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## **Employers' Concerns Regarding Research Participation**

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## **Abstract**

Occupational health research is dependent on the cooperation and participation of employers. We describe employers' reasons for non-participation in a prospective study examining risk factors for carpal tunnel syndrome (CTS) and the usefulness of pre-placement, post-offer nerve conduction screening. Companies were contacted to solicit participation. Non-participation explanations were reviewed. Of 73 eligible employers, a total of 58 declined participation (participation rate: 20.5%). Reasons for non-participation included lack of interest (32.8%), liability concerns (awareness of CTS may increase workers' compensation (WC) claims) (22.4%), time constraints (19%), lack of direct benefit to the employer (8.6%), and company policy restraints (6.9%). Data from one employer were reviewed to determine if WC claims for upper extremity disorders increased as a result of study participation. Claim rates showed no change in trend pre and post study inception. Expanding much needed research to prevent occupational injuries and illnesses requires addressing employers' concerns and promoting research benefits.

**Key Words:** workers' compensation, workplace, carpal tunnel syndrome, occupational health, employees, research subject recruitment, research

## **Background**

In 2005, an estimated 4.2 million nonfatal workplace injuries and illnesses occurred in the U.S. resulting in associated costs from loss of functional status, quality of life, and long-term productivity.<sup>1</sup> The magnitude of workplace hazards is underscored by the fact that occupational injuries and illnesses are often underestimated due to underreporting from companies,<sup>2</sup> exclusion of various employee categories from national estimates,<sup>2,3</sup> lack of recognition of the work-relatedness of some disorders,<sup>3</sup> and changes in federal record-keeping regulations.<sup>4</sup> To better understand and effectively reduce occupational illnesses, injuries, and related costs, researchers must often depend on the cooperation and participation of employers to provide access to working populations. The ability to contact and recruit working adults is important to the study of work-related diseases, and also to the study of population health since about 60% of adults are employed.<sup>5</sup>

Despite the need for employers' support in occupational research, techniques to recruit and build such partnerships are rarely explored. While a number of studies exist on the recruitment of individual research participants<sup>6,7</sup> few report participation rates of employers or reasons for employer involvement or non-involvement in research studies.<sup>8,9</sup> This lack of data on employers' decisions related to research participation is evident in the worksite health promotion literature and to an even greater extent in the occupational safety and health literature.<sup>10,11</sup> Based on available literature and personal experience, employers might be reluctant to participate in research focused on work-related disorders for several reasons. Some might be concerned about the cost in time, money, and manpower of conducting research within normal work procedures<sup>8,10,11</sup> and

its relevance to, or distraction from their primary goal of delivering a product or service. Additional reasons cited for employer non-participation include lack of interest,<sup>10</sup> rapid turnover of senior management,<sup>10</sup> company policy,<sup>10</sup> and satisfaction with current safety record.<sup>11</sup> Others might also worry that involving employees in research studies will raise worker awareness or knowledge about the potential work-relatedness of some disorders, thus increasing the reported rates of occurrence and workers' compensation (WC) costs. While some employers' concerns can be addressed by study design or through recruitment materials, easing concerns regarding a possible increase in WC claims with employers is difficult given the lack of published literature on the topic. To our knowledge, the only study that examined the effects of raising workers' awareness and knowledge from a workplace screening and employee education found these interventions had no effect on the reports of Occupational Safety and Health Administration (OSHA) recordable injuries, WC claims and costs, or commercial insurance visits during an 11 month follow-up period.<sup>12</sup>

Recruitment of employers proved more difficult and time-intensive than expected in a prospective study of work-related risk factors for carpal tunnel syndrome (CTS) and the usefulness of pre-placement, post-offer nerve conduction screening. To share our challenges and lessons learned, we describe strategies for company recruitment and reasons for employers' non-participation in our Predictors of Carpal Tunnel Syndrome (PrediCTS) study. In addition, we examined frequency of WC claims before and after research participation to determine if employees' involvement in research affected claim rates.

## **Methods**

### *Study Design Requirements*

The current study was conducted as part of the PrediCTS study, an ongoing prospective study of CTS in newly hired workers. The overall PrediCTS study aims are 1) to assess personal and work-related risk factors associated with CTS and 2) to evaluate the utility of pre-placement, post-offer nerve conduction tests. To accomplish these goals, newly hired employees were recruited from participating companies in the greater Metropolitan area of St. Louis. Employer support and approval of the study were required prior to recruitment of new workers. Employers provided access to potential study participants via new employee orientations, existing post-offer health testing, and company mailings to employees. Eligibility criteria limited recruitment to newly hired employees at least 18 years of age and working a minimum of 30 hours per week. Individuals who were pregnant, had a prior diagnosis of CTS, had peripheral neuropathy, or had contraindications to nerve conduction testing were not eligible to participate. This study was approved by the Washington University School of Medicine Institutional Review Board and all subjects provided written, informed consent. Because of the potential for WC litigation, we obtained a Certificate of Confidentiality in order to provide the highest possible protection of confidentiality for employers and individual workers. A total of 1108 participants were enrolled into the study.

Employees who agreed to participate underwent a one-hour baseline screening protocol which included a nerve conduction test using the NC-stat® (Neurometrix Corporation, Waltham, MA), an automated nerve testing device; a physical exam of the arms and

hands; and a self-administered questionnaire that assessed demographics, symptoms, past work history, medical history, and work exposures. All data collection was conducted by a member of the research team: an occupational therapist, an occupational therapy assistant, a physical therapy assistant, or a medical student. Baseline testing was performed at a convenient time and location for subjects to encourage participation. Beyond the baseline testing, participants received additional questionnaires by mail at 6 months, 18 months, and 36 months after baseline. Approximately one-third of the cohort also received worksite observations six months post-hire. All data collection activities, except worksite observations, were intended to occur outside of normal working hours, unless the company or organization preferred activities occur during work hours.

To minimize the demands of the study for each individual company, recruitment and data collection needs were tailored to fit the natural work processes and hiring procedures of the company. For example, some employers allowed a member of the study team to present the study overview and invitation to employees at the company orientation, while other employers preferred to present the information themselves or to provide a study invitation to employees through the mail. Interested employees were asked to contact the study team to arrange baseline screening at a private testing location on their worksite, usually after work hours. Additionally, several companies allowed recruitment and baseline testing to occur at the time of a scheduled pre-placement, post-offer screening. The research study team assumed responsibility for coordinating and conducting all data collection within the companies.

### *Identification of Potential Employers*

Prior to the initiation of study activities, our research team obtained agreements of study participation from several large organizations that anticipated hiring new workers.

However, from the time of grant submission to study implementation, hiring levels decreased within our previously identified partners due to an economic downturn, thus creating a need to recruit new employers to the study. From March 2004 to July 2006, several methods were used to identify potential employers for recruitment to the study. Networking with local occupational health clinics and other health organizations provided the study team with current information about local companies' hiring status and contact information. Internet searches for job postings through websites, newspapers and online human resources departments also identified employers who were actively hiring, a key eligibility requirement of the study. Local business journals and news media sources were scanned daily to identify prospective companies based on news of current or future business activities. We sent informational mailings to members of ten local organizations whose activities involved safety and health, trade unions, insurance, and workers' compensation. These mailings invited group members to contact the study team with names of potential employers. Study team members also provided information on our study recruitment at meetings of employer, insurance, and workplace health and safety groups. Individual contacts with members from unions both locally and nationally were utilized to foster labor support for participation. Press releases and news articles were posted in six local sources for public, labor and health news. Public and private database searches, guided by the study design, allowed selection of companies based on size (number of employees), location, Standard Occupational Classification industry

codes, and availability of contact information. We attempted to recruit employers with both high and low hand-intensity jobs in order to contrast physical exposures in subjects who ultimately developed signs and symptoms for CTS. Employers also had to meet the following eligibility criteria: 1) accessibility to workers on the jobsite to directly observe and assess workplace tasks and physical exposures; 2) low levels of variability in employee work activities; 3) located in the greater St. Louis Metropolitan area; and 4) employing over 100 workers with the intention of hiring at least 20 new employees over the course of a one-year period of time. We excluded smaller employers because the number of subjects studied would be small in relation to the recruitment effort required.

### *Employer Recruitment*

To recruit targeted employers, study team members contacted the human resources and/or safety directors of manufacturing, telecommunication, distribution, healthcare, and construction companies through mail, fax, telephone, or email. Recruitment materials included a personal invitation letter, a one-page outline of study goals and procedures, and a more in-depth description of the study. Employers were informed of potential study benefits for their organization, such as receiving composite data on their workforce with comparative benchmarks to other local employers and a cost-benefit analysis of pre-placement, post-offer screening options tailored to their workforce. A study team member contacted each company by telephone utilizing a phone script that outlined participation requirements. Most often, the company had already received general study information via an initial mailing. Employers who declined participation were asked to describe reasons for non-participation with an open-ended question. We categorized the different

employer responses given for non-participation and report the frequencies of these categories.

### *WC Claim Rates*

To address the concern that employer participation in a research study may lead to increases in WC claims, we examined WC data from the largest participating employer, a large urban teaching hospital. Specifically, data were reviewed to determine if claim rates increased following employee participation in the PrediCTS study. For this company, employees were eligible for enrollment into the study based on job title and invited to participate at the time of their pre-placement, post-offer health screening; we recruited hospital support staff with little or no direct patient contact to minimize concerns over patient confidentiality. Our study's recruitment of subjects mirrored the hiring patterns of the hospital, where housekeepers and food service workers were the largest group of newly hired workers. Following baseline testing, participants received a brief letter describing their own baseline nerve conduction and physical exam results; results were classified as 1) normal, 2) borderline for some findings or 3) abnormal for some findings with the suggestion to seek medical help from their personal physician.

We assessed differences in WC claim rates of upper extremity musculoskeletal disorders (UE MSDs) for the period two years prior to and two years following study inception, using both a narrow and broad UE MSD case definition. The narrow case definition included claims that listed specific causation by repetitive motion or miscellaneous cumulative causes to the upper extremities. The broad case definition also included

claims caused by strain or injury by lifting, holding or grasping, pushing, reaching, and twisting, or other unspecified causes. WC claim rates were calculated by dividing the number of UE MSDs claims for each year (July 1 –June 30) by each year’s productive work hours and are presented per 10,000 full-time equivalent (FTE) workers. Rate ratios (RR) and 95% confidence intervals (CI) were calculated to determine statistical significance.

In addition, we considered possible survivor bias since potential WC claims might have been missed due to employees leaving the teaching hospital before a claim was filed. We assessed if workers ending employment at the hospital differed significantly from those remaining employed in terms of self-reported physical symptoms or job restrictions and changes due to symptoms six months after baseline. All statistical analyses were conducted using SPSS (version 14.0).<sup>13</sup>

## Results

### *Employer Participation*

Figure 1 presents a flowchart of the number of eligible, responsive, and participating employers. We initially considered 180 employers for potential recruitment. Twenty-six (14.4%) did not respond to mailings or multiple telephone calls. Of the 154 responding companies, 49 (31.8%) did not meet study eligibility requirements. The most common cause for ineligibility was hiring of part-time, temporary or seasonal workers rather than full-time workers. A few companies were ineligible because they employed predominately non-English speaking workers for whom our study was unable to accommodate the language barrier. Several companies were eliminated because it would have been infeasible to collect the worksite data; the employees frequently traveled, such as long haul truckers or barge workers, or the company was located too far outside of the Metropolitan St. Louis area. Other companies employed fewer than 100 people. Thirty-two (30.5%) of the remaining potential companies were not hiring new workers. Of the 73 companies known to be eligible, 15 (20.5%) agreed to participate in the PrediCTS study and 58 (79.5%) declined. Figure 2 illustrates the reasons most commonly stated for non-participation among the 58 employers who declined. These included ‘unspecified lack of interest’ (n=19; 32.8%), ‘liability concerns’ (n=13; 22.4%), ‘time constraints’ (n=11; 19.0%), ‘lack of direct benefit to the employer’ (n=5; 8.6%), and ‘company policy restraints’ (n=4; 6.9%). We were unable to obtain reasons for non-participation for six (10.3%) employers who declined participation. The category ‘liability concerns’ included employers who specifically stated concern that study participation would increase awareness of CTS and in turn may increase workers’ compensation (WC) claims or

declared other liability concerns. 'Time constraints' included employers who expressed lack of time at the management level or who felt that additional programs or operational changes within the company would overwhelm employees. 'Lack of direct benefit to employers' included employers who didn't see the study as beneficial to them, who didn't believe their employees were at risk for CTS, or who only desired to participate in intervention studies. Employers in the 'company policy restraints' category responded that their organization does not participate in research studies or reported having a policy prohibiting research participation.

The 15 employers that agreed to participate included four manufacturing plants; three healthcare facilities; three trade union apprenticeship training schools; one biotech company; one beverage bottling distribution center; one insurance company; one commercial dairy; and one utility company. Our research team had prior working relationships or personal contacts with eight of these employers.

### *WC Claim Rates*

A total of 427 study participants were employed at the teaching hospital; at time of analysis, 72% of this population had been enrolled in the study for at least one year. The participants were 62% female and 65% black, with a mean age of 34 years (SD 11.8). Table 1 lists the frequency of the participants' job types to provide an overview of the work performed by participating employees. The largest employment category among the participants was housekeepers (41.2%), which reflects the hospital's hiring pattern in non-clinical jobs.

Claims were evaluated using two different case definitions. Using the narrow case definition (specific causation attributed to repetitive or cumulative actions), 75 UE MSDs claims were filed with the teaching hospital for the two years before and 64 claims after the study's inception (rates of 17.5 and 15.1 per 10,000 FTE workers respectively). These rates did not differ significantly (RR 0.86, 95% CI 0.62-1.20). Furthermore, no PrediCTS study participant filed a WC claim under this definition. The broader case definition of all UE MSDs yielded 331 claims made to the facility prior to and 319 claims after the study's inception (77.2 and 75.1 claims per 10,000 FTE workers respectively, RR 0.97, 95% CI 0.83-1.14). Four PrediCTS study participants filed WC claims under this definition. The four claims filed were strain or injury to thumb by pushing and pulling, strain or injury to shoulder using tools, strain or injury to wrist due to twisting, and injury to shoulder by lifting. Thus, no PrediCTS study participants filed a CTS claim.

To examine potential survivor bias and evaluate whether subjects left the teaching hospital for reasons related to injuries, the reported symptoms and lost work time on questionnaires of participants who left the hospital were compared to those who remained. Of the 235 study participants with 6 month follow-up data at time of analysis, three had dropped from the study and 68 left the teaching hospital. Of the study participants remaining at the hospital, 44% reported symptoms and 6% reported job restrictions or changes because of symptoms versus 37% and 5% reported by participants leaving the hospital (p-value 0.28 and 0.61, respectively).

## **Discussion**

This study examines recruitment challenges and reasons for employers' non-participation in a prospective study of CTS in newly hired workers. Of the 180 employers originally approached to participate in the PrediCTS study, only 73 were eligible. The participation rate among eligible employers was 20.5% (n=15). Reasons for non-participation provided by employers included general lack of interest on the part of employers, liability concerns, lack of time at the management level or employee level, perception that the study was not beneficial to the company, a belief that employees were not at risk for CTS, and presence of a company policy prohibiting research participation

Liability concerns were a major concern for employers, specifically the concern that study participation would increase employees' awareness of CTS and thus increase WC claims. However, participation in the PrediCTS study did not increase the rate of upper extremity WC claims in one participating employer, an urban teaching hospital for whom we had access to detailed claim data. Our results are consistent with Melhorn's study, which found no increase in OSHA recordable injuries or WC claims after a musculoskeletal screening program aimed at increasing employee education and awareness.<sup>12</sup> The lack of an increase in WC claims following participation relieved concerns expressed by some employers; additional study of this issue may help alleviate this barrier to recruitment. Liability concerns may also have driven some employers' responses of 'lack of interest' and 'company policy.' To the extent this is true, liability concerns could reflect a much larger contribution to non-participation than was found in this study.

The PrediCTS study design initially limited the number of companies that were targeted for recruitment. However, even after identifying employers appropriate for the research design, non-participation rates exceeded our expectations, which were based on our previous workplace intervention research.<sup>14-17</sup> Our study's employer participation rate of 20.5% is lower than the high employer participation rates reported by some health promotion researchers,<sup>18</sup> but is similar to the low participation rates, ranging from 9-22%, in four Dutch worksite-based interventions.<sup>8</sup> Past research has shown reasons for participation or non-participation for individual subjects,<sup>6,7,18</sup> but the reasons why employers may not participate has received little attention.<sup>8-11</sup> Consistent with our study, employers' satisfaction with their current safety records, company policies restricting research, and lack of interest, time, personnel, and resources have been cited as reasons for non-participation.<sup>8,10,11,19</sup> The theory of diffusion of innovations describes organizational factors predicting intervention adoption.<sup>20,21</sup> These organizational factors may also be useful to researchers recruiting employers into health studies. From the diffusion theory and our experience with the PrediCTS study, organizational factors that may be related to employers' participation or non-participation include: 1) intraorganizational variables, such as employer size, financial and organizational stability, centralization, and complex or diffuse organizational structures; and 2) leadership characteristics, such as attitudes of key leaders, management style, and endorsement of the importance of employee health and well-being.<sup>9,10,20-22</sup>

A limitation of our study is our lack of obtaining employers' reasons for participation in the PrediCTS study. Worker safety as a company priority has been one reason reported in the literature for research participation.<sup>11</sup> In the current study, presence of a previous working relationship with the employers approached was usually advantageous in securing participation. It is also important to consider the presence of trade unions when recruiting an employer. Unions have historically served as advocates to increase workers' safety and health<sup>23</sup> and some labor unions have reported that participation in occupational health research provides benefits to members and assists in collective bargaining.<sup>10</sup> In the PrediCTS study, trade apprenticeship programs were generally receptive and useful in providing direct access to an audience of potential study participants. Overall, union endorsement of the study was obtained with greater ease than that of general employer acceptance and participation. Nonetheless, while union support did help gain access to meet with key management leaders in the employers of interest, we found, like others,<sup>9</sup> that union support did not necessarily ensure employers' participation. Researchers should consider the role that positive or negative labor-management relations may play in recruitment of employers.<sup>10</sup>

### *Recommendations*

Based on the reasons given for employers' non-participation in our study, researchers recruiting worksites into etiologic or health promotion research could benefit by taking several factors into consideration when designing their study and recruitment strategies. A study's research design can facilitate or constrain recruitment by determining the eligibility criteria for potential employers and subjects, frequency of data collection and

need for access to the employees. For example, the need for newly hired workers due to the PrediCTS study design was a major barrier for employer eligibility. Protocols must be designed to minimize demand on employers' time and resources for administering the study within the company, and recruitment materials should highlight the actual resources required from the employer. Our study, for example, allocated research personnel to introduce the study during company orientations, prepare and distribute subject mailings, and schedule subject appointments. All communication with the subject occurred outside of work hours unless the company or organization preferred contact during work time.

Recruitment methods should aim to raise employers' awareness of the issue being studied, which in turn might evoke interest in the research study. Increasing awareness might also help companies understand how the specific research study could benefit them in the future. Additionally, offering incentives early in the recruitment process, an approach that has been effective in increasing individual-level recruitment,<sup>6,7</sup> has been used by other researchers to improve employer research participation.<sup>11,18</sup>

We agree with Kwak et al.<sup>8</sup> that there is a need for consistently reporting employer-level participation rates, as well as recruitment efforts and reasons for non-participation as described and illustrated in figures 1 and 2 of this publication. Studies published in the worksite health intervention literature,<sup>8,24</sup> and especially in the occupational health literature,<sup>10</sup> rarely report employer-level recruitment methods and participation rates. In a review of 25 worksite-based intervention studies, only 25% reported the proportion of participating employers from those determined eligible, and only one study listed the

original number of worksites approached for participation.<sup>24</sup> There is, however, a growing recognition of the need to publish and share employer-level recruitment procedures, outcomes, and lessons learned.<sup>8,10,24</sup>

Another implication of this article is the need for increased collaboration between occupational health and safety researchers, employers, and government agencies. The National Institute of Occupational Safety and Health has encouraged and led such integrated research through their partnership program, the National Occupational Research Agenda (NORA). Federal agencies and programs, such as NORA, should recognize the difficulties in securing worksite participation and help to foster more favorable employer-level recruitment.

## **Conclusions**

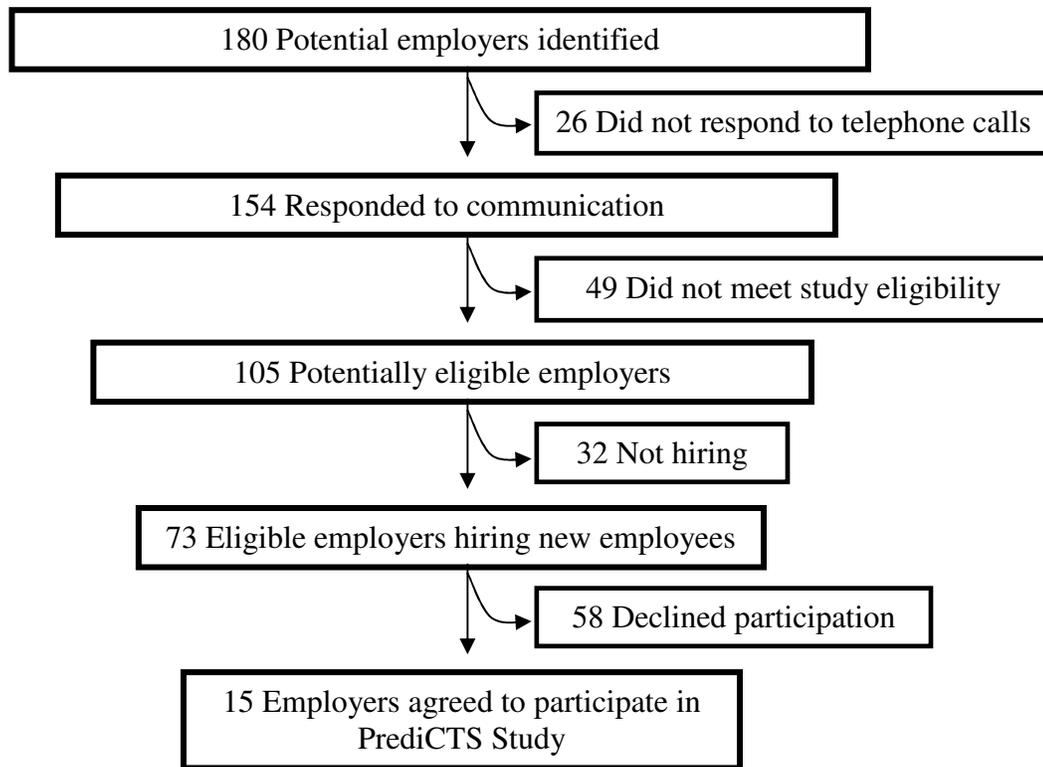
The current study contributes to the limited literature available exploring employers' decisions in research participation. Researchers must be aware of both study design constraints and potential reasons for employers' reluctance to participate in order to develop effective recruitment strategies. Tailoring recruitment methods to address and lessen known concerns at the outset may prove more time-efficient and successful in company-level recruitment. Ultimately, to increase the success of employer recruitment, researchers should publish their recruitment methods, participation rates, and lessons learned. In addition, employers should be aware that cooperation with occupational health researchers is critical in order to improve prevention strategies and reduce work-related injuries and illnesses.

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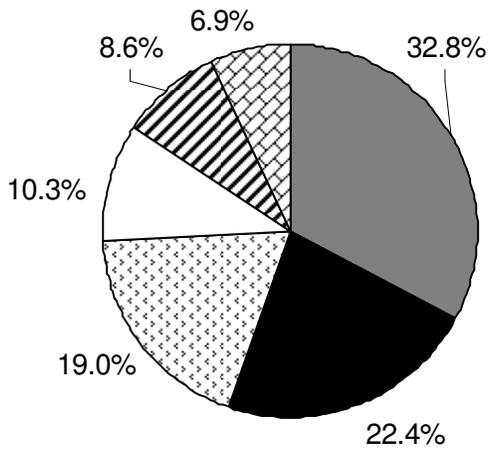
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**Figure 1. Flow diagram of employer eligibility, response, and participation in the PrediCTS study.**



- Unspecified lack of interest
- Liability concerns (WC claims increase)
- ▨ Time constraints
- Unknown
- ▨ Lack of direct benefit to employer
- ▨ Company policy

**Figure 2. Frequency of reasons stated by employers for non-participation in the PrediCTS study.**

**Table 1. Frequency of job type of PrediCTS study participants employed at the teaching hospital.**

<u>Job Type</u>	<u>Study Population</u> (n=427) %
Clerical	
Computer and telephone	13.8
Medical charts	3.7
Food & Nutrition	12.9
Housekeeping	41.2
Technician	
Lab	9
Radiation/medical	14.3
Other	5