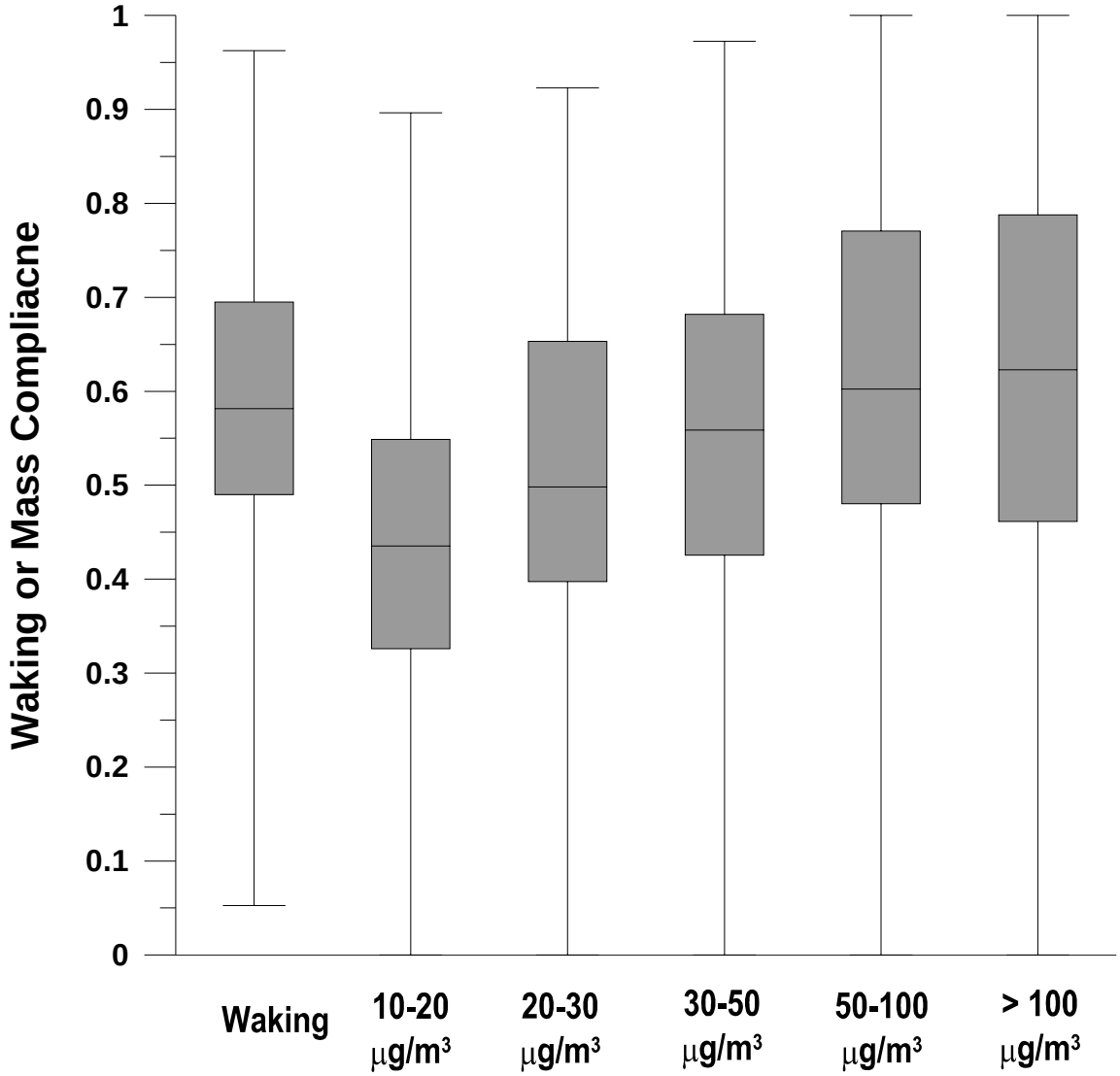
Figure 2.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50-100 μg/m³
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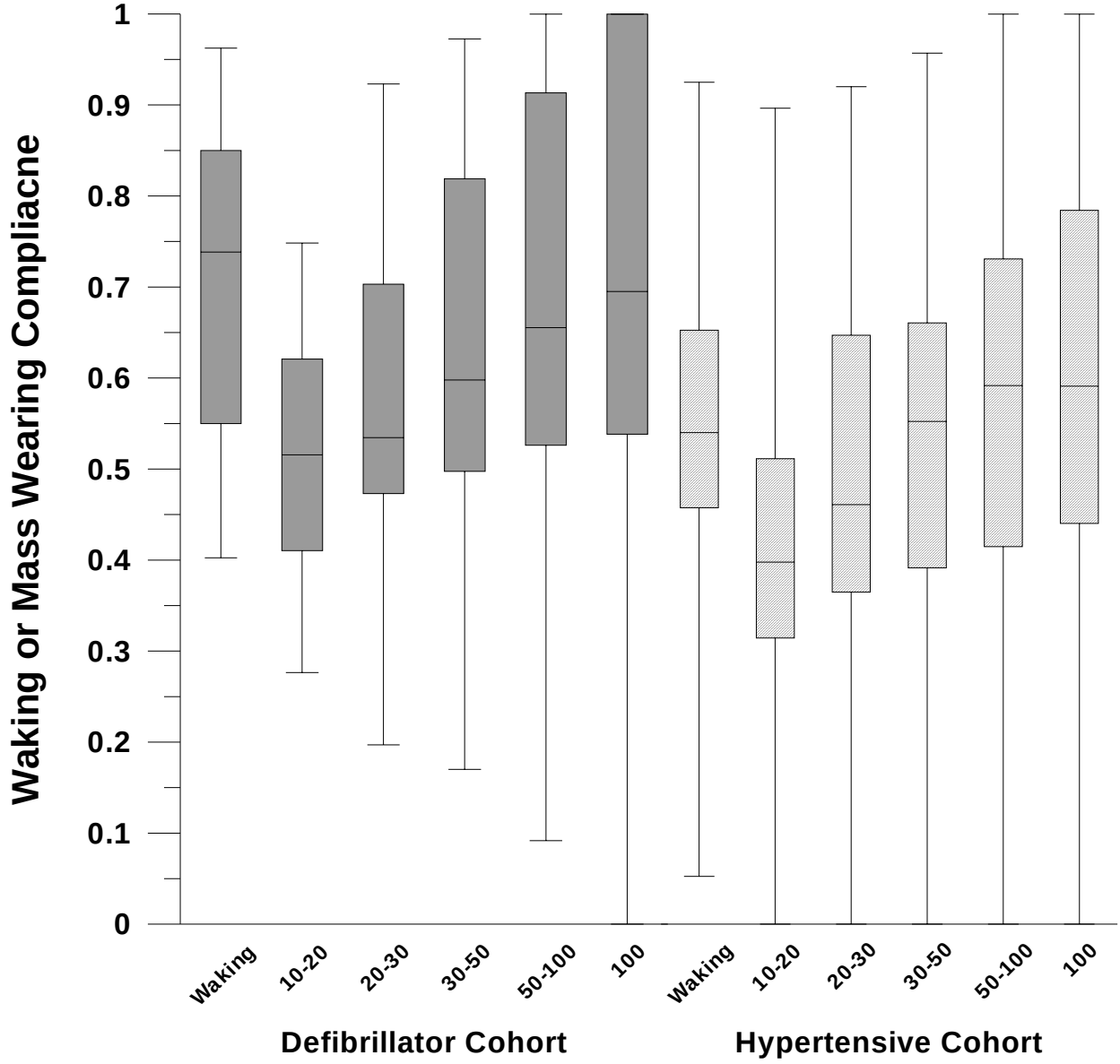
Figure 3.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1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Waking
10-20
20-30
30-50
50-100
100
Waking
10-20
20-30
30-50
50-100
100
Defibrillator Cohort
Hypertensive Cohort

Figure 4.

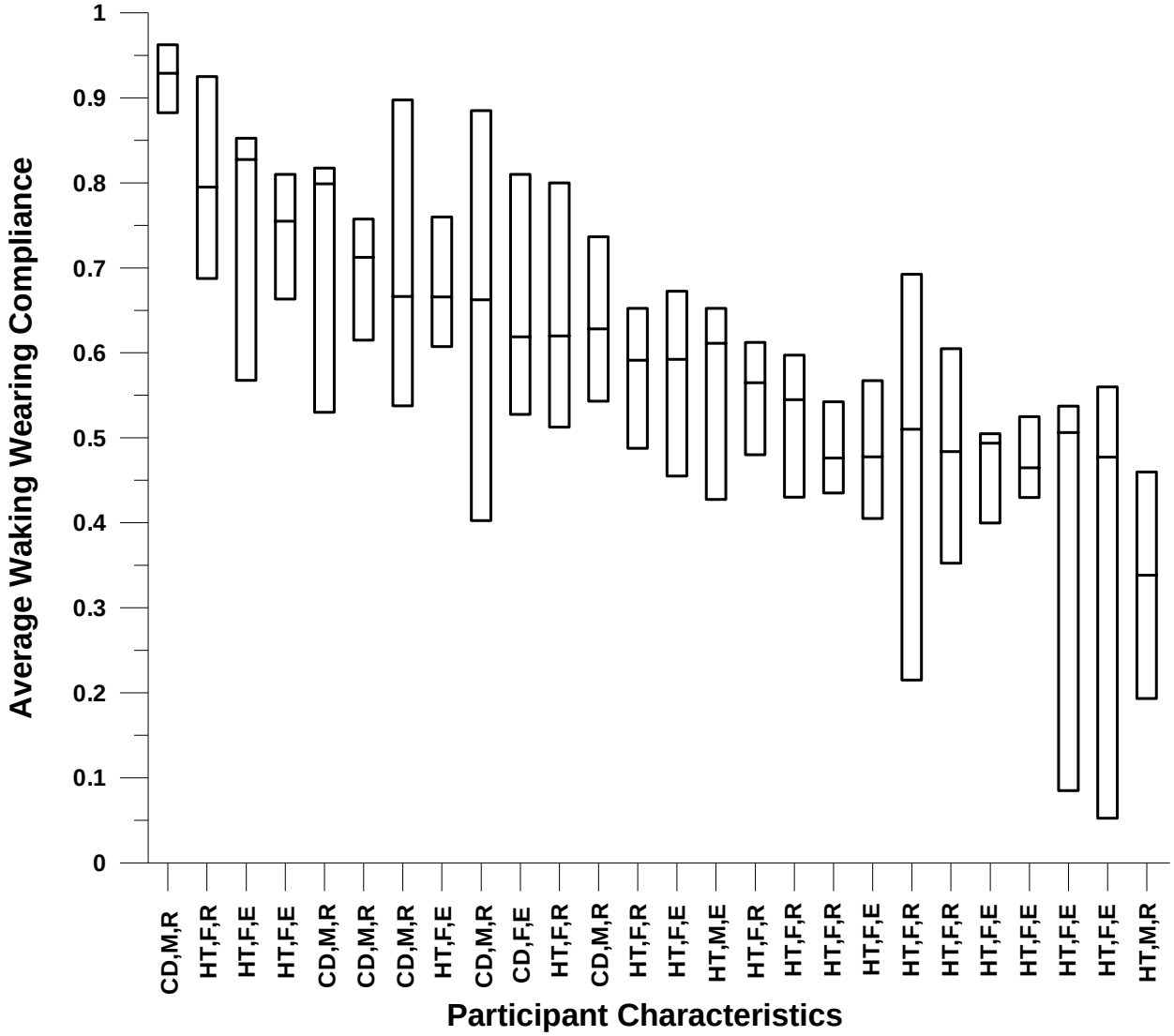
Average Waking Wearing Compliance
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
CD,M,R
HT,F,R
HT,F,E
HT,F,E
CD,M,R
CD,M,R
CD,M,R
HT,F,E
CD,M,R
CD,F,E
HT,F,R
CD,M,R
HT,F,R
HT,F,E
HT,M,E
HT,F,R
HT,F,R
HT,F,R
HT,F,E
HT,F,R
HT,F,R
HT,F,E
HT,F,E
HT,F,E
HT,F,E
HT,M,R
Participant Characteristics

Figure 5.

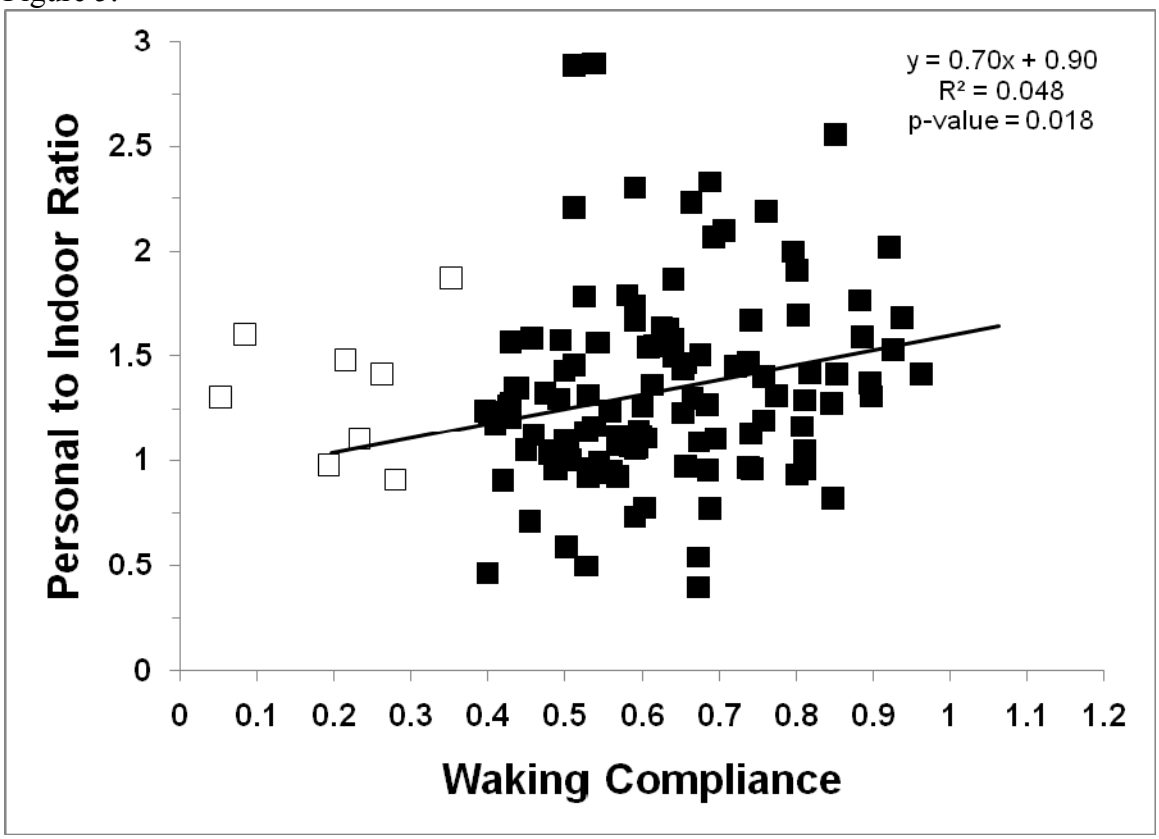
y = 0.70x + 0.90
R² = 0.048
p-value = 0.018
Personal to Indoor Ratio
Waking Compliance
0
0.5
1
1.5
2
2.5
3
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
1.1
1.2

Table 1. Seasonal average waking compliance for each participant, identified by cohort (HT = hypertensive, CD = cardiac defibrillator), gender, and employment status. Results are the average of the values calculated by the three analysts.

Table 2. Variability in the waking and mass compliance measurements across three analysts as represented by the coefficient of variation (CV). Values are the grand average and average standard deviation across all participants and seasons.

Table 3. General linear model results from two analyses. Model 1 examined effect of cohort, gender, occupation, season, and PM concentration range on compliance. Model 2 replaced cohort, gender, and occupation with individual participants (ID) and added the interaction terms.

Table 1.

Cohort	Gender	Occupation	Summer	Fall	Winter	Spring	Average
HT	Female	Retired	0.69	0.90	0.93	0.70	0.80
HT	Female	Retired	0.51	0.22	0.51	0.69	0.48
HT	Female	Retired	0.50	0.46	0.54	0.44	0.48
HT	Female	Employed	0.41	0.42	0.57	0.54	0.48
HT	Male	Employed	0.43	0.65	0.59	0.63	0.58
HT	Female	Retired	0.50	0.59	0.43	0.60	0.53
HT	Female	Employed	0.44	0.49	0.53	0.43	0.47
HT	Female	Employed	0.54	0.51	0.09	0.50	0.41
HT	Female	Retired	0.61	0.41	0.35	0.56	0.48
HT	Female	Employed	0.45	0.56	0.05	0.51	0.39
HT	Female	Retired	0.48	0.61	0.60	0.53	0.56
HT	Female	Retired	0.58	0.60	0.65	0.49	0.58
HT	Female	Employed	0.66	0.61	0.76	0.68	0.67
HT	Female	Employed	0.67	0.46	0.60	0.59	0.58
HT	Female	Retired	0.51	0.67	0.80	0.57	0.64
HT	Female	Employed	0.40	0.51	0.49	0.50	0.47
HT	Female	Employed	0.81	0.85	0.85	0.57	0.77
HT	Female	Employed	0.66	0.74	0.77	0.81	0.75
HT	Male	Retired	0.46	0.28	0.40	0.19	0.33
CD	Male	Retired	0.92	0.88	0.96	0.94	0.93
CD	Male	Retired	0.40	0.48	0.85	0.89	0.65
CD	Male	Retired	0.90	0.74	0.54	0.59	0.69
CD	Male	Retired	0.54	0.58	0.74	0.67	0.63
CD	Male	Retired	0.53	0.80	0.82	0.80	0.74
CD	Male	Retired	0.74	0.69	0.62	0.76	0.70
CD	Female	Employed	0.53	0.81	0.55	0.69	0.64

Table 2.

	Waking	**10-20 μg/m^3**	**20-30 μg/m^3**	**30-50 μg/m^3**	**50-100 μg/m^3**	**> 100 μg/m^3**
Grand Avg	0.59	0.44	0.51	0.56	0.60	0.60
Avg Std Dev	0.15	0.09	0.11	0.12	0.14	0.17
CV	0.25	0.21	0.21	0.22	0.23	0.28

Table 3.

Model 1	**DF**	**Mean Square**	**F-value**	**p-value**
Cohort	1	0.14	0.09	0.775
Gender	1	0.28	6.32	*0.012*
Occupation	1	0.19	4.29	*0.039*
Season	3	0.02	0.50	0.683
Conc range	5	0.41	9.45	*< 0.0001*

Model 2	**DF**	**Mean Square**	**F-value**	**p-value**
ID	25	0.52	44.28	*<0.0001*
Season	3	0.02	1.87	0.1348
Conc range	5	0.41	35.33	*< 0.0001*
ID*Season	125	0.01	1.23	*<0.0001*
ID*Conc range	75	0.11	9.45	0.0676