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The Characteristics and Patterns of Smoking for Japanese Men Hospitalized With Cardiovascular Disease

by

#### Ayako Okada

#### DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

#### DOCTOR OF PHILOSOPHY

in

Nursing

in the

#### GRADUATE DIVISION

of the

# THE CHARACTERISTICS AND PATTERNS OF SMOKING FOR JAPANESE MEN HOSPITALIZED WITH CARDIOVASCULAR DISEASE

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By

Ayako Okada

# Dedication

This dissertation is lovingly dedicated to Emiko, my mother, Masao, my late father, and Miyoko, my aunt. This work is also dedicated to the Newcomb Family, including Yumiko, Richard, and Edward; the Russell Family, including Rosanna, Jay, Lin, and Christina; the Barberi Family, including Michie, Peter, Taka, and Miku; and Mr. Watanebe Kinya and his wife, Mizuho, for their warm-hearted support and encouragement during my doctoral studies.

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#### Abstracts

# THE CHARACTERISTICS AND PATTERNS OF SMOKING FOR JAPANESE MEN HOSPITALIZED WITH CARDIOVASCULAR DISEASE

Ayako Okada

University of California, San Francisco, 2012

Cardiovascular disease (CVD) is a major health problem in Japan. Among the risk factors for CVD, eigarette smoking is the strongest and smoking cessation reduces mortality, morbidity, hospital readmissions, restenosis after coronary revascularizations, and the need for coronary artery bypass surgery. A few of patients sustained smoking cessation after hospital discharge. The aim of this study of Japanese men who were hospitalized with CVD was to explore the demographic and clinical characteristics of smokers, their pattern of smoking, knowledge of smoking, and past attempts to quit. The data were collected individual interview based on a questionnaire. The questionnaire included modified Global Adult Tobacco Survey (GATS) core questionnaire (CDC, 2008; GTSS, 2010), Smoking and Health Problem Questionnaire (Ministry of Health and Welfare, 1999), Fagerstrom Test for Nicotine Dependence, Minnesota Withdrawal Scale, Patient Health Questionnaire-9, Enriched Social Support Instrument, and Confidence questionnaire.

A cross-sectional study of 104 men smokers who were hospitalized CVD was conducted in four Japanese hospitals that specialize in cardiovascular disease in Japan. Mean age was 60.6 ( $\pm$ 13.5) years, most (55.7%) were 60 or over. Almost half of the men had high school or some college or diploma education, and one third had a bachelors or

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graduate degree and most (60%) were married. Half of the sample was admitted because of AP or MI (46.1%), 14.4% admitted because of CHF and 11.5% admitted because of arrhythmias. Most subjects (about 80%) were moderately to high nicotine dependent. Their knowledge of smoking and its effect on their health was limited. Two third of participant made at least one quit attempt in the past and most of them used self-help methods and less utilized pharmacological treatment. The nurses were less likely than physician to offer smoking cessation intervention.

Pearson correlation confident test were performed to examine relationship among selected variables. Withdrawal symptoms (MNWS) (r=-0.31, p=0.00) and social support (ESSI) (r=0.25, p=0.01) were statistically significantly correlated with confidence to resist the urge to smoke. The result of this study will be useful in developing effective and culturally unique smoking cessation intervention programs, for the Japanese population with CVD.

Grad Evor

Erika S. Froelicher, RN, Ph.D., FAAN, Committee Chair

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#### **CHAPTER I**

#### **INTRODUCTION**

### **The Study Problem**

Cardiovascular disease (CVD) is a major health problem in Japan. Its prevalence has increased, and it is the most frequent reason for hospital admissions and outpatient visits when compared with other organ-specific diseases (Ministry of Health, Labour and Welfare, 2010a). The total medical cost for CVD accounts for 20% of overall medical cost in Japan, making it the most costly disease in the country (Ministry of Health, Labour and Welfare, 2010c). Because CVD causes many major health problems, its prevention and management in the Japanese population is important for controlling the demand for medical care, mitigating medical cost, and reducing patient suffering.

Among the risk factors for CVD, cigarette smoking is the strongest (U.S. Department of Health and Human Services, 2008; Hozawa et al., 2007; Nakamura et al., 2008; Woodward et al., 2005). Current smokers with coronary heart disease (CHD) have a mortality rate 3.68 times higher than persons who never smoked (Iso et al., 2005). Smoking is a major, modifiable risk factor and accelerates the pathological progression of CVD (Benowitz, 2009). Smokers who continued to smoke after a myocardial infarction (MI) had a 2.27 times higher risk of death than patients who quit smoking (Kinjo et al., 2005).

Smoking cessation reduces mortality (Hajek, Taylor, & Mills, 2002; Reid et al., 2003), morbidity (Reid et al., 2003), hospital readmissions (Hajek et al., 2002), restenosis after coronary revascularizations, and the need for coronary artery bypass surgery (Reid et al., 2003). Following smoking cessation, the risk of CHD and CVD death declines within 2 years (Iso et al., 2005). In addition, within 5 years, smoking cessation may cause an

individual's risk of subsequent CVD events to approximate the level of those who never smoked (Reid et al., 2003). The significant risk reduction effects of smoking cessation on CVD mortality have also been reported in several studies that involved the Japanese population (Honjo et al., 2009; Iso et al., 2005; Kinjo et al., 2005). Although roughly 70% of Japanese patients quit smoking after an MI, only 10-31% of patients sustained smoking cessation for 6 to 12 months after hospital discharge (Fujiwara, 2005; Hasuo et al., 2005).

## Smoking Prevalence in Patients with CVD in Japan

The most recent data on smoking in Japan, which was collected in 2008, shows that 36.8% of men and 9.1% of women were regular smokers (Ministry of Health, Labour and Welfare, 2009). Although the nationwide smoking rate of patients hospitalized with CVD has not been estimated, most male patients with CVD are middle-aged or older (Ministry of Health, Labour and Welfare. 2010d). The smoking rate of over middle-aged men is remarkably high in comparison with other age or gender groups: 48.6% for men aged 30-39, 51.9% for men aged 40-49, and 41.2% for men aged 50-59 (Ministry of Health, Labour and Welfare, 2009).

Overall, smoking rates have significantly declined since 1998 when more than 60% of men aged 20-40 smoked. Although these data are encouraging and show that the smoking rate for middle-aged men in Japan has been declining over the past decade, roughly half of this group still smokes (Ministry of Health, Labour and Welfare, 2009). Based on the smoking rates by gender and age in the past, roughly half of Japanese men who have CVD may smoke or have a smoking history. By contrast, most female patients with CVD are in their 50s or older and postmenopausal. The smoking rate of this age group of women is low in comparison with other age groups: 9.5% for women aged 50-59, 4.9%

for women aged 60-69, and 3.2% for women over the age of 70 (Ministry of Health, Labour and Welfare, 2009). Thus, among those with CVD, about half of Japanese men and less than 10% of the women smoke or have a smoking history.

## **Smoking Cessation in Patients with CVD in Japan**

Because smoking is prohibited in Japanese hospitals, smoking cessation is imposed de facto on all CVD patients who are hospitalized. Data have shown that roughly 70% of patients quit smoking after an MI and sustained cessation for 3 months after hospital discharge (Kinjo et al., 2005). However, few (10-31%) patients with CVD abstained from smoking for 6-12 months after hospital discharge (Fujiwara, 2005; Hasuo et al., 2005). For CVD patients, hospitalization may offer an ideal opportunity to initiate a serious attempt to quit smoking; most patients who were hospitalized, however, relapsed after hospital discharge (Kinjo et al., 2005).

#### **Understanding Smoking Behavior**

Smoking behavior is complex and involves both physiological and behavioral components: starting smoking, quitting smoking, maintaining smoking and abstinence, smoking intermittently, and fluctuating between smoking and smoking cessation (Froelicher & Kozuki, 2002). Because smoking cessation is often a long-term struggle, patients repeatedly experience relapses and remissions, engaging in various behavioral phases (U.S. Department of Health and Human Services, 2008).

Changing smoking behavior does not progress in linear fashion (Froelicher & Kozuki, 2002). An individual's smoking behavior may change rapidly and fluctuate greatly, reflecting his or her decisional balance, especially during stressful situations (Froelicher & Kozuki, 2002).

Perceived self-efficacy is a key determinant of smoking and smoking cessation behaviors (Froelicher & Kozuki, 2002; Sivarjan Froelicher et al, 2004). The confidence to quit smoking has been shown in numerous studies to correlate with smoking cessation outcomes. Thus, perceived self-efficacy provides a strong conceptual framework to explain smoking behavioral status.

#### **Smoking-Related Studies of Patients with CVD in Japan**

Little is known about the smoking patterns and characteristics of Japanese patients hospitalized with CVD. Only one descriptive study has explored factors associated with the posthospital smoking behavior of Japanese men who were diagnosed with an MI (Hasuo et al., 2005). The researchers examined smoking behaviors at 6 and 12 months after discharge and found that length of stay (LOS) in a hospital and smoking status at the time of hospital admission were significantly associated with smoking behaviors at 6 and 12 months. In addition, at the 6-month observation, nicotine dependency and self-efficacy were significantly associated with smoking behavior. The researchers found that patients whose LOS was more than 15 days (compared with those whose LOS was less than 15 days) had more than three times as many (odds ratio [OR] = 3.6, CI: 1.73, 7.34) cessation results, using cotinine verification. They also found that patients who had stopped smoking for at least 1 day before hospital admission for a procedure or treatment were more than 5 times more likely to remain nonsmokers at 6 months (OR = 5.6, CI: 2.31, 13.39; Hasuo et al., 2005). To develop effective interventions for smoking cessation and relapse prevention in Japanese patients with CVD, Ishikawa et al. (2006) recommended that health care providers explore the reasons for relapse.

An intervention study that involved smoking cessation in Japan deserves special mention (Hasuo, Tanaka, & Oshima, 2004). This randomized clinical trial (RCT) recruited patients who had been admitted to the hospital with a cancer or CVD diagnosis to examine the efficacy of a follow-up telephone intervention. Of the 106 subjects in the study, 87% were men. Their mean age was 60 (range: 36-81 years old). Most had CVD (52.6% CVD, 35.1% cancer, and 12.3% other). The intervention consisted of three counseling calls after discharge, at 7, 21, and 42 days. Point-prevalence of smoking cessation at 6 months was 66.7% in the intervention group and 65.3% in the control group; at 12 months, it was 56.1% and 51.0%, respectively. The ORs were 0.82 (CI: 0.31, 2.17) at 6 months and 0.99 (CI: 0.42, 2.45) at 12 months (p >.05).

Although Hasuo et al.'s (2004) study is important because it was the first smoking cessation intervention study to be conducted in Japanese patients hospitalized with a CVD diagnosis, it has several noteworthy limitations: (1) The research did not include risk factors for relapse to smoking, and (2) the study sample included cancer patients (35%) and patients with other medical diagnoses (12 %) in addition to patients with CVD (Hasuo, Tanaka, & Oshima, 2004). These limitations compromise the study's generalizability. Nonetheless, Hasuo et al.'s study was an important first step toward understanding some smoking-related factors in Japanese men and women who had a variety of chronic diseases. The aim of the present study was to gain an in-depth understanding of the history and patterns of smoking in patients with CVD and to comprehensively review all of the known factors that put a smoker at risk of relapse.

#### **Study Aims and Innovation**

## **Study Aims**

The overall aim of this study of Japanese men who were hospitalized with CVD was to explore the demographic and clinical characteristics of smokers, their pattern of smoking, knowledge of smoking, and past attempts to quit. Specifically, the study assessed (1) demographic and clinical characteristics; (2) history and patterns of smoking; (3) beliefs and knowledge about smoking; (4) nicotine dependencies, withdrawal symptoms, depressive symptoms, social support, and confidence to resist the urge to smoke; (5) the nature of previous quit attempts; (6) preferred methods for future quit attempts; and (7) the relationships between nicotine dependency, nicotine withdrawal symptoms, depressive symptoms, perceived social support, and confidence to quit smoking.

## **Innovative Approach**

To my knowledge, this was the first study to assess the characteristics of smokers and patterns of smoking and smoking cessation of Japanese men hospitalized with CVD. And, it explored their confidence to future attempts quit. This approach was unique because it explored the Japanese population with CVD and examined specific patterns of smoking and characteristics of hospitalized patients. Most previous studies of Japanese patients with CVD have been conducted on out-patients or the general population that has not experienced smoking-induced diseases.

This study's results will be useful in developing effective and culturally unique, smoking cessation intervention programs for the Japanese men with CVD. It will also provide Japanese nurses with the knowledge they need to improve their practice in counseling patients with CVD to sustain abstinence once they quit smoking. Furthermore, this study will guide identifying smokers' preferences for smoking cessation interventions nurses in the future.

#### **CHAPTER II**

## LITERATURE REVIEW

Cigarette smoking is one of the strongest and most modifiable risk factors for CVD (Nakamura et al., 2004; U.S. Department of Health and Human Services, 2008; Woodward et al., 2005). Smoking cessation has been shown to have a significant risk-reduction effect on mortality from CVD among the Japanese population (Honjo et al., 2009). About 70% of hospitalized patients quit smoking after an MI (Kinjo et al., 2005). Because hospital policies ban smoking, patients who were smokers before entering the hospital must stop smoking and refrain from smoking for 7 to 10 days. Thus, hospital admission appears to be an ideal opportunity to initiate interventions to help patients with withdrawal symptoms and to strongly encourage them not to resume smoking after they are discharged. However, one study reported that only 31% of patients with CVD refrained from smoking for 6 to 12 months after hospital discharge (Hasuo, Tanaka, Wakisaka, Fujii, Ohshima, 2005). By comparison, 63% of cancer patients abstained from smoking for up to 6 months after hospitalization (Tanaka et al., 2003). The explanation for this difference in abstinence rates may be that Japanese people are aware that smoking causes cancer but are less informed about its effect on the development of CVD.

Exploring the long-term effectiveness of smoking cessation treatments for patients with CVD is most important, particularly beyond 6 months after hospital discharge. Patients must be provided with interventions that are personalized and are powerful enough to sustain their smoking cessation behavior permanently, providing secondary prevention of CVD in the process. The aim of this chapter is to review the English and Japanese literature on the effects of smoking cessation interventions on patients who are hospitalized

for CVD and to evaluate their smoking status 6 to 12 months after hospital discharge. The chapter begins with a discussion of U.S. standards for smoking interventions and proceeds to a review of relevant literature. A brief discussion follows that describes the major theoretical foundations used in intervention studies.

#### Background

Standards for smoking cessation interventions have been promulgated in U.S. federal guidelines (U.S. Department of Health and Human Services, 2008). First published in 1996, the clinical practice guidelines included 3,000 articles on tobacco treatment published between 1975 and 1994. In 2000, the guidelines were updated to include the findings of 3000 more articles published between 1995 and 1999. An additional 2,700 articles were incorporated in the 2008 guidelines, bringing the repository of literature up to 8,700 articles.

Despite the extensive literature available, the clinical practice guidelines recommend further investigation into the effectiveness of preventing smoking cessation relapse after a person is discharged from the hospital (U.S. Department of Health and Human Services, 2008). A Cochrane review comprised of 36 studies of hospital inpatients assessed the effectiveness of relapse-prevention interventions for smoking cessation (Hajek, Stead, West, Jarvis, & Lancaster, 2009). The review found no benefit from brief and skills-based relapse prevention methods for smokers who underwent a period of enforced abstinence during hospitalization (Hajek et al., 2009). In addition, in the subgroup analysis, the researchers reported that the lack of evidence of significant benefits from the interventions in hospitalized patients who had not smoked in the hospital was based on pooling data from only three studies (Hajek, Taylor, & Mills, 2002; Hasuo,

Tanaka, & Oshima, 2004; Schmitz, Spiga, Rhoades, Fuentes, & Grabowski, 1999). Hajek et al. (2009) did not evaluate all studies that examined the effectiveness of relapse interventions initiated in the hospital.

Another Cochrane review of 33 studies assessed the effectiveness of interventions for smoking cessation in hospitalized patients (Rigotti, Munafo, & Stead, 2007). It analyzed cardiovascular patients as a subgroup and determined the effect of the intensity of the intervention. Intensive interventions with follow-up support increased smoking cessation rates (OR = 1.81, 95% CI: 1.54, 2.15, Rigotti et al., 2007). Less intensive interventions did not increase smoking cessation rates (Rigotti et al., 2007). This finding was based on the data that Rigotti et al. (2007) extracted from a larger Cochrane analysis that used only subjects with CVD. The results were based in part on a multi-risk factor intervention that led to mixed effects from other interventions. These mixed effects made it difficult to evaluate the independent effectiveness of smoking cessation interventions.

Barth, Critchley, and Bengel (2008) reviewed 16 studies to assess the effectiveness of "psychosocial smoking cessation interventions" that were designed specifically for patients with CVD. The review included two types of smoking cessation interventions: a separate psychosocial intervention that focused on smoking cessation, and a comprehensive cardiac rehabilitation intervention that addressed other risk factors, such as diet and regular exercise (Barth et al., 2008). This review was limited to the evaluation of the effects of the overall psychosocial intervention or to the mixed effects of the other cardiac, risk-factor reduction, interventions, such as exercise and nutrition. Separate estimates for tobacco control were not provided in this study.

Rice and Stead (2008) provided a subgroup analysis in their review of the

effectiveness of a smoking cessation intervention offered by nurses to hospitalized smokers with CVD. Seven studies found that a smoking cessation intervention by nurses significantly increased quit rates (RR = 1.29, CI: 1.14, 1.45) when compared with usual care for patients hospitalized with a CVD diagnosis.

These articles make an important contribution to the literature because they offer insight into Japanese patients. However, the reviews did not perform independent estimates of the efficacy of smoking cessation interventions for hospitalized patients with CVD.

This dissertation compares randomized clinical trials (RCTs) and quasi-experimental studies of the effects of smoking cessation interventions with usual care for patients hospitalized with CVD. The review of the English and Japanese literature will follow in that order. The efficacy of interventions will be evaluated by comparing 6- and 12-month abstinence rates for smoking cessation in patients with CVD after hospital discharge.

#### **Search Methods and Selection of Studies**

Computerized searches of CINAHL, PsycINFO®, PubMed, and Japana Centra Revuo Medicina (*igaku chuou zassi*), a Japanese database for health professional publications, was conducted using these keywords: cigarette smoking, smoking cessation, and CVD. The timeframe of each search differed slightly: CINAHL 1983-2010, PsycINFO® 1980-2010, PubMed 1965-2010, and Japana Centra Revuo Medicina (*igaku chuou zassi*) 1983-2009. Each search was limited to human adults and RCTs or quasi-experimental trials. Studies in English and Japanese were accepted.

The search yielded 325 articles (277 in English and 48 in Japanese). Abstracts of each article were reviewed for inclusion using the following criteria: (a) subjects diagnosed

with CVD including coronary syndrome (e.g., MI, angina pectoris), heart failure, peripheral arterial disease, or hypertension; (b) smoking abstinence as a primary outcome measure; (c) initiation of intervention during hospitalization; and (d) evaluation follow-up of subjects' smoking status at least 6 months after discharge. Exclusion criteria were (a) multiple risk factor interventions, (b) secondary analysis of studies, (c) "reduction in smoking" was reported rather than abstinence, (d) a diagnosis of a psychiatric comorbidity, (e) lack of information on contents of the intervention, and (f) lack of documentation on smokers who were lost to follow-up. After applying these criteria, 15 English-language studies were selected for detailed review.

#### **Studies Published in English**

Of the 15 studies, 6 were conducted in the United States (Dornelas, Sampson, Gray, Waters, & Thompson, 2000; Froelicher et al., 2004; Mohiuddin et al., 2007; Ockene et al., 1992; Rigotti, McKool, & Shiffman, 1994; Taylor, Houston-Miller, Killen, & DeBusk, 1990); 5 in Canada (Chouinard & Robichaud-Ekstrand, 2005; Johnson, Budz, Mackay, & Miller, 1999; Reid et al., 2003; Reid, Pipe, Quinlan, & Oda, 2007; Smith & Burgess, 2009) and 1 each in Australia (Feeney, et al., 2001), England (Hajek et al., 2002), the Netherlands (Bolman, de Vries, & van Breukelen, 2002a), and Norway (Quist-Paulsen & Gallefoss, 2003). Thirteen studies used an RCT design; two used quasi-experimental designs. In most of the studies, recruitment was conducted during hospital admission in a university hospital or a community hospital with research and teaching facilities that provided tertiary care. One study recruited subjects from a hospital's cardiac catheterization laboratory (Ockene et al., 1992). Five studies were multicenter (Bolman, de Vries, & van Breukelen, 2002a; Froelicher et al., 2004; Hajek et al., 2002; Ockene et al., 1992; Taylor, Houston-Miller, Killen, & DeBusk, 1990). Eight studies were single-site studies, that is, conducted in one hospital (Feeney et al., 2001; Johnson, Budz, Mackay, & Miller, 1999; Mohiuddin et al., 2007; Quist-Paulsen & Gallefoss, 2003; Reid et al., 2003; Reid, Pipe, Quinlan, & Oda, 2007; Rigotti, McKool, & Shiffman, 1994; Smith & Burgess, 2009). Two studies did not provide information on the institutional setting (Chouinard & Robichaud-Ekstrand, 2005; Dornelas, Sampson, Gray, Waters, & Thompson, 2000).

**Characteristics of subjects.** Sample sizes ranged from 87 to 789 subjects. Eight studies recruited more than 200 subjects, five studies recruited between 100 to 200 subjects, and two studies enrolled fewer than 100 subjects. The average age of subjects was in the 50s for 14 studies. In one study, the mean age was in the low 60s (Froelicher, 2004).

Most of the subjects were men. In two studies, the sample was 60-70% men (Mohiuddin et al., 2007; Reid et al., 2007). Ten studies included 70-80% men (Bolman et al., 2002a ; Chouinard & Robichaud-Ekstrand, 2005; Dornelas et al., 2000; Feeney, et al., 2001; Hajek et al., 2002; Johnson et al., 1999; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Reid et al., 2003; Rigotti et al., 1994). One study included more than 80% men (Smith & Burgess, 2009). And, only one study focused exclusively on female smokers (Froelicher et al., 2004).

Five studies from Canada and the United States reported the ethnicity of their sample (Dornelas et al., 2000; Froelicher et al., 2004; Mohiuddin et al., 2007; Rigotti et al., 1994; Smith & Burgess, 2009a). However, the description of ethnicity was limited to African American or White smokers. One study described ethnicity in greater detail, that is, Asian, Hispanic, Native American, or other (Froelicher, Christopherson, Miller, & Martin, 2002). Ten studies were conducted in countries where the population was

homogeneous and reflected the nation's ethnicity (Bolman et al., 2002a; Chouinard & Robichaud-Ekstrand, 2005; Feeney, et al, 2000; Hajek et al., 2002; Johnson et al., 1999; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Reid et al., 2003; Reid et al., 2007; Taylor et al., 1990).

Most of the subjects in these studies had completed high school or 12-13 years of education. Six of the studies included more than half of the subjects who reported less than a high school education (Chouinard & Robichaud-Ekstrand, 2005; Hajek et al., 2002; Johnson et al., 1999; Mohiuddin et al., 2007; Reid et al., 2003; Smith & Burgess, 2009).

Eight studies reported the subjects' marital status. A high proportion of men were married (61.5-86%; Chouinard & Robichaud-Ekstrand, 2005; Dornelas et al., 2000; Hajek et al., 2002; Johnson et al., 1999; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Smith & Burgess, 2000). Fewer women reported being married (40%; (Froelicher et al., 2004).

Of the seven studies that inquired about employment status, two reported that more than 70% of subjects were employed (Smith & Burgess, 2009; Taylor et al., 1990). Three studies reported that about half of their subjects were employed (Hajek et al., 2002; Quist-Paulsen & Gallefoss, 2003; Rigotti et al., 1994). And, two studies reported that about 36% of subjects were employed (Chouinard & Robichaud-Ekstrand, 2005; Froelicher et al., 2004). In addition, in these last two studies, more than half of the subjects were classified as earning low to middle income (Chouinard & Robichaud-Ekstrand, 2005; Froelicher et al., 2004).

**Medical diagnoses.** The subjects who were smokers were admitted to the hospital with one or more CVD diagnosis or for medical interventions for CVD. Most of the studies

included only subjects with diagnosed CHD. Several studies recruited subjects with more extensive CVD diagnoses. Nine studies included subjects with CAD or who had received cardiac catheter intervention (i.e., percutaneous transluminal coronary angioplasty (PTCA) or a stent) or coronary artery graft surgery (CAGS) (Dornelas et al., 2000; Feeney, et al, 2001; Hajek et al., 2002; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Reid et al., 2003; Reid et al., 2007; Smith & Burgess, 2009; Taylor et al., 1990). Three studies included subjects with heart failure, hypertension, or peripheral artery disease (Froelicher et al., 2004; Mohiuddin et al., 2007; Rigotti et al., 1994). One study recruited subjects having cardiac surgery, which possibly included coronary artery graft surgery or other types of cardiac surgery (Johnson et al., 1999). One study recruited subjects with cerebrovascular disease and diabetes mellitus (Froelicher et al., 2004).

Nicotine dependency and tobacco use. In most of the studies, smoking status was assessed by asking "What was the average years smoked? and what was the average number of cigarettes smoked per day?" Eleven of the 13 studies reported the average number of years that subjects had smoked; some had smoked for 30-40 years (Bolman et al., 2002a; Chouinard & Robichaud-Ekstrand, 2005; Froelicher et al., 2004; Johnson et al., 1999; Mohiuddin et al., 2007; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Reid et al., 2007; Smith & Burgess, 2009; Taylor et al., 1990).

The average number of cigarettes smoked per day was reported in 13 studies (Dornelas et al., 2000; Feeney et al, 2001; Froelicher et al., 2004; Hajek et al., 2002; Johnson et al., 1999; Mohiuddin et al., 2007; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Reid et al., 2003; Reid et al., 2007; Rigotti et al., 1994; Smith & Burgess, 2009; Taylor et al., 1990). Most of the studies reported an average of 20-30 cigarettes

smoked per day, indicating that the subjects comprised heavy smokers. Two studies reported the average number of cigarettes smoked per day to be fewer than 20 (Froelicher et al., 2004; Quist-Paulsen & Gallefoss, 2003). However, the subjects in these two studies had smoked for approximately 40 and 38 years, respectively (Froelicher et al., 2004; Quist-Paulsen & Gallefoss, 2003). Thus, these subjects were heavy smokers.

Three studies reported the proportion of daily cigarette usage. In one study, 63% of smokers used more than 16 cigarettes a day (Reid et al., 2007). In another, 75% of smokers used more than 16 cigarettes a day (Quist-Paulsen & Gallefoss, 2003). In a third study, about 60 % of smokers used fewer than 20 cigarettes a day (Feeney et al, 2001).

Nicotine dependence was reported in 12 studies (Bolman et al., 2002a; Chouinard & Robichaud-Ekstrand, 2005; Dornelas et al., 2000; Feeney et al, 2001; Froelicher et al., 2004; Johnson et al., 1999; Mohiuddin et al., 2007; Ockene et al., 1992; Reid et al., 2003; Rigotti et al., 1994; Smith & Burgess, 2009; Taylor et al., 1990). Several scales were used to obtain this information: the Fagerstrom Tolerance Questionnaire (full or short form), the Modified Fagerstrom Tolerance Questionnaire and the Stanford Dependence Index. Based on the average dependency scores, subjects were moderately or highly nicotine dependent. Three studies reported low nicotine dependency (Bolman, de et al., 2002a; Feeney et al, 2001; Taylor et al., 1990).

Other factors under study were tobacco use, previous quit attempts, and withdrawal symptoms. The experience of a past quit attempt influences relapse and the skills needed to deal with difficult situations. Ten studies assessed prior quit attempts (Bolman et al., 2002a; Froelicher et al., 2004; Johnson et al., 1999; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Reid et al., 2003; Reid et al., 2007; Rigotti et al., 1994; Smith & Burgess,

2009; Taylor et al., 1990). Withdrawal symptoms are the physiological response to nicotine deficiency during a smoking cessation intervention. Only one study assessed and reported withdrawal symptoms (Froelicher et al., 2004). In this study, 32% of subjects acknowledged that they experienced some form of withdrawal symptoms (Froelicher et al., 2004). The other studies assessed withdrawal symptoms at baseline using an existing scale, or it was included in part of the nicotine dependency assessment, but the authors did not report the experiences with the withdrawal symptoms (Rigotti et al., 1994: Smith & Burgess, 2009; Taylor et al., 1990).

**Predictors of successful quitting or relapse.** According to the clinical practice guidelines issued by the U.S. government, variables associated with higher abstinence rates were high motivation, readiness to change, moderate-to-high self-efficacy, and supportive social networks (U.S. Department of Health and Human Services, 2008). Variables associated with low abstinence rates included high nicotine dependency (i.e., more than 20 cigarettes per day), psychiatric comorbidity and substance use, high stress level, and exposure to other smokers (U.S. Department of Health and Human Services, 2008). Based on this evidence, assessment should also evaluate available sources of social support, stress levels, history of psychiatric disease or substance abuse, and exposure to other smokers.

Two studies assessed social support at baseline (Bolman et al., 2002a; Johnson et al., 1999). Four studies assessed psychiatric comorbidity or substance use at baseline (Chouinard & Robichaud-Ekstrand, 2005; Froelicher et al., 2004; Quist-Paulsen & Gallefoss, 2003; Smith & Burgess, 2009). Three studies assessed baseline exposure to other smokers after a subject was discharged from the hospital (Johnson et al., 1999; Quist-Paulsen & Gallefoss, 2003; Taylor et al., 1990)

Variables related to smoking. Researchers focused their attention on the following demographic data: age, gender, ethnic background, education, marital status, income (household or family), working status, and number of family members in the household. The following clinical data were assessed: diagnosis on hospital admission, medical procedures and interventions, history of cardiovascular problems, CVD risk factors, history of depression and present symptoms of depression, and length of hospitalization. Regarding smoking history and patterns of smoking, the following factors were assessed: number of cigarettes smoked per day, the age a patient began smoking, number of years smoked, timing of first cigarette, quit attempts in the past, nicotine dependency, confidence or self-efficacy to guit and confidence to resist the urge to smoke, intention to quit or stage of readiness to change, withdrawal symptoms, alcohol consumption, smoking restrictions at home, number of smokers in the household, social support, whether the patient smoked before the index hospital admission, preferred assistance with smoking cessation (none or self-help/counseling), nicotine replacement therapy in the hospital, and knowledge and health beliefs about smoking.

Besides the factors associated with a patient's smoking history, patterns, or environment as listed above, self-efficacy, nicotine dependency, withdrawal symptoms, depression, and perceived social support are key factors associated with smoking. Self-efficacy and nicotine dependency have been established as main contributors to smoking status or abstinence (Froelicher & Kozuki 2002).

Moderate-to-high self-efficacy is associated with a high abstinence rate and a smoke free status (U.S. Department of Health and Human Services, 2008; Hasuo, Tanaka, Wakisaka, Fujii, & Ohshima, 2005). Conversely, low self-efficacy leads to a continuation

of smoking or relapse after successful cessation (Baer, Holt, & Lichtenstein, 1986; van Berkel, van der Vlugt, & Boersma, 2000; Colletti, Supnick, & Payne, 1985; Condiotte & Lichtenstein, 1981). When assessing willingness to quit smoking, a subject's self-efficacy is an important predictor of subsequent smoking behavior. High nicotine dependency is associated with low abstinence rates (U.S. Department of Health and Human Services, 2008). High nicotine dependency tends to be associated with strong withdrawal symptoms that can be caused by an individual's physiological discomforts. For this reason, nicotine dependency and withdrawal symptoms are used as a theoretical framework in this study to explain the physiological and psychosocial mechanism of smoking behavior.

## **Studies Published in Japanese**

Most of the Japanese smoking-related studies were conducted in primary care settings. Subjects were recruited during annual health check-ups in the public health environment, occupational health setting, or outpatient setting. Three studies examined smoking behavior or smoking cessation intervention in hospitalized CVD patients. Hasuo, Tanaka, and Oshima (2004) conducted an RCT for hospitalized CVD and cancer patients in Osaka, Japan. The study's aim was to examine the efficacy of a telephone follow-up intervention for CVD and cancer patients after hospital discharge. Of the 106 subjects, 87% were men. The mean age was 60 (range: 36-81 years old). The subjects' medical diagnoses were apportioned as follows: CVD 52.6%, cancer 35.1%, and other 12.3%. The subjects were randomly assigned to either an intervention group (57 subjects) or a control group (49 subjects). The characteristics of the two groups were not statistically significantly different at baseline.

The inpatient smoking cessation intervention provided to both the intervention and

control groups. The intervention included self-help educational materials, counseling, and provided materials including a calendar or smoking cessation in the hospital. Three telephone counseling calls at 7, 21, and 42 days after discharge were provided for the intervention group. Smoking status was assessed by mailed questionnaire at 3, 6, and 12 months after discharge. Biochemical confirmation (measuring urine cotinine) was obtained at the 12-month evaluation point.

The point prevalence at 6 months was 66.7 % in the intervention group and 65.3% in the control group; at 12 months, it was 56.1% and 51.0%, respectively. No statistically significant difference was observed between the intervention group and the control group at either the 6- or 12-month follow-up.

One descriptive study examined the factors that are associated with smoking behavior in Japanese men with an MI diagnosis after hospital discharge (Hasuo, Tanaka, Wakisaka, Fujii, & Ohshima, 2005). LOS, smoking status on the day of hospital admission, nicotine dependency, and self-efficacy were statistically significantly associations with smoking behavior at 6 months after discharge. At 12 months, the LOS and smoking status on hospital admission were statistically significantly associated with the subjects' smoking behavior. The factors associated with smoking cessation behavior were (a) more than a 15-day hospital stay (OR = 3.6, CI: 1.73, 7.34) and (b) quitting smoking at least 1 day before hospital admission (OR = 5.57, CI: 2.31, 13.39).

Several epidemiological studies of CVD patients found that smoking increased the risk of future cardiac events and mortality. By contrast, smoking cessation reduced the risk of subsequent CVD mortality (Honjo et al., 2009; Kinjo et al., 2005; Iso et al., 2005). However, realistically, only two studies explored some of the phenomena related to smoking for hospitalized Japanese patients with CVD.

#### **Theoretical Framework**

The two most relevant theories that are applicable to smoking cessation and relapse are the physiological theory of nicotine dependence and addiction and the self-efficacy theory.

## **Physiological Theory: Nicotine Dependence**

Addiction to nicotine, the bane of habituated smokers, is mediated primarily by the actions of nicotine on the brain's nicotine acetylcholine receptors (nAChRs) and the alpha4-beta2 nAChR subtype. These are the main receptors for mediating nicotine dependence (Benowitz, 2008). The pleasure a person derives from smoking begins when he or she inhales cigarette smoke, and the nicotine contained therein is carried deep into the lungs. The lungs' alveoli rapidly absorb nicotine within a few seconds. Within a few minutes, it diffuses into the brain tissue, transported there by pulmonary venous, central, and arterial circulation (Benowitz, 2008).

When nicotine reaches the brain and binds to nAChRs, it facilitates the release of neurotransmitters, which include acetylcholine, beta-endorphin, dopamine, GABA, glutamate, norepinephrine, and serotonin. These neurotransmitters mediate various sensations in the smoker: appetite suppression, arousal, cognitive enhancement, memory enhancement, mood modulation, pleasure, and reduction of anxiety and tension (Benowitz, 2008). Dopamine release has a specific and critical effect on nicotine dependence because it produces pleasurable feelings and brain reward. Chronic nicotine exposure leads to the development of neuroadaptation, which is associated with an increase in brain nicotine cholinergic receptors and develops tolerance. Smoking cessation after neuroadaptation has been developed and can result in a decrease in the neurological brain reward and can also result in both a deficient dopamine response to novel stimuli during a state of malaise and an inability to experience drug-induced pleasures. An individual also experiences withdrawal symptoms during smoking cessation. The combination of these two consequences that are brain reward and withdrawal symptoms often leads to relapse.

The symptoms of nicotine withdrawal are defined as "a variety of unpleasant symptoms (e.g., difficulty concentrating, irritability, anxiety, anger, depressed mood, sleep disturbance, and craving) that occur after the use of an addictive drug that is reduced or stopped, and withdrawal symptoms are thought to increase the risk for relapse" (U.S. Department of Health and Human Services, 2008, p. 81). Those withdrawal symptoms begin within a few hours after cessation or reduction of nicotine use. The first peak of withdrawal symptoms usually occurs after 3-10 days and usually peaks in intensity between the first and fourth days after quitting smoking (American Psychiatric Association, 2000). Multiple withdrawal symptoms, as described above, may appear and impair an individual's social and mental functions (American Psychiatric Association, 2000).

Reasons for relapse are classified as positive responses and negative responses after smoking cessation (Benowitz, 2008). Positive responses range from obtaining pleasure and reinforcement to arousal and mood control enhancement. Avoiding negative consequences reduces withdrawal symptoms, such as anxiety, irritability, and dysphoria. Neural plasticity changes can be long-lasting and range from months to even years after smoking cessation. Thus, an individual who has quit smoking may experience these

symptoms for a long time.

## **Psychosocial Theory: Self-efficacy Theory**

The self-efficacy theory, which has its roots in the social cognitive learning theory. This is the most empirically oriented and relevant for guiding behavioral interventions, aiding interpretation of study findings, and explaining smoking behaviors (Bandura 1996, & Froelicher & Kozuki, 2002). In this theory, human behavior is defined as "the manifestation of the dynamic interaction of inner forces, most of which operate below the level of consciousness" (Bandura, 1986, p. 2). Human behavior relies on a self-regulatory system (Bandura, 1986). The self-regulatory system enables an individual to control his or her behavior, including "generic skills for diagnosing task demands, constructing and evaluating alternative course of action, setting proximal goals to guide one's efforts, and creating self-incentive to sustain engagement in taxing activities and to manage stress and debilitating intrusive thoughts" (Bandura, 1997, p. 51). Exercising and strengthening a self-regulatory system is essential if one is to implement a change in behavior.

Self-efficacy contains perceived expectations and outcomes (Bandura, 1995; Bandura, 1986; Bandura, 1997). Self-efficacy is a judgment of one's capability to accomplish a given task or to perform at a specific level (Bandura, 1986; Bandura, 1997). Outcome expectation is a judgment on the consequences of successfully accomplishing a given task (Bandura, 1986; Bandura, 1997). Perceived self-efficacy plays a significant role in the regulation of human behavior. Until people believe that they are able to behave or perform to produce a desired outcome, change does not occur (Bandura, 1999). The evidence that self-efficacy is applicable to smoking and smoking cessation behaviors has been documented extensively (Froelicher et al., 2004; Rigotti et al., 1994; Smith &

Burgess, 2009; Taylor et al., 1990).

High self-efficacy is associated with a smoke-free status (U.S. Department of Health and Human Services, 2008). Japanese data consistently concur with this finding. Specifically, data show that for hospitalized patients with an MI, high self-efficacy was related to high smoking cessation rates at 3 and 6 months after discharge. The point prevalence of abstinence rates at 6 months after discharge was 59% in patients with high self-efficacy, 48% in patients with moderate self-efficacy, and 34% in patients with low self-efficacy (Hasuo, Tanaka, Wakisaka, Fujii, & Ohshima, 2005).

Conversely, low self-efficacy leads to a continuation of smoking and relapse. The self-efficacy scores of relapsed smokers were lower than smokers who sustained abstinence (p < .001; Baer, Holt, & Lichtenstein, 1986). The association between low self-efficacy and continuation of smoking or relapse was consistently found in self-efficacy scale studies (van Berkel, van der Vlugt, & Boersma, 2000; Colletti, Supnick, & Payne, 1985; Condiotte & Lichtenstein, 1981).

## **Depression, CVD, and Smoking**

Depression is common in patients with CVD. It occurs not only in patients who have experienced an MI, but it is also common in patients who have been hospitalized for unstable angina, an angioplasty, bypass surgery, or valve surgery Even higher prevalence rates of depression have been reported in patients with heart failure (Lichtman et al., 2008; McManus, Pipkin, & Whooley, 2005; Rutledge, Reis, Linke, Greenberg, & Mills, 2006).

The relationship between depression and smoking has been recently identified (Freedland, Carney, & Skala, 2005; Glassman et al., 1990). Depression is more common among smokers than nonsmokers, and smokers are more frequently depressed (Freedland,

Carney, & Skala, 2005; Glassman et al., 1990). After a CVD event, patients who are persistently depressed are less likely to quit smoking, take medications regularly, and consistently attend cardiac rehabilitation than patients who are not depressed (Kronish et al, 2006).

## **Social Support**

Lack of social support, emotional support, and depression are correlated. A study of patients who have had an MI reported that patients with high perceived support had lower scores for depression (Barefoot et al., 2003). Social support itself is associated with smoking cessation (Janzon et al., 2005; Nollen, Catley, Davies, Hall, & Ahluwalia, 2005). In addition, one study reviewed literature reported that improving social support reduced smoking rates (Ryckman, Bercaw, Ellis, Wolf, & Elgert, 2006).

Chapter III presents the detail of methodology of study includes study design, setting, sample, and procedures for data collection, and a detailed description of the measurements.

#### **CHAPTER III**

## METHODOLOGY

In this chapter, the study design, setting, sample, and procedures for data collection are described. A detailed description of the measurements and a discussion of ethical considerations are included. The chapter closes with a plan for data management, coding of variables, and analysis.

## **Research Design**

A cross-sectional design was selected for this study because it is a suitable method of obtaining information on a population and for describing and exploring specific characteristics and patterns using instruments that have been well-established in previous smoking studies.

## Settings

Potential participants were recruited from four Japanese hospitals that specialize in cardiovascular disease: the Sakakibara Heart Institute (SHI), the Kanagawa Cardiopulmonary Center (KCRC), the Chiba Cardiovascular Center (CCC), and the Kawasaki Saiwai Hospital (KSH). The hospitals, which are all located in suburban areas and neighboring prefectures of the Tokyo metropolitan area, provide comprehensive, high-level medical and surgical cardiovascular care and cardiac rehabilitation. Patients were admitted to the four hospitals with a primary diagnosis of CVD. Details about the hospitals such as their location, total numbers of beds, and annual number of cases by categories of diagnoses or cardiac procedures are shown in Table 3.1.

The sample was comprised of smokers who were hospitalized. A smoker is defined as an individual who has smoked at least 100 cigarettes in their lifetime.

## Table 3.1

Name and location	Total number of			gnosis	Catheter intervention	Surgi proced	
	beds	MI	AP	HF	PCI ,PTCA, Stent	CABG	Valve
Sakakibara Heart Institute in Tokyo	320	00	00	00	847	200	88
Kanagawa Cardiopulmonary Center in Kanagawa	239	NA*	NA	NA	317	7	0
Chiba Cardiovascular Center In Chiba	220	NA	NA	NA	381	19	7
Kawasaki Saiwai Hospital in Kanagawa	203	NA	NA	NA	796	NA	63

Number of Beds and Patients by Diagnosis and Procedures in Each Hospital

*Note*. MI = myocardial infarction; AP = angina pectoris; CHF = coronary heart failure; PCI = percutaneous coronary intervention; PTCA = percuteneous transluninal catheterization angioplasty; CABG = coronary artery bypass graft;  $N A^*$ = information not separately identified.

Smokers recruited for this study were not required to be daily smokers, that is, individuals who smoke at least one tobacco product every day or nearly every day (Centers for Disease Control and Prevention, 2008; Global Tobacco Surveillance System (GTSS), 2010).

Further, potential male participants were required to meet other inclusion criteria: aged at least 18 years old and had been admitted to the hospital with a CVD diagnosis that included angina pectoris, congestive heart failure, or myocardial infarction; or had undergone a percutaneous coronary intervention; or had any of the following cardiac operations: aortic vessel replacement, coronary artery bypass graft, peripheral arterial disease, or valve replacement.

Patients were excluded if they were unable to speak, read, and write Japanese; had a history of psychiatric disorder(s); were unconscious or using sedative medication that would interfere with reliable data collection; or were critically ill or medically unstable. Medical instability refers to an unstable hemodynamic condition or complications after a cardiac event or after cardiac intervention procedures.

## Sample size

NQuery version 4 software was used to calculate sample size. The original sample size projections of 205 subjects included a logistic regression analysis to test a prediction model. Assuming  $\alpha = 0.05$ ,  $\beta = 0.20$ , power = 1-  $\beta$  or (1-0.20 = 0.80), and a medium effect size. Although the number of patients projected for recruitment seemed sufficient to meet the sample-size calculation of 205, the Japan earthquake of March 2012, which occurred soon after data collection began, caused many electrical outages, which severely reduced data collection possibilities. Considering the circumstances and recognizing that roughly 10 subjects for each variable of interest were likely to be sufficient for the analysis, 100 subjects were deemed adequate for the planned analysis. The doctoral committee concurred. Thus, the 104 subjects who were recruited were adequate for the planned analysis.

#### Measurements

## Demographic and clinical data and smoking patterns.

A questionnaire was used to assess the subjects' demographic and clinical characteristics, history of smoking, and smoking patterns. The questionnaire was based on two previously developed instruments: the modified Global Adult Tobacco Survey (Centers for Disease Control and Prevention, 2008; Global Tobacco Surveillance System (GTSS, 2010) and a smoking and health problem questionnaire, developed by the Ministry of Health and Welfare, that had been used for a national tobacco survey in Japan (see Table 3.2).

## Table 3.2

Demographic data		Range and response options
Age	18-1	100
Gender	1. M	fale
	2. F	emale
Education	1.	No formal schooling
	2.	Less than junior high school
	3.	High school
	4.	College or diploma school (2-3 years)
	5.	University (4 years)
	6.	Master degree
	7.	Doctoral degree
	8.	Post graduate degree
	9.	Don't know
Marital status	1.	Single
	2.	Married
	3.	Separated
	4.	Divorced
	5.	Widowed
Income	1.	Less than 2,000,000 yen
	2.	2,000,000-3,999,999 yen
	3.	4,000,000-5,999,999 yen
	4.	6,000,000-7,999,999 yen
	5.	Over 8,000,000 yen
Employment	1.	Government employee
	2.	Non-government employee
	3.	Self-employed, commerce, or industry
	4.	Agriculture, forestry, or fishery
	5.	Part-time or temporarily employed
	6.	Student
	7.	Homemaker
	8.	Retired
	9.	Unemployed, able to work
	10.	Unemployed, unable to work
	11.	Don't know
CVD Diagnosis	1.	AP
-	2.	MI
	3.	CHF
	4.	Arrhythmia
	5.	Other
Surgical procedure	1.	PTCA
- •	2.	STENT
	3.	CABGS
	4.	VR
	5.	AVR
	6.	Other

Demographic and Smoking Variables: Sources of Data, Range and Response Option.

## Table 3.2

## Demographic and Smoking Variables: Sources of Data, Range and Response Options

*(continued).* 

Length of hospital stay	$1-\infty$ day
Symptoms attributed with CVD or to	1. Chest pain
procedures	2. Incisional pain
	3. Dyspnea
	4. Edema
	5. Fatigue
	6. Palpitation
	7. Others
Smoking patterns	
Number of cigarette smoke per day	1-∞/ day
How soon after you wake up do you	3. Within 5 minutes
smoke your first cigarette	2. 6-30 minutes
	1. 31-60 minutes
	0 After 60 minutes
Age initiated to start to smoking	<u></u>
Years of smoke habitually	$\infty$ - $\infty$
Beliefs about Health Benefits	1. Very likely
	2. Likely
	3. Unlikely
	4. Very unlikely
Numbers of Quit attempts	$\infty$ -0
Numbers of Quit attempts (last 12)	0-∞

*Note.* CVD = cardiovascular disease; AP = angina pectoris; MI = myocardial infraction; CHF = coronary heart failure; PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass graft; VR = valve replacement; AVR = aortic vessel replacement.

To assess the smokers' beliefs and knowledge about the health benefits of smoking cessation, three questions, developed and tested by the U. S. National Cancer Institute's Community Intervention Trial for Smoking Cassation, were asked. They were (1) "How likely do you think it is that you will avoid or decrease serious health problems from smoking if you quit?" (2) "If a person has smoked for more than 20 years, there is little health benefit to quitting." and (3) "My smoking is harming my health." (Centers for Disease Control, 1990).

The questions above have been used in earlier smoking cessation studies of patients with CVD (Froelicher, Christopherson, Miller, & Martin, 2002 & Sohn et al., 2007). Three additional questions, used in an earlier study that described the health beliefs of Korean patients who were hospitalized with CVD, inquired about disease-specific threats to health (Sohn et al., 2007). They were (4) "How likely do you think it is that you will avoid or decrease your chances of developing lung cancer if you quit smoking?" (5) "How likely do you think it is that you will avoid or decrease if you quit smoking?" and (6) "How likely do you think it is that you will avoid or decrease your chances of developing respiratory disease if you quit smoking?" The response choices for Questions 1, 4, 5, and 6, on a Likert scale, were "very likely" to "very unlikely" and "uncertain". The response choices for Questions 2 and 3 ranged from "strongly agree" to "strongly disagree" and "I do not know" (Sohn et al., 2007).

Instruments. Selected measures for this study are shown Table 3.3

*Nicotine dependency.* The Fagerstrom Test for Nicotine Dependence (FTND (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) was used to measure the degree of nicotine dependency. The FTND, which was derived from the Fagerstrom Tolerance Questionnaire (Fagerstrom, 1978), was originally developed to assess the severity of nicotine dependency. It comprises six questions. The FTND scores range from 1 to 10; a higher score indicates higher nicotine dependency.

Cronbach's alpha was 0.68 for the English version (Etter, 2008). The Japanese FTND has been previously used in studies that targeted hospitalized CVD patients (Hasuo et al., 2004; Hasuo et al., 2005). The reliability and validity of this measure was not reported by these authors.

## Table 3.3

## Instruments to Measure Nicotine Dependence, Withdrawal Symptoms, Depression,

Scale	Variables		Response options	Possible	Direction score
		tems		scores	
FTND	Nicotine		Question 1, 4 (0-3)	0-10	↑More
	dependency		Question 2, 3, 5, 6 (0-1)		dependence
MNWS	Withdrawal		0= none, $1=$ slight, $2=$ mild,	0-36	↑Severe symptoms
*	symptoms*		3= moderate, 4= severe		
PHQ-9	Depression		0 =  not at all, $1 = $ several days,	0-27	
	_		2= more than half the days,		depression
			3= nearly everyday		
CQ	Self-efficac		0-100%	0-100 for	↑Self-efficacy to
	у	4		each	resist to urge to
					smoke
ESSI	Social		Question 1-6	7-32	smoke ↑ social supports
ESSI			Question 1-6 1=none of the time, 2=a little	7-32	
ESSI	Social support		1=none of the time, 2=a little	7-32	
ESSI			1=none of the time, 2=a little time, 3=some of the time, 4=	7-32	
ESSI			1=none of the time, 2=a little time, 3=some of the time, 4= most of the time, 5= al of the	7-32	
ESSI			1=none of the time, 2=a little time, 3=some of the time, 4=	7-32	

Self-efficacy, and Social Support

*Note.* FTND = Fagerstrom Test for Nicotine Dependence; MNWS = Minnesota Withdrawal Scale (Japanese version); PHQ-9 = Patient Health Questionnaire-9; CQ = Confidence questionnaire; ESSI = Enriched Social Support Instrument

*Withdrawal symptoms.* The Minnesota Nicotine Withdrawal Scale (MNWS) was used to assess symptoms of nicotine withdrawal, specifically those experienced within 24 hours. The 8 items in English and 9 items in Japanese refer to irritability, anxiety, depressed mood, desire to smoke, difficulty concentrating, increased appetite, sleep problems, and restlessness. The MNWS items are rated on a 5-point scale; 0 = no *withdrawal symptoms*, 1 = slight, 2 = mild, 3 = moderate, and 4 = severe; the range of scores was 0 to 32 in English and 1 to 36 in Japanese (Hughes & Hatsukami, 1986; Ohishi, Green, Nakamura, & Ohashi, 2005).

The Japanese MNWS assessed 373 subjects (310 men) who were recruited for a

smoking cessation program in Osaka, Japan (Ohishi, Green, Nakamura, & Ohashi, 2005). Cronbach's alpha was 0.80 for the whole scale and 0.78 for items related to withdrawal symptoms (Ohishi, Green, Nakamura, & Ohashi, 2005).

*Self-efficacy.* The Confidence Questionnaire was used to measure self-efficacy for quitting smoking. It contains 14 high-risk situations that may cause a smoking relapse (Miller & Taylor, 1995). Each situation was ranked 0% (*not at all confident*) to 100% (*very confident*); scores ranged from 0 to 100. A score of less than 70% denotes high-risk of relapse (Froelicher et al., 2004). In an earlier study, Cronbach's alpha was 0.86 for patients hospitalized with CVD (Froelicher et al., 2004).

*Depression.* The Patient Health Questionnire-9 (PHQ-9), which was used to measure depressive symptoms, is based on the Primary Care Evaluation of Mental Disorders (Spitzer, Kroenke, & Williams, 1999; Lichtman, et al 2008). In studies of patients with CVD, the sensitivity of the PHQ-9 was 0.8 (95% CI 0.71, 0.87) and specificity of the instrument was 0.92 (95% CI 0.88, 0.95), which demonstrates its validity as a tool to measure depressive symptoms in patients with CVD (Gilbody, Richards, Brealey, & Hewitt, 2007; McManus, Pipkin, & Whooley, 2005; Stafford, Berk, & Jackson, 2007).

The PHQ-9 includes nine items that ascertain symptoms of depression according to the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (American Psychiatric Association, 2000). Patients choose one of four responses to indicate how often they experienced each symptom during the past 2 weeks. The questions are scored as follows: 0 = not at all, 1 = several days, 2 = more than half the days, and 3 = every day. As a severity measure, the possible scores can range from 0 to 27 (Stafford et al.,

2007). The PHQ-9 has been translated into Arabic, Dutch, English, German, Italian, Japanese, and Spanish (Gilbody et al., 2007).

*Social support.* To measure perceived emotional social support in this study, the ENRICHD Social Support Instrument (ESSI) was used. The ESSI was developed and tested in a study of patients with CVD (Mitchell et al., 2003). It contains seven questions and uses a 5-point, Likert-type scale in which 1 = "none of the time" and 5 = "all the time". For the last item, the answer "yes" = 2 and "no" = 1. The total possible score ranges from 7 to 32. Cronbach's alpha was 0.86 in a study of patients with CVD (Mitchell et al., 2003).

*Translation of instruments into Japanese.* Of the five instruments that were used in this study, three were available in Japanese. The CQ and the ESSI required translation. The translation of the instruments was based on the guidelines for cross-cultural adaptation and translation of self-report measures (Beaton, Bombardier, Guillemin, & Ferraz, 2000). The initial translation was done by two independent individuals who are fluent in English and Japanese, who have a nursing background, and who also understand sensitive cultural nuances. The two individuals translated the instruments independently, after which their translations were combined. Two different translators back translated the instruments into English. These back-translators are fluent in English and Japanese but do not have a medical background. The English and Japanese versions of the translated, Japanese versions of the instruments were then reviewed by health professionals and translators. The two, newly translated, Japanese versions of the instruments were then reviewed by health professionals and translators. The two, newly translated, Japanese versions of the instruments were then reviewed by health professionals and translators. The two, newly translated, Japanese versions of the instruments were pretested in a small number of Japanese people to evaluate ease of use and comprehension by Japanese patients with CVD. An individualized short interview was held to assess the need for changes. None being suggested, it was determined that the instruments were understandable and feasible for use in this study.

#### **Data Collection**

This study was approved by the UCSF Committee on Human Research and the ethics committees of the four participating hospitals in Japan. Orientation to the study's purpose and process was provided to the cardiologists and nurses who staffed relevant hospital wards. They were also instructed to inform their patients of the study and to notify the principal investigator if any wished to participate.

To recruit participants, CVD patients were approached by the ward physician or nurse who briefly explained the study and its purpose. If a patient was interested in participating, the cardiologist or nurse requested that the investigator visit with the patient to explain the study in greater detail. If a patient agreed to participate, he provided written consent (see Appendix G and H, Consent Form). After informed consent was obtained, the investigator checked the patient's eligibility to participate by asking him questions directly or reviewing his medical record (see Appendix I and J, Screening Form). For eligible patients, the investigator scheduled a date and time for an interview. The interview was conducted in the patient's room or in a private room in the cardiac ward. The interview, which took about 45 min, consisted of a standard approach to administer the questionnaires (see Appendix K and L, Questionnaire). The data were then abstracted from the patient's medical record.

### **Ethical Considerations**

Each potential participant was asked to give written informed consent. He was given verbal and written information that explained the study's purpose, the process, his responsibilities, and the length of the interview. In addition, the investigator made herself available to answer any questions at a time convenient to the patient either in his private

room or in a private conference room on the cardiac ward. Each patient was allowed adequate time to decide whether to participate in this study.

To protect the participants' privacy, the investigator obtained their information directly. Participants were approached during non-visiting hours and were interviewed at the time prearranged with the participant.

If a participant reported suicidal ideation (Item 9 on the PHQ-9), he was told that his physician would be informed for his safety and welfare. The attending physician was notified of this finding to initiate referral of the patient to a mental health professional for further evaluation and treatment, if indicated (Lichtman, et al 2008). Each patient was advised of this procedure during the consent process.

## **Data Management and Analysis**

Double data entry was employed to ensure maximum accuracy of the data entry procedures. All data were entered into SPSS version18 and analyzed. To answer the study's Aims 1-6: (1) to assess the demographic and clinical characteristic variables, the distribution was represented as means (standard deviations, median mode, and minimum and maximum value. Frequencies and proportions were used for categoricaly and ordinal variables. For all aims, frequencies and percentages were calculated for dichotomous and ordinal variables. Distributions means (SD), medians, modes were calculated for continuous variables. For Aim 7, a correlation metric using Pearson's correlation was used to identify bivariate relationships.

Chapter IV presents the results for each of the study's aims. Tables are provided.

#### **CHAPTER IV**

### FINDINGS

In this chapter the results for the each of the study aims are provided in text and, tables. Data collection took place in four hospitals in Japan from May of 2011 to February of 2012. A total of 104 men were enrolled in this study. The results for each of the research questions are as follows.

#### Aim 1. Assess demographic and clinical characteristics.

The demographic information for the sample is found in Table 4.1 and 4.2. A total of 104 men enrolled, whose mean age was 60.6 ( $\pm$ 13.5) years. Most (55.7%) were 60 or over. Almost half (46.2%) of the men had high school or some college or diploma education, and one third had a bachelors or graduate degree. Most (60%) were married. The average household size (including the subject) was 2.8 ( $\pm$ 1.4); ranging from one to seven. More than half of the men (56.7%) were employed full-time and one third of these smokers (27.9%) were unemployed or retired. About 60 % of the sample reported a household annual income of more than 4,000,000 yen (about \$47,058). This income supports two or more adults in most households (67%). Additionally, income from 23.1% of the men in sample supported one or more children.

The clinical characteristics for the sample are shown in Table 4.2 and 4.3. Most of the sample was recruited from three of the hospitals (94.2%); one hospital contributed 5.8%. Because the manager of the cardiac ward at KSH was transferred after the data collection began, it was necessary to brief a new manager on the data collection methods and readjust the methods of coordination with the manager. The average length of hospitalization was 17 days. In general, a patient who has had a heart attack and underwent any coronary

Table 4.1

	%	n
Education		
Less than junior high school completed	24.1	25
High school or college or diploma school completed	46.2	48
University (4 years) or more completed	29.9	31
Marital Status		
Married	59.6	62
Other	40.3	42
Work Status		
Full-time employment	56.7	59
Part-time employment	14.4	15
Unemployed or retired	27.9	29
Annual Household Income		
High (≥4,000,000 yen) (1 yen= \$0.011764)	59.7	62
Low (<3,999,999 yen) (1 yen= \$0.011764)	40.4	42
Number of Adults Supported by Income		
One	32.7	34
Two or more	67.3	70
Number of Children Supported by Income		
None	76.9	80
$\geq 1$	23.1	24

Demographic Data for Japanese Men Hospitalized with CVD (n=104)

## Table 4.2

Distribution of Smoking Related Variables (n=104)

	Mean (SD)	Ranges
Age	60.6 (±13.5)	27-88
LOS /days	16.8 (±14.7)	2-67
BMI	24.5(±3.5)	15.8-38.1
Distribution of Dependence	y and Psychosocial Variable	es
FTND	5.1 (±2.2)	0-10
MNWS	8.3 (±6.7)	0-25
PHQ-9	4.2 (±4.2)	0-18
ESSI	19.2 (±3.62)	9-25
SE (Confidence)	63.9 (±22.2)	7.14-100

Note. Length of Stay (LOS); Body Mass Index (BMI); Fagerstrom Test Nicotine Dependence (FTND); Minnesota Nicotine Withdrawal Scale MNWS; Patient Health Questionnaire (PHQ-9); Enriched Social Support Instrument (ESSI); Self-efficacy (SE).

catheter intervention stays in the hospital about 5-10 days in Japan. Smokers diagnosed with CHF, smokers who underwent multiple treatments such as Angioplasty and CABGS, or had any complications raised the average length of stay. The subjects' medical diagnoses for the index hospital admission are listed in Table 4.3. Almost half of the sample was admitted because of AP or MI (46.1%). Some of the patients (27.9 %) specified other reasons for admission which reflected predominantly procedures or PAD. Additionally, 14.4% were admitted because of CHF and 11.5% were admitted because of arrhythmias. During the index hospitalization, 35.6% received stents and 53% reported "other treatments". The other treatments included ablation, the implanting of a pacemaker or implanting cardioverter defibrillator. Other treatments included treatment through internal medicine for CHF patients. Few (4.8 %) underwent CABGS or coronary angiography (1.9%). Subjects who underwent any cardiac surgeries already stopped smoking at least one month before hospitalization. About half of the patients reported one or more symptom (chest pain, dyspnea, or fatigue) in their CVD diagnosis as shown in Table 4.3. One-third of the patients experienced edema and palpitation that were related to arrhythmia and CHF; and one-third of the patients experienced incisional or medical procedural pain or discomfort. The other symptoms that were reported by these smokers were numbress of fingers, forearm, headache, stiffness of neck, abdominal pain, heavy stomach, or claudication. Regarding the history of CVD, 25% reported a history of having had an AP or an MI in the past; one-third (28.8%) had arrhythmia; 10.6 % had CHF, 6.7% had PAD, and 4.8% had a stroke.

The men's cardiovascular risk factors are shown in Table 4.3. In addition to smoking, the following risk factors were reported: 53.8% had a positive family history of CVD;

Table 4.3

5 1 1	(	/
	%	n
Hospitals		
SHI	34.6	36
КСРС	27.9	29
CCC	31.7	33
KSH	5.8	6
Primary CVD Diagnosis		
AP	22.1	23
MI	24.0	25
CHF	14.4	15
Arrhythmia	11.5	12
Other	27.9	29
Treatment		
Angioplasty	1.9	2
Stent insertion	35.6	37
Coronary Artery Bypass Surgery	4.8	5
Valve Replacement	3.0	2.9
Aortic Vessel Replacement	3.8	4
Other	53.0	51
Symptoms (all that apply)		
Chest pain	49.0	51
Incisional and procedural pain or discomfort	30.8	32
Dyspnea	49.0	51
Edema	27.9	29
Fatigue	55.8	58
Palpitation	35.6	37
Others	48.1	50
CVD history	1011	20
Chest pain	14.4	15
MI	10.6	11
CHF	8.7	9
Arrhythmia	28.8	30
Valve deformity	10.6	11
Vessel dissection	3.8	4
PAD	5.8 6.7	47
Stroke	6.7 4.8	5
50060	4.0	3

Clinical Characteristics for Japanese Men Hospitalized CVD (n=104)

Table 4.3

	%	n
CVD Risk Factors (all that apply)		
Family history (n =56)	53.8	56
Father	69.6	39
Mother	55.4	31
Hypertension	48.1	50
Lipid abnormality	45.2	47
Physical inactivity	65.4	68
Diabetes Mellitus, type II	24.0	25
Overweight	47.1	49
Alcohol Intake		
No	35.6	37
Yes	64.4	67
Amount of Alcohol Intake (n=67)		
Less than 40g of alcohol	53.7	36
More than 40g of alcohol	46.3	31
Frequency to Take Alcohol		
Less than 3 times a week	37.3	25
4-5 times a week	10.4	7
Almost everyday	52.2	35

Clinical Characteristics for Japanese Men Hospitalized CVD (n=104) Cont'd

65.4% had a sedentary lifestyle; 48.1% had a history of hypertension; 45.2% had a history of lipid abnormality; and 24% had history of type 2 diabetes mellitus. Even though it was found that the average BMI was only 24.5 ( $\pm$ 3.5), 47.1% of this study subjects reported that they perceived themselves as overweight (see Table 4.2 and Table 4.3). Most (64.4%) reported that they regularly consumed some alcohol (see Table 4.3). Half of those subjects drank almost every day and consumed more than 40g of alcohol.

## Aim 2. Assess the sample's history and patterns of smoking.

The smoking history and patterns of smoking of the sample are given in Table 4.4. Initiation of smoking began from age 3 to 25. The mean age of first smoking was at age at 16.2 ( $\pm$ 3.9). Habitual smoking was reported on average at age 19.1 ( $\pm$ 3.0). Except for the outlier that one smoker who initiated smoking at age 3 years, the initiation of smoking clustered around the period of high school. After completion of high school habitual smoking was normal for the sample.

The number of cigarettes smoked per day ranged from 3 to 55 with an average of about one packet [mean=20.6 ( $\pm$ 3.5)] of cigarettes per day. Out of the 2.8 ( $\pm$ 1.4) average household members per family (see Table 4. 4), the average of 1.4 ( $\pm$ 0.6) family members of the household were also smokers. Table 4.5 contains the information about whether smoking was restricted at home or at the subject's workplaces: more than one-third reported that there was a restriction for where the subjects could smoke (home 39.4%; work 34.6%). The spaces where the smokers were able to smoke in their home were near the ventilation funnel in the kitchen, balcony, or their own room. Additionally, smokers were prohibited to smoke in front of grandchildren such as babies and little children.

#### Table 4.4

*History and Patterns of Smoking; (n=104)* 

	Mean ( $\pm$ SD)	Range
Number of cigarettes smoked per day	$20.6 (\pm 3.5)$	3-55
First cigarette after waking up (min) $\mathbf{a}$	26.6 (±75.6)	0-720
Age when first smoked	16.2 (±3.9)	3-25
Age of habitually smoking	19.1 (±3.0)	13-30
Number of household members	2.77 (±1.4)	1-7
Number of smokers in household	1.4 (±0.6)	1-4
Nature of previous quit attempts (n=67)	2.5 (±2.6)	1-15

<sup>a</sup> After exclusion of two extreme values (720 & 240) the mean was 19.6 ( $\pm$ 3.6).

## Table 4.5

	%	n
Smoking restriction at home	39.4	41
Smoking ban or any restriction at work place	34.6	36

## *Policies about Smoking at Home and at Work (n=104)*

## Aim 3. Assess beliefs and knowledge about smoking.

An assessment of the sample's knowledge about the effects of cigarette smoking is shown in Table 4.6. In response to the question "Smoking is harming my health" 81.7% were aware of this information, and 56.7% also knew that there are health benefits from quitting smoking after having smoked for 20 years. There were three additional statements for sample members to evaluate "One can avoid the development of lung cancer by quitting smoking" 65.4% answered yes. To the statement "One can avoid heart disease by quitting smoking" 74.0% answered yes. To the last knowledge evaluation statement; "One can avoid the development of respiratory disease by quitting smoking", 80.7% answered correctly yes. In response to the question "How likely do you think it is that you will avoid or decrease serious health problems from smoking if you quit?" 74.1% answered correctly that one's health problems can be reduced by quitting smoking.

Table 4.6

	%	n
Avoid or decrease health problems from quitting smoking	74.1	77
Health benefit to quitting after 20 years smoked	56.7	59
My smoking is harming my health	81.7	85
Avoid development of lung cancer from quitting smoking?	65.4	68
Avoid development of heart disease from quitting smoking?	74.0	77
Avoid development of respiratory disease from quitting smoking?	80.7	84

## Knowledge and Beliefs of Smoking (n=104)

# Aim 4. Assess the severity of nicotine dependency, withdrawal symptoms, depressive symptoms, perceived social support, and confidence to resist urge to smoke.

The sample's nicotine dependence score (FTND) ranged from 0 to 10 with a mean of 5.1 ( $\pm$ 2.2) as show in Table 4.2. With regard to the reported severity of nicotine dependency, only 20.6% reported low nicotine dependence (<3). Most (52.9%) reported moderate (4-6) and many (26.5%) (7-10) reported high dependence on nicotine (see Table 4.7). Furthermore, in answer to the single question "How soon after you wake up in the morning do you smoke the first cigarette," the range was 0 to 720 minutes with an average of 26.6 ( $\pm$ 75.6). After exclusion of the two extreme observations (720 and 240 minutes), the mean was 19.6 ( $\pm$ 3.6). The study subjects were moderately to highly dependent on nicotine. Withdrawal symptom (MNWS) ranged from 0 to 25 with a mean of 8.3 ( $\pm$ 6.7) as show in Table 4.2. Most subjects reported that they experienced one or more symptoms of withdrawal and their severity was mild to moderate.

#### Table 4.7

	%	n
Low (score 0-3)	20.6	21
Moderate (score 4-6)	52.9	54
High (score 7-10)	26.5	27

*Severity of Nicotine Dependence (FTND) (n=102)* 

The distributions of symptoms of depression using the depression screener PHQ-9 are shown in Table 4.2 and classification of depression is given in Table 4.8. The mean was  $4.25 (\pm 4.19)$ , the median was 3, and range was 0-18 based on a possible range of 0 to 27.

Most subjects (64.7%) reported no symptoms of depression and 35.3% reported depressive symptoms (20.6% minimal symptoms, 12.9% mild symptoms, 2% severe symptoms) (see Table 4.8). None reported a score  $\geq$ 20 i.e., major depression.

An assessment of perceived social support was made using the ESSI. The mean ESSI score was 19.2 ( $\pm$ 3.6) and range was 9-25 (see Table 4.2). The proportion of subjects that were classified as having low social support was 35.6% (see Table 4.8).

The distribution of the confidence to resist the urge to smoke (self-efficacy scores) is shown in Table 4.2. and 4.8. On a scale of 0 to 100, the mean score of a total of 14 items of self-efficacy score was a mean of 63.9 ( $\pm 22.2$ ) and was ranged from 7.14 to 100. When self-efficacy was evaluated, 59.1% were assessed as having low self-efficacy and 40.6% were assessed having high self-efficacy in relation to resisting the urge to smoke.

## Table 4.8

Depression (PHQ-9) (n=102)	%	n
None (<5)	64.7	66
5-9	20.6	21
10-14	12.9	13
15-19	2.0	2
≥20	0	0
Social Support (ESSI) (n=104)		
High social support	62.4	63
Low social support	37.6	38
Self-efficacy		
Low (<70 %)	59.4	60
High (≥70%)	40.6	41

Frequencies of Psychosocial Variables

#### Aim 5. The nature of previous attempts to quit smoking.

Of the 104 men, 65% (67 out of 104) had made at least one attempt to quit in the past. Of these, 20.9% had done so in the past 12 months (see Table 4.9). The total number of quit attempts ranged from 1 to 15 with a mean of 2.5 ( $\pm$ 2.6) (see Table 4.4).

The reasons given for their quit attempt (n=67) are shown in rank order in Table 4.9. Highest ranked (55.2%) was "bad for health." Next ranked (35.8%) was "having experienced a bad health condition." Third ranked (32.8%) was "cost of cigarettes."

The most common source of advice to quit was the physician. Table 4.9 shows the least common reasons for quitting were "smoking is becoming restricted in my office" (10.4%) and "having difficulty finding a place to smoke in public" (14.9%). The methods that subjects reported that they used in their past quit attempts (n=67) were "My own way" (or self-help) (98.5%) (see Table 4.9). Medications were used by only 12 men (17.9%) (5 used a nicotine patch and 8 used nicotine gum).

## Aim 6. Methods that smokers preferred to use in any future quit attempts.

The men indicated the following preferences for smoking cessation methods in their future quit attempts. "My own way "was given by 87.1%, and pharmacological treatment was given by 20.8%, and non-pharmacological interventions such as education and counseling was reported by 10.9%. A few (6.9%) would consider a combination of treatments.

Table 4.9

	Nature	of Previous	Quit Attempts	(n=67)
--	--------	-------------	---------------	--------

	%	n
Quit attempt last 12 months	20.9	14
Reason for quit attempt (checked ALL that apply)		
Bad for health	55.2	37
Have experienced bad health condition	35.8	24
To protect health for family members	28.4	19
Scared that I won't be able to stop smoking	11.9	8
Advised by family or friends	31.3	21
Advised by health care providers	28.4	19
Type of providers (n=19)		
MD	26.9	18
Nurse	13.4	9
Dentists	0	0
Others	1.5	1
Getting difficult to find a place to smoke in public place	14.9	10
Become restricted to smoke in my office or place to work	10.4	7
Troubles other people	25.4	17
Cost of cigarettes	32.8	22
Others	35.8	24
Methods for quitting		
My own way	98.5	66
Medication (all that apply) (n=12)	17.9	12
Nicotine patch	41.7	5
Nicotine gum	66.7	8
Others	50.0	6

Aim 7. To determine the relationships between nicotine dependencies, nicotine withdrawal symptoms, depressive symptoms, social support, and confidence to quit smoking.

A correlation matrix (see Table 4.10) provides the following associations.

The association of nicotine dependence (FTND), withdrawal symptoms (MNWS), depressive symptoms (PHQ-9), and perceived social support (ESSI) with confidence to resist the urge to smoke were evaluated. Two variables were statistically significantly correlated with confidence to resist the urge to smoke. These were withdrawal symptoms (MNWS) (r=-0.31, p=0.00) and social support (ESSI) (r=0.25, p=0.01).

The two measures of responses to withdrawal from nicotine once the patients was hospitalized (FTND and MNWS) were statistically significantly positively correlated with each other (r=0.24, p=0.01). Depressive symptoms (PHQ-9) were statistically significantly strongly correlated with withdrawal symptoms (MNWS) (r=0.51, p=0.00). Previous quit attempts were not correlated with any of the other variables. Furthermore, education and income were significantly moderately correlated (r=0.32, p=0.00). Education was also significantly moderately negatively correlated with depression (r=-0.21, p=0.02) as well as moderately negatively correlated with withdraw symptoms (r=-0.3, p=0.00).

This chapter provided the results for the seven study aims. In the next chapter, these findings are discussed and compared to the existing literature. The limitations and strengths of the study are delineated, and recommendations for practice, education, research and policy are provided.

				1	19	æ	4	5	9	7	8
	1. Education	Pearson	- d	1							
	2. Annual income	Pearson	чd	.317 .001**	г						
	3. Nicotine dependence	Pearson	- d	101 .311	.180 .070	1					
<u> </u>	4. Withdrawal symptom	Pearson	чd	309 .002**	098 .330	.240 .016*	-				
	5. РНQ-9	Pearson	ъч	206 .038*	1 <i>9</i> 2 .053	.136 .174	.510 .000 <b>*</b> *	-			
	<ol> <li>Perceived social support</li> </ol>	Pearson	- ዋ	-,039 .696	.036 .721	.074 .462	136 .177	187 .061	Π		
	7. Quit attempt	Pearson	чd	034 .734	.135 .175	.043 .667	.027 .790	043 .665	.025 .807	1	
~	8. Confidence	Pearson	ካ ብ	.192 .055	.008 .937	165 .099	301 .002**	.004 .966	.255 .010*	026 .793	-

#### **CHAPTER V**

## DISCUSSION

Chapter V presents this study's major findings and how these findings build on existing science that focuses on physiological and psychosocial factors for smoking and smoking cessation. Following a review of the study's strengths and limitations, its implications for practice, education, and policy development will be discussed. Finally, recommendations for future research will be offered.

This study investigated the characteristics and patterns of Japanese male smokers who were hospitalized with CVD. The participants were required to comply with a ban on smoking during their hospital stay. In this study, participants were aged 60 and older, well-educated, and categorized as having a middle-to-high annual income in Japanese society. More than one half of the men were employed full time; about one third were retired. Most were married and lived with two to three family members. The other CVD risk factors besides smoking, 65% of participants perceived they were physically inactive; roughly 50% had a family history of CVD, hypertension, or lipid abnormality; and 24% had a history of diabetes.

In contrast to previous studies, participants were slightly older, well-educated, employed full time, and had a middle-to-high annual income (Bolman, et al., 2002a; Chouinard & Robichaud-Ekstrand, 2005; Dornelas et al., 2000; Feeney et al., 2001; Froelicher et al., 2004; Hajek et al., 2002; Johnson et al., 1999; Reid et al., 2003; Rigotti et al., 1994; Smith & Burgess, 2000). Compared with a Korean study (Sohn et al., 2007), the subjects had more education and more were married. About 40% of participants reported that they could not smoke at home; 35% said they could not smoke at work. In their

research, Sohn et al. (2007) reported that 68% of subjects could not smoke at home; 20% were prohibited from smoking in the work place. Surprisingly, more Korean subjects were allowed to smoke in the work place than at home.

Half of the participants were diagnosed with AP or MI; the rest were diagnosed with arrhythmia, CHF, or PAD. They underwent various treatments during their hospital stay: internal medicine for CHF, implantation of a pacemaker or a cardioverter defibrillator, a cardiac or vascular operation, or coronary artery catheterization. Some of them underwent two or more treatments during a single hospitalization. In Japan, generally speaking, the average LOS in hospital for all causes was 18.5 days in 2009 (Ministry of Health, Labour, and Welfare, 2010a). In this study, LOS was 17days, but it covered a wide range (2-67 days). Participants diagnosed with an MI who were admitted to the hospital through its emergency department and progressed without any complications following clinical pathways had an LOS of 10-14 days. However, those diagnosed with CHF who received internal medical treatment or those who had a cardiac operation and subsequent complications may have increased the average LOS. Based on Japan's health care delivery system, the average LOS in this study was appropriate. However, compared with Western or Korean societies in which LOS is less than 10 days, the period of hospitalization was much longer (Chouinard & Robichaud-Ekstrand, 2005; Dornelas et al., 2000; Froelicher et al., 2004; Hajek et al., 2002; Johnson et al., 1999; Ockene et al., 1992; Quist-Paulsen & Gallefoss, 2003; Smith & Burgess, 2009; Sohn et al., 2007).

The longer LOS may have affected results for withdrawal symptoms on the MNWS. Although most subjects (about 80%) were moderately to highly nicotine dependent in this study, they reported less severe withdrawal symptoms from nicotine on

the MNWS (mean = 8.3 [ $\pm$  6.7]; MNWS scores can range from 0 to 36, a higher score implies severe symptoms). The severity and manifestation of withdrawal symptoms can vary widely from smoker to smoker. Besides these characteristics that differences in withdrawal symptoms from nicotine, the MNWS score is still considered low.

There are several reasons influencing the MNWS score can be considered. To assess withdrawal symptoms, the MNWS asks smokers to rate their discomfort symptoms over the past 24 hr. Nicotine withdrawal symptoms usually peak 3-10 days after smoking cessation or a reduction of nicotine use. They are usually most intense between the first and fourth days after cessation (American Psychiatric Association, 2000). However, study interviews were not conducted on the day of hospital admission or the day after admission. They were scheduled based on whether the participants' condition was stable or they were not in critical condition. Most of the interviews were conducted a week or more after hospital admission. However, in the interview process, one can overlook the assessment of withdrawal symptoms at their peak. Thus, it is possible to underestimate withdrawal symptoms from nicotine. Furthermore, Japanese men aged 60 and older consider patience a virtue, and they do not express their discomfort openly. This may also have influenced the severity of the withdrawal symptoms that they reported.

In comparing nicotine dependency and withdrawal symptoms with other studies, Western and Korean subjects have reported moderate-to-high nicotine dependency, even though those were measured by different instruments (Bolman, de Vries, & van Breukelen, 2002a; Chouinard & Robichaud-Ekstrand, 2005; Dornelas, Sampson, Gray, Waters, & Thompson, 2000; Feeney et al., 2001; Froelicher et al., 2004; Hajek et al., 2002; Johnson, Budz, Mackay, & Miller, 1999; Mohiuddin et al., 2007; Ockene et al., 1992; Quist-Paulsen

& Gallefoss, 2003; Reid et al., 2003; Reid, Pipe, Quinlan, & Oda, 2007; Rigotti, McKool, & Shiffman, 1994; Smith & Burgess, 2009; Sohn et al., 2007; Taylor, Houston-Miller, Killen, & DeBusk, 1990 ). Only Froelicher et al. (2004) assessed withdrawal symptoms. Although they reported that one third of smokers experienced some withdrawal symptoms, they did not assess their severity. In addition, the study subjects were women who were offered nicotine replacement therapy if requested during hospitalization. In this study, nicotine replacement therapy was not offered. For the reasons above, comparing the results of withdrawal symptoms with other studies is difficult.

Withdrawal symptoms correlated with confidence to resist the urge to smoke (r = -0.31, p = .00). The evidence that self-efficacy is applicable to smoking and smoking cessation behaviors has been documented: High-self efficacy is associated with being smoke free; low self-efficacy leads to continuation of smoking and relapse (van Berkel, van der Vlugt, & Boersma, 2000; Colletti, Supnick, & Payne, 1985; Condiotte & Lichtenstein, 1981; Froelicher et al., 2004; Rigotti et al., 1994; Smith & Burgess, 2009; Taylor et al., 1990; U.S. Department of Health and Human Services, 2008). If smokers gain better control of withdrawal symptoms, self-efficacy rises and with it the confidence to resist the urge to smoke. Even though a causal inference could not be drawn in this study, controlling withdrawal symptoms is most important, which is consistent with guideline recommendations (U.S. Department of Health and Human Services, 2008).

This study discovered several interesting characteristics in the participants' smoking patterns including their knowledge and beliefs, smoking behavior, and its related factors. Study participants started smoking habitually before age 20 [mean =  $1 9.1 (\pm 3.0)$ ] and smoked about 20 cigarettes per day [mean =  $20.6 (\pm 3.5)$ ]. These characteristics are

similar to those of smokers in a Western study (Dornelas et al., 2000; Feeney et al, 2001; Hajek et al., 2002; Johnson et al., 1999; Mohiuddin et al., 2007; Ockene et al., 1992; Reid et al., 2003; Reid et al., 2007; Rigotti et al., 1994; Smith & Burgess, 2009; Taylor et al., 1990). By comparison, 25.3 % of recent, regular, male smokers in Japan's general population smoke more than 20 cigarettes per day, and one third of them started smoking habitually before age 20. The participants in this study smoked more and many of them started smoking at a younger age than the general population of Japanese men.

About two thirds of participants (65%) made at least one quit attempt in the past; the total number of quit attempts ranged from 1 to 15 with a mean of 2.5 ( $\pm$  2.6). Past smoking studies reported similar results: Over 50-70% of smokers made serious attempts to quit in the past (Sohn et al., 2007; Reid et al., 2007); the total number of quit attempts was 2.6 ( $\pm$  3.9; Sohn et al., 2007). However, compared with the general population of Japanese men, the participants in this study made more quit attempts (52.1%), and they made quit attempts multiple times (Ministry of Health, Labour and Welfare, 2010a).

The principal reasons participants attempted to quit smoking were two: health and the cost of cigarettes. Even though they said that the former was their number one reason for quitting, their knowledge of smoking and its effect on their health was limited. In regards to knowledge and beliefs about smoking, 81.7% of participants were aware that smoking is harmful. In a Korean study (Sohn et al., 2007), 66.0% of smokers were aware that smoking is harming their health; in a Western study (Froelicher et al., 2004), roughly 90% of smokers were aware of that fact. Further, only 56.7% of smokers in this study knew that quitting smoking has health benefits, even for someone who has smoked for 20 years. In the Korean study (Sohn et al. 2007), 71.7% of smokers knew that quitting smoking has

health benefits; in the Western study (Froelicher et al., 2004), 80 % of smokers knew that. The Japanese subjects' deficit of knowledge about the benefits of quitting smoking should be a point of emphasis in the smoking cessation intervention. The smoking cessation intervention should offer a balanced explanation of both the harmful effects of smoking and the benefits of quitting.

In addition, this study also tested the participants' knowledge of the effects of quitting smoking on the development of lung cancer, heart disease, and respiratory disease. In answer to questions whether these three diseases could be avoided by quitting smoking, 65.4%, 74.0%, and 80.7% of Japanese subjects responded *yes*, respectively. By contrast, 66.0%, 78.3%, and 86.6% of Korean subjects responded *yes*, respectively (Sohn et al., 2007). The Korean subjects were marginally more knowledgeable than the Japanese subjects in this study. However, the benefit of quitting smoking for heart disease was less recognized than for respiratory disease, even though smoking cessation may cause one's risk of subsequent CVD events to approximate the level of those who never smoked within 5 years (Reid et al., 2003). This fact also needs emphasis in the smoking cessation intervention for smokers with CVD.

In Japanese general population; about half of current regular smokers recognized that smoking increased their risk of CVD versus and 87.5% current regular smokers recognized that smoking increases the risk of lung cancer. More subjects recognized that smoking increases the risk of lung cancer; whereas fewer knew that smoking increases the risk of CVD, which indicate that public education and patient education in Japan need to be addressed and that the harmful effects of smoking and the benefits of smoking cessation, for CVD especially, must be emphasized.

In past quit attempts (n = 67), most of the study's subjects (98.5%) reported that they used self-help ("My own way"). Medication was used by only 12 men (5 used a nicotine patch, and 8 used nicotine gum: the answer all that apply). These findings are similar to those of the Korean study (Sohn et al., 2007). Anecdotally, many participants believed that the key to success depends on the strength of an individual's will power not to smoke. This may explain the finding that most of the smokers (87.1%) reported that their preference for future quit attempts was "My own way". Pharmacological treatment was preferred by 20.8%, nonpharmacological interventions such as education and counseling was preferred by 10.9%, and some subjects would (6.9%) prefer a combination treatment. Of note, 9.8% of male smokers in the Japanese general population reportedly use nicotine gum, 9.2% use a smoking cessation intervention programs, and only 2.2% use nicotine patches (Ministry of Health, Labour and Welfare, 2010a). Based on this data, pharmacological treatment may control withdrawal symptoms better than the smoking cessation intervention program; it may bolster confidence to resist the urge to smoke.

The most common sources of support to quit smoking for hospitalized participants were physicians (26.9 %) and, less so, nurses (13.4%). The Korean study reported that about 56% of smokers were advised to quit smoking during hospitalization by some type of health care provider (Sohn et al., 2007). Sohn et al. (2007) found that the nurses were less likely than physicians to offer smoking cessation advice during a smoker's hospitalization. Both in Japan and Korea, nurses were less likely than physician to offer smoking cessation interventions, but the frequency with which nurses provide smoking cessation support for smokers during hospitalization was much lower by Japanese than Korean health care providers. Race & Stead (2008) reported that the smoking cessation intervention offered

by nurses to hospitalized smokers with CVD was effective, therefore there are clear implications that nurses should participate and implement smoking cessation intervention in the future. In addition, implementation of smoking cessation support in their practice is urgently needed, nurses should provide the information to increase the smokers' knowledge and provide skills to help smokers who are hospitalized with CVD.

As for psychosocial factors, 35.3% of smokers reported some level of depressive symptoms (20.6% minimal symptoms, 12.9% mild symptoms, 2% severe symptoms). In their study, Froelicher et al. (2004) found that female smokers reported high levels of depression (56.7%); Sohn et al. (2007) reported that 17.5% of the smokers in their study were depressed, which is lower than that of the subjects in this study. Although the literature states that depression is common in patients with CVD (Lichtman et al., 2008; McManus, Pipkin, & Whooley, 2005; Rutledge, Reis, Linke, Greenberg, & Mills, 2006), the frequency of depressive symptoms in this study's subjects was low.

This study evaluated symptoms caused by nicotine withdrawal and depression. The questionnaires (i.e., the MNWS and the PHQ-9) used similar, common language when asking about depressed mood, difficulty concentrating, or insomnia and sleep problems. These symptoms can often occur during hospitalization, particularly in the intensive care unit (ICU) where patients have little privacy, are bombarded by the ambient noise of staff and medical equipment, and are subject to a lighted room and surroundings around the clock. If smokers believe that their symptoms are caused by the ICU environment, they might not report their symptoms as being caused by depression or withdrawal from nicotine.

About two thirds of participants drank alcohol (65%), and about half of those

(46.3%) consume more than 40 g of alcohol at one time. Regarding the frequency of alcohol intake, half of the participants drank almost every day (52.2%) and 10.4% drank 4 to 5 times a week. This alcohol intake is quite high. In the general population of Japanese men, by comparison, 35.9% drink alcohol more than 3 times a week and consume more than 20 g of alcohol at the one time (Ministry of Health, Labour and Welfare, 2010a). The Korean study (Sohn et al., 2007), which also evaluated alcohol use, reported that more than half of smokers (53.4%) reported high consumption of alcoholic beverages. Sohn et al. (2007) noted the importance of assessing alcohol abuse and smoking during hospitalization and should be provide smoking cessation intervention that designed for alcohol use. This study assessed only alcohol intake and did not evaluate alcohol abuse with an instrument designed for that purpose. Further assessment of alcohol use and abuse may be needed to provide suitable smoking cessation intervention, particularly for Japanese men.

Regarding social isolation, the mean ESSI score was 19.2 ( $\pm$  3.6), which was lower than that in the Korean study (mean = 27.6[ $\pm$  3.6]). The proportion of subjects in this study who were classified as having low social support was 37.6%. Social support was statistically correlated with the confidence to resist the urge to smoke (r = .25, p = .01). Social isolation, therefore, should be considered to be an important, influential factor. This finding is consistent with a guideline by U.S. Department of Health and Human Services, (2008) stated that a high abstinence rate is associated with a supportive social network (U.S. Department of Health and Human Services, 2008).

## **Strengths and Limitations**

## Strengths

This is the first study of Japanese male smokers who were hospitalized with CVD.

The comprehensive assessment of their physical, psychosocial, and nicotine dependence provides clinicians and scientists with important new information. The detailed description of previous quit attempts, the methods used in such attempts, and preferred methods for future quit attempts provide the background information necessary for the development of culturally appropriate smoking cessation approaches. Including men from community hospitals and private hospitals that were major referral centers allows for generalizability to male smokers who have CVD. This study identified withdrawal symptoms and social support as two variables that are highly correlated with the confidence to resist the urge to smoke. This finding leads to important new questions for future hypothesis testing.

## Limitations

Because this study included only men, its findings cannot be generalized to Japanese women. Cross-sectional study design precludes causal inference. Furthermore, survival bias and mobility bias are likely because only persons who survived their heart attack, who were able to be admitted to the hospital, and who were stable participated in this study. In addition, being unable to collect data immediately from patients upon admission may have understated their withdrawal symptoms. Also, the convenience sampling method likely caused some selection bias of unknown magnitude.

## **Implications for Practice**

To improve patients' confidence to resist the urge to smoke, nurses should assess their symptoms of withdrawal from nicotine and assist them in managing their symptoms during hospitalization. Nurses must first know how to assess the symptoms of nicotine withdrawal before they can manage symptoms or patient discomfort. Clearly, pharmacological therapy has been shown to be effective, safe, and helpful for patients.

Accordingly, nurses should request prescriptions for such medication from the patients' physicians. However, in this study, most of participants did not use pharmacological therapy. It is likely that Japanese patients may be hesitant about using pharmacological therapy and less aware that it can be a helpful method for smokers. To incorporate pharmacological therapy into their practice, nurses and other health care providers must become knowledgeable about their use if they are to counsel smokers appropriately. As an aside, hospitals should consider an initiative to screen every patient admitted to the hospital to determine if he or she is a smoker; if so, the patient should be advised to quit and be given a referral for smoking cessation counseling. Finally, alcoholism must be assessed, in addition to alcohol intake, using an instrument designed for that purpose. This approach may lead to more thorough patient assessment and provide a more suitable smoking cessation intervention.

# **Implications for Education**

Based on this study's finding that only 13.3 % of nurses (i.e., nine nurses) advised participants to quit smoking, it appears that nurses are not active in counseling patients about smoking cessation. Nurses must become more aware of the importance of smoking cessation and gain the education and skills to effectively counsel patients about it. In the interim, they should be advised to refer patients to a smoking cessation program. For nurses who are already in the workforce, seminars and workshops on intervention content and skills could be another valuable initiative.

Undergraduate and graduate nursing programs should incorporate into their curricula not only the harmful outcomes of long-term smoking but also how to educate and counsel patients effectively. This initiative should provide evidence-based smoking

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cessation interventions and prepare nurses with the skills to deliver other behavioral interventions to reduce CVD risk, such as regular exercise, proper food choice, or self-monitoring.

# **Implications for Policy Development**

More than one third of study participants reported that they were restricted from smoking at home (39.4%) or at work (34.6%). This finding has implications for public policy development. For example, should smoking bans be instituted or smokers made an educational priority? Ministries of health may be well-advised to institute workplace policies that enforce such policies to protect workers' safety. However, workplace location, outdoors or indoors, is an issue that must be considered. A smoking ban may not be appropriate for all occupations, for example, construction workers, farmers, or fishermen who work outdoors. Protecting the health of smokers who work outdoors or work alone should be addressed as a separate issue. Participants also cited the cost of cigarettes as a motivating reason to quit smoking. Accordingly, policy makers should weigh the pros and cons of increasing the cost of cigarettes to protect smokers' health.

# **Recommendations for Future Research**

A study that includes women and a large sample of urban and rural settings would increase the validity of this study's findings. Such a study, together with the present study, would provide the information necessary to formulate culturally specific interventions that would be acceptable to Japanese men and women.

The results of this study will be useful in developing effective and culturally unique smoking cessation intervention programs for the Japanese population with CVD. It will also help Japanese nurses improve their practice in counseling patients with CVD to sustain

abstinence once they have quit smoking. Furthermore, this study will aid nurses in identifying the preferences smokers have for future smoking cessation interventions.

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APPENDICES



### Human Research Protection Program Committee on Human Research

### **Notification of Expedited Review Approval**

 Principal Investigator
 Co-Principal Investigator

 Erika S Froelicher
 Initial Review Submission Packet

 Study Title:
 Smoking patterns and willingness to quit smoking in Japanese men hospitalized patients with cardiovascular diseases

 IRB #:
 11-05679

 Reference #:
 018598

 Committee of Record:
 San Francisco General Hospital Panel

 Study Risk Assignment:
 Minimal

Approval Date: 05/04/2011 Expiration Date: 05/03/2012

Regulatory Determinations Pertaining to this Approval (if applicable):

This research is not subject to HIPAA.

All changes to a study must receive CHR approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

**Expiration Notice:** The iMedRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for <u>continuing review</u> approval has been submitted by the required time. In addition, you are required to submit a <u>study closeout</u> report at the completion of the project.

Approved Documents: To obtain a list of documents that were <u>approved with this submission</u>, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of <u>all currently approved documents</u>, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR <u>website</u> has more information.



### Human Research Protection Program Committee on Human Research

### Notification of Expedited Review Approval

<u>Principal Investigator</u> Erika S Froelicher		Co-Principal Investigator
Type of Submission: Study Title:	Modification Form Smoking patterns and willing patients with cardiovascular o	ness to quit smoking in Japanese men hospitalized liseases
IRB #: Reference #:	11-05679 026250	
Committee of Record:	San Francisco General Hosp	tal Panel
Study Risk Assignment	: Minimal	
Approval Date:	07/28/2011	Expiration Date: 05/03/2012

Regulatory Determinations Pertaining to this Approval (if applicable):

IRB Comments (if applicable):

All changes to a study must receive CHR approval before they are implemented. Follow the <u>modification</u> request instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

**Expiration Notice:** The iMedRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for <u>continuing review</u> approval has been submitted by the required time. In addition, you are required to submit a <u>study closeout</u> report at the completion of the project.

**Approved Documents:** To obtain a list of documents that were <u>approved with this submission</u>, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of <u>all currently approved documents</u>, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR <u>website</u> has more information.

# Appendix B: Ethic approval letter Sakakibara Heart Institute

January, 16, 2011

Ayako Okada, RN, CNS, PhDc 3857 22<sup>nd</sup> Street San Francisco, CA, 94114 U.S.A.

Umemura Jun, MD, Vice President & Director of Cardiology Department Sakakibara Heart Institute Chikako, Miura., RN, MS. Director of Nursing Department Sakakibara Heart Institute 3-16-1 Asahicho Fuchu-shi Tokyo, Japan 183-0003

Dear Ms. Ayako Okada

•.

I am Jun Umemura and a vice president and director of the cardiovascular department at the Sakakibara Heart Institute. This letter is to inform that we, Sakakibara Heart Institute are please to support your dissertation study that assesses patterns of smoking for patients hospitalized with CVD after your study obtained approval from ethical commette at our institute. Your dissertation topic is unique and innovative and is very important for our understanding of Japanese patients and has the potential to inform future smoking cessation interventions. Your study will contribute to the development of effective smoking cessation intervention for patients with CVD as well as the future advancement of cardiovascular nursing in Japan; specifically nursing intervention for cardiovascular disease prevention in Japanese patients with CVD.

Letter of Support

Vice President & Director of Cardiology Department Director of Nursing Department Sakakibara Heart Institute

Signature \_\_\_\_\_

Sakakibara Heart Institute

Signature Chikako Miura

平成 23 (西暦 2011 ) 年 5月 25 日

# 倫理委員会審査結果通知書

University of California, San Francisco, School of Nursing, Physiological Nursing 学生 岡田彩子 殿 看護部 主任部長 三浦稚郁子 殿

看護部 主任部長 三浦	椎郁子 殿
申請につき	榊原記念病院 院長 友池 仁暢 印 まして、下記の通り決定しましたので通知いたします。
	記
審査対象(研究名)	循環器疾患で入院治療を受ける男性患者の喫煙・禁煙パターン の特徴、及び禁煙への自信とその関連要因に関する研究
申請者	University of California, San Francisco, School of Nursing, Physiological Nursing 学生 岡田彩子 看護部 主任部長 三浦稚郁子
審查事項	研究実施の可否
倫理委員会開催日	平成 23 年 5 月 24 日
審查区分	<ul> <li>■ 本委員会</li> <li>□ 臨時委員会</li> <li>□ その他( )</li> </ul>
倫理委員会審査結果	<ul> <li>□ 承認</li> <li>■ 条件付き承認</li> <li>□ 不承認</li> <li>□ 継続審議</li> <li>□ 非該当</li> </ul>
医療機関の長の意見	<ul> <li>□ 承認</li> <li>■ 条件付き承認</li> <li>□ 不承認</li> <li>□ 継続審議</li> <li>□ 非該当</li> </ul>
条件及び特記事項	説明文書を以下の点で適切な内容表現に改めること ① タイトルの付け方 ② 看護部長の紹介、インタビューやプライバシーに関する箇所の 言い回し ③ 「研究に参加することの弊害」の内容を明記あるいは標題の修 正

以上

### 平成 23 年 6 月 10 日

# 修正報告書

院 長 殿 倫理委員会委員長 殿

申請者:

.

University of California, San Francisco, School of Nursing, Physiological Nursing 学生 岡田彩子 看護部 主任部長 三浦稚郁子

平成 23 年 5 月 24 日開催の倫理委員会本委員会において審査され、条件付き承認·不承認· 継続審査 とされた臨床研究につきまして下記の通り修正しましたので報告致します。

記

課題名	循環器疾患で入院治療を受ける男性患者の喫煙・禁煙パターンの特 徴、及び禁煙への自信とその関連要因に関する研究
指示事項	説明文書を以下の点で適切な内容表現に改めること ①タイトルの付け方 ②看護部長の紹介、インタビューやプライバシーに関する箇所の言い回し ③「研究に参加することの弊害」の内容を明記あるいは標題の修正
修正内容	別紙の通り。
L	以上

.....

上記修正を確認し、実施を承認する。

平成 23 年 7 月12日

榊原記念病院	É			A.J.Z
倫理委員会	委員長	維田	隆夫	FF
院	長	友池	仁暢	
				VIEL

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# Appendix B: Ethic approval letter Chiba Cardiovascular Center



### (別紙様式3)

循 七 第 2 7 7 号 平成23年 5月 2日

# 倫理審查結果通知書

受付番号 第4号

課題名

循環器疾患で入院治療を受ける男性患者の喫煙・禁煙パターンの特徴、 及び禁煙への自信とその関連要因に関する研究

申 請 者 看護局 主任看護師 山内英樹 様

千葉県循環器	諸病セン	ンター	代葉県循
千葉県循環器 センター長	小野	純	13年14日に フター最

平成23年4月12日付で申請のあった上記課題について、下記のとおり決定したので通 知する。

56						
審査結果	承認	条件付承認	変更の勧告	不承認	非該当	
理由又は勧告	ř					
付帯条件					and the second	
1. 研究協力	り者を増や	すこと。				
2. 同意書語	説明文中の	問い合わせ先は山口	内主任看護師あて	とすること。		
3. 同意書詞	説明文中の	略語をわかりやすい	い表現に訂正する	らこと。		
	E 社田のに	え方について、患者	者さんに配慮した	方法を検討す	すること。	

83

January 17, 2011

Letter of Support

Ayako Okada, RN, CNS, PhDc 3857 22<sup>nd</sup> Street San Francisco, CA, 94114 U.S.A.

Miyazaki, Akira., MD, Director of Cardiology Department & Kameda, Hideko, RN. Director of Nursing Department Chiba Cardiovascular Center 575 Tsurumai Ichihara-shi Chiba, Japan 290-0512

Dear Ms. Ayako Okada

I am the director of the cardiovascular department at the Chiba Cardiovascular Center. This letter is to inform that we, Chiba Cardiovascular Center are please to support your dissertation study that assesses patterns of smoking for patients hospitalized with CVD. Your dissertation topic is unique and innovative and is very important for our understanding of Japanese patients and has the potential to inform future smoking cessation interventions. Your study will contribute to the development of effective smoking cessation intervention for patients with CVD as well as the future advancement of cardiovascular nursing in Japan; specifically nursing intervention for cardiovascular disease prevention in Japanese patients with CVD.

Director of Cardiology Department Chiba Cardiovascular Center Director of Nursing Department Chiba Cardiovascular Center

Signature alin prygolie

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Signature Hideko Kameda

# 倫理審查承認証明書

平成23年2月15日に開催された平成22年度第3回倫理委員会にお いて、本施設での看護研究実施の受入れと事前の患者情報提供に関す る同意について審査され、次の研究が本施設で実施されることについ て承認を得たことを証明します。

研究テーマ:循環器疾患で入院治療を受ける男性患者の喫煙・禁煙パ ターンの特徴、及び禁煙への自信とその関連要因に関す る研究

研 究 者:岡田 彩子

平成 23 年 2 月 16 日

所	在	地	横浜	市金沢国	区富岡東	更 6-16	6-1		
名		称		独立行政沿 川県立彼					
代	表者B	氏名	所	長	廣	瀬	好	文	

Date 2011/ 2 123

## Letter of Support

Ayako Okada, RN, CNS, PhDc 3857 22<sup>nd</sup> Street San Francisco, CA, 94114 U.S.A.

Shigehiko, Tokunaga., MD, Director of Cardiac Surgery Department & Naoko, Nagaba., RN. Director of Nursing Department Kanagwa Cardiovascular Respiratory Center 6-16-1 Tomiokahigashi Kanazawa-ku Kanagawa, Japan 236-0051

Dear Ms. Ayako Okada

I am the director of the cardiac surgery department at the Kanagwa Cardiovascular & Respiratory Center. This letter is to inform that we, Kanagwa Cardiovascular & Respiratory Center are please to support your dissertation study that assesses patterns of smoking for patients hospitalized with CVD. Your dissertation topic is unique and innovative and is very important for our understanding of Japanese patients and has the potential to inform future smoking cessation interventions. Your study will contribute to the development of effective smoking cessation intervention for patients with CVD as well as the future advancement of cardiovascular nursing in Japan; specifically nursing intervention for cardiovascular disease prevention in Japanese patients with CVD.

Director of Cardiac Surgery Department Kanagwa Cardiovascular & Respiratory Center

Signature Shignfiles Tehres

Director of Nursing Department Kanagwa Cardiovascular & Respiratory Center

Signature naako. Nagaba.

Date June 18/2011

Letter of Support

Ayako Okada, RN, CNS, PhDc 3857 22<sup>nd</sup> Street San Francisco, CA, 94114 U.S.A.

Ishii Eiki, MD., President Oketa Riki, MD., Chair of Committee of Human Research & Kumiko, Sato., RN., Director of Nursing Department Kawasaki Saiwai Hospital 39-1 Miyako-cho Saiwai-ku Kawasaki-shi Kanagawa, Japan 212-0021

Dear Ms. Ayako Okada

I am the director of the cardiac surgery department at the Kawasaki Saiwai Hospital. This letter is to inform that we, Kawasaki Saiwai Hospital are please to support your dissertation study that assesses patterns of smoking for patients hospitalized with CVD. Your dissertation topic is unique and innovative and is very important for our understanding of Japanese patients and has the potential to inform future smoking cessation interventions. Your study will contribute to the development of effective smoking cessation intervention for patients with CVD as well as the future advancement of cardiovascular nursing in Japan; specifically nursing intervention for cardiovascular disease prevention in Japanese patients with CVD.

President at Kawasaki Saiwai Hospital

Ishii Eiki, MD.

Signature Liki Ishir

Director of Nursing Department Kawasaki Saiwai Hospital Sat**a**o Kumiko, RN

Signature Kumiko. Sato

Chair of Committee for Human Research at Kawasaki Saiwai Hospital Oketa Riki, MD.

Signature Rik: Cheda

 差出人:
 Karl-Olov Fagerström <karl.fagerstrom@swipnet.se>

 送信日時:
 2011年1月6日木曜日 15:40

 宛先:
 Okada, Ayako

 件名:
 FTND

 フラグの内容:
 ご協力お願いします

 フラグま
 フラグあり

 分類項目:
 分類項目 オレンジ

Dear Mr Okado.

Thank you very much for your interest in my scale. There are no problems whatsoever in using it. You have my permission to use the FTND here.

It is certainly translated into the Japanese language before. You can please ask Prof Masakazu Nakamura who is a good colleague of mine. His e-mail address is <a href="mailto:nakamura@kenkoukagaku.jp">nakamura@kenkoukagaku.jp</a>

Good luck with your research.

Karl Fagerstrom

Från: Okada, Ayako [mailto:Ayako.Okada@ucsf.edu] Skickat: den 5 januari 2011 21:40 Till: <u>karl.fagerstrom@swipnet.se</u> Kopia: Okada, Ayako Ämne: FTND

Dear Dr. Karl O. Fagerström,

The purpose of the e-mail is would like to ask you to use the FTND to my doctoral dissertation study. I am Ayako Okada and am a Japanese international student at UCSF school of nursing. My area of research is that cardiovascular disease prevention. My dissertation topic will be to explore the smoking patterns of patients who are hospitalized with cardiovascular disease (CVD) in Japan.

I would like to obtain a permission to use FTND scale in my study and would like to translated in Japanese. If you could kindly offer the permission to reprint, could you inform me the steps I may take or any forms I need to fill out.

1

In advance, thank you very much for your any assistance, help, or advice that you could provide me.

Best regards,

Ayako Okada

Appendix D: Japan Health Care Research approval letter (MNWS)

### 禁煙調査票(日本語版)使用登録申込書

財団法人パブリックヘルスリサーチセンター 殿

### 使用登録する調査票

喫煙衝動に関する調査票(BQSU)	
ミネソタ式 ニコチン禁断症状調査票(MNWS)	
禁煙時のクオリティ・オブ・ライフ (QOL) に関する調査票(ScQOL)	
喫煙の影響に関する調査票(SEI)	

研究題目

循環器疾患で入院治療を受ける患者の喫煙・禁煙パターンの特徴、及び禁煙への自信とその関連要因に関する研究

#### 研究目的

循環器務	実患で入院した日本人の患者を対象に以下の項目を調査していく
(1)	人口統計学的、および臨床的特徴を明らかにする
(2)	喫煙パターンを記述する
(3)	喫煙に関する知識を評価する
(4)	過去の禁煙経験の特徴を明らかにする
(5)	今後の禁煙への挑戦時に活用したい方法を明らかにする
(6)	禁煙への自信を評価する
(7)	うつ状態に関連する症状の体験を評価する
(8)	ニコチン依存度を評価する
(9)	ニコチン離脱症状の体験を評価する
(10)	Independent and interdependent self-construals
(11)	うつに関連する症状の体験、ニコチン依存度、ニコチン離脱症状の体験、および
	・ ・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・

Independent and interdependent self-construals と禁煙への自信の関連性を明らかにする

#### 対象者数

のべ 205 名(複数回使用する場合は研究対象者の複数倍となります)

# 研究主体

# 研究代表者

	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
氏名:岡田	彩子
所属: Unive	rsity of California, San Francisco, School of Nursing, Physiological Nursing
	rtment
住所:3857	22 <sup>nd</sup> Street, San Francisco, CA, 94114
電話:1-415	-970-1081 (home) 1-415-786-3278 (mobile)
FAX:	
e-mail : Ayal	co.Okada@ucsf.edu

連絡先(研究代表者と同一の場合、記入不要)

氏名:		
所属:		
所属: 住所: 電話: FAX:		
電話:		
FAX:		
e-mail :		

 ・研究毎に申請してください。
 ・研究主体が研究者の場合,登録申込のみで使用可能です。研究主体が企業の場合,1調査 栗の場合使用登録料として 200,000 円, 複数調査票の場合は1 調査票につき 150,000 円をお 支払ください。

・使用申込を受理した後、申込のあった調査票の PDF ファイルを e-mail 添付にて送ります。 ・ 調査票の体裁は変更しないでください。

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### ミネソタ式 ニコチン禁断症状調査票

	ぜんぜん あてはまらない	わずかに あてはまる	少し あてはまる	かなり あてはまる	非常に あてはまる
とてもタバコが吸いたい	0	1	2	3	4
気分が落ち込む	0	1	2	3	4
イライラ・欲求不満・ 怒りを感じる	0	1	2	3	4
不安を感じる	0	1	2	3	4
集中できない	0	1	2	3	4
落ち着かない	0	1	2	3	4
食欲が増す	0	1	2	3	4
寝つきが悪い	0	1	2	3	4
眠っても途中で目が覚める	0	1	2	3	4

# 下記のそれぞれの質問について、この一日間(24 時間)のあなたの状態に一番よくあてはまる番号 に○をつけてください。

MNWS\_Japanese\_ver.1.0

Appendix E: Pfizer Japan Inc (PHQ-9; Japanese)

### 兵庫県立大学看護学部看護基礎講座 岡田 彩子様

このたびはご連絡いただきありがとうございました。 「PHQ·9 日本語版 こころとからだの質問票」 の使用でございますが、 「自主研究」として着手していただくことにつきましては 2011 年 1 月に Pfizer 社ご担当から許諾のご回答をさせて いただいたかと存じます。

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研究はすでに終了されておられるかもしれませんので、 研究申請書は、簡易サマリーで結構です。(倫理委員会申請中でも結構です。)

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他の全ての研究機関、学会、自治体等にお願い申し上げさせていただいて おりますので、ご賢察・ご検討いただければ幸いです。



Lippincott Williams & Wilkins 351 W. Camden Street Baltimore, MD 21201 410 528 4000 tel www.LWW.com

#### DATE: 1/31/11

Ayoko Okada 3857 22<sup>nd</sup> Street San Francisco, CA 94114

Fee: \$0.00

#### Re: Journal of Cardiopulmonary Prevention & Rehabilitation Spec Mat: HCR, 2003; 23(6):402, Appendix 1

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### UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO BE IN RESEARCH

Study Title: Characteristics and Patterns of Smoking in Japanese Men Patients Hospitalized with Cardiovascular Disease (CVD)

This is a research study, and you do not have to take part. The researcher, Erika Froelicher, RN, PhD., and Ayako Okada, RN, CNS,  $PhD_{(c),}$  from the UCSF School of Nursing Department of Physiological Nursing will explain this study to you. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have smoked at least 100 cigarettes in their lifetime and you at least one tobacco product every day or nearly every day. You are 18 years of age or older, 2) men, 3) have a CVD diagnosis.

In this study, the researchers are doing a survey to learn more about what smoking pattern and nature of previous quit attempts, and preferences methods for future quit attempts for men patients hospitalized with CVD in Japan. In addition what factor may influence to the confidence to future quit attempts for the patients. There is no sponsor paying for this research. About 205 people will participate in this study.

#### What will happen if I take part in this study?

If you agree to be in this study, the researcher will check your medical chart to confirm detail eligibility for this study. The researcher will check your data: hospital of admission, medical diagnose, medical or surgical procedure, and your age. If you are eligible for this study, you will complete a survey at the Sakakibara Heart Institute, Chiba Cardiovascular Center, Kanagawa Cardiovascular Respiratory Center or Kawasaki Saiwai Hospital. The survey asks about you to describe your experiences with smoking habit, previous quit attempts, symptoms regarding nicotine withdrawal, and feeling about your life or social relationships. In addition, the researcher will ask you regarding your feeling or mood during last 2 weeks, how confidence to quit smoking, feelings and behaviors in various situations in your life and perceived your social support. It will take you about 45 to 50 minutes that less than an hour to complete the survey.

If you obtain high score on the Patient Health Questionnaire-9 (PHQ-9) (asks you about your mood or feeling during last 2 weeks), which implies you may suffer from moderate to severe depressive symptom. Then you will be informed your score and its' interpretation. You will be asked to let your attending physician(s) be informed your PHQ-9 score for your safety and welfare.

#### Are there any risks to me or my privacy?

Some of the survey questions may make you feel uncomfortable or raise unpleasant memories. You are free to skip any question.

We will do our best to protect the information we collect from you. Information which identifies you will be kept secure. The survey itself will not include details which directly identify you,

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such as your name or address. Please do not put this information on your survey. The completed surveys will be kept secure and separate from information which identifies you. Only a small number of researchers will have direct access to completed surveys. If this study is published or presented at scientific meetings, names and other information that might identify you will not be used.

### Are there benefits?

There is no benefit to you. The survey results will be used for research.

#### Can I say "No"?

Yes, you do not have to complete a survey. If you choose not to be in this study you will not lose any of your regular benefits, and you can still receive medical care from at the Sakakibara Heart Institute, Chiba Cardiovascular Center or Kanagawa cardiovascular respiratory center.

#### Are there any payments or costs?

You will not be paid for completing the survey. There are no costs to you.

#### Who can answer my questions about the study?

You can talk with the study researcher about any questions, concerns, or complaints you have about this study. Contact the study researcher(s) Ayako Okada, RN, CNS, PhD© at 090-1205-7172 or director of nursing department Chikako Miura, RN, MS at 042-314-3111(Sakakibara Heart Institute): or director of nursing department Naoko Nagaba, RN, at 045-701-9581 (Kanagawa Cardiovascular and Respiratory Center): or Certified critical care nurse Hideki Yamauchi, RN, MS 0436-88-3111 -ext 2743 (Chiba Cardiovascular Center): or director of nursing department Kumiko Sato, RN 044-544-4611(Kawasaki Saiwai Hospital)

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at 415-476-1814.

#### CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY.

You have been given copies of this consent form to keep.

If you wish to be in this study, please sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

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[Mar2011]

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# カリフォルニア大学,サンフランシスコ校 研究参加への同意

# 研究テーマ:日本人男性の循環器疾患入院患者の喫煙の特徴及びパターンに関す る研究

本研究は日本人の男性循環器疾患患者の喫煙パターンを探求することが主な目的です。 加えて皆様の過去の禁煙体験や、今後の禁煙挑戦時に使用を試みたい禁煙支援の方法、 今後の禁煙への自信及びそれに関連している要因も調査します。本研究は、カリフォル ニア大学サンフランシスコ校看護学研究科身体生理看護学講座の Erika Froelicher, RN, PhD と岡田彩子, RN, CNS, PhD<sub>(e)</sub>が共同で行う研究です。本研究に関する事は、本研究 員の岡田彩子が説明を致します。

また本研究は、榊原記念病院の倫理委員会の承認を得ており、当院看護部長の三浦稚郁 子の協力のもとに行っている研究です。

あなたは、今までの生涯で100本以上のタバコを喫煙し、かつ入院前に毎日、またはほ ぼ毎日最低1本のタバコを吸っている喫煙者である事、並びに、1)18歳以上、2)男 性、3)循環器疾患で入院している患者であることから、本研究の対象への参加をおた ずねしています。

本研究は、循環器疾患で入院されている男性患者様の禁煙パターン、過去の禁煙体験、 今後の禁煙挑戦時に使いたい禁煙支援の要望などを明らかにするアンケート調査です。 さらに将来の禁煙への自身とそれに関連する因子を明らかにすることが目的です。本研 究は特定のスポンサーの助成は受けておりません。本研究は205名の方に参加のご協力 いただいたく予定でおります。

#### 本研究に参加した場合にお願いすることについて

もし本研究参加に同意していただける場合、榊原記念病院に入院中に、アンケート調査 (インタビュー)にご協力をお願いします。

インタビューでは、あなたの喫煙習慣、過去の禁煙への試み、ニコチン離脱症状の体験、 日常生活で感じる事や社会生活における人間関係などについて質問させていただきます。 加えて、あなたの過去2週間の感情や気持ち・心的状態、将来の禁煙に関する自信、日 常の様々な状況下でのあなたの行動や気持ち、社会的支援に関する事を質問させていた だきます。インタビューの所要時間は最長で45分~50分を予定しており、1時間以内 で全て終了すると想定しております。

インタビューの質問には、「心と体の質問紙」が含まれています(あなたの過去2週間 の気持ちや心的状態に関する質問)。もしあなたが、その質問項目で高い得点を得た場 合、心や体が不調になっている可能性が考えられます。その場合、本研究員は、あなた の点数とその解釈についてお話させていただきます。そして、あなたから承諾を得た後

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に、あなたの心身の安全のために、あなたの担当医にも、心と体の質問紙の結果を報告 させていただくことがあります。

本研究へ参加することで生じる弊害やプライバシーの保持について

インタビュー中、いくつかの質問があなたを不愉快にさせてしまったり、答えたくない と思う内容が含まれるかもしれません。しかし、答えたくないと思われる質問に対して は、無理にお答えいただなくても結構です。

私たちはご協力くださった皆様の個人情報の保護に最善を尽くします。皆様の個人が特定される情報は安全に管理致します。アンケート内容には個人を特定する質問、例えば 氏名や住所などは一切含まれません。ご回答いただいたアンケート用紙は、個人を特定 する情報とは別に保管され、本研究関係する数人のみ、アンケートの情報にアクセスす ることができます。

本研究結果を科学雑誌や学術集会において公表する場合は、氏名や他の個人が特定される情報は一切使用されません。

本研究参加に生ずる利益について

あなたへの直接的な利益はありません。アンケート結果は本研究目的の為にのみ使用させていただきます。

本研究への不参加について

本アンケート調査への参加・不参加はあなたが自由に選択する事が出来ます。本研究に 参加されない場合でも、あなたに不利益や不都合が生じることはありません。榊原記念 病院で通常提供される医療ケアを受けることができます。

研究参加により生ずる支払いについて

本研究参加によって生じる費用は一切ありません。

#### 本研究に関する質問の問い合わせ先

本研究に関する問い合わせ(ご質問、ご意見またはご不満等)は、本研究員であるカリフォルニア大学看護学研究科身体生理学講座に在籍する岡田彩子 RN, CNS, PhD©までお願い致します。[電話番号:090-1205-7172]

または、榊原記念病院における本研究責任者である看護部長の三浦稚郁子までご連絡下さい。[電話番号:042-314-3111].

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[Mar2011]

Page 2 of 3

本研究全般、及び研究参加における個人の権利に関するご質問、ご意見等を本研究担当 者以外に問い合わせをご希望の場合は、カリフォルニア大学サンフランシスコ校人的研 究委員会:電話番号 1-415-476-1814 までご連絡下さい。

# 本研究参加への同意

本研究への参加はあなたの任意によるものです。 この同意書のコピーをあなたの保管用にお渡しいたします。

本研究への参加に同意をしてくださる場合、以下に署名お願い致します。

年月日

研究参加者署名

年月日

同意取得者の署名

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Name of institute: 1=SIH, 2=KCRC, 3=CCC Study code: 1 1 Date and time of interview: 1 **Screening Questions** 1. Have you smoked more than 100 cigarettes during your lifetime? Yes =0 No=  $1 \rightarrow$  subject is not invited to participate 2. Do you currently smoke tobacco on a daily basis or less than daily? Daily =2Less than daily =1Not at all  $=0 \rightarrow$  subject is not invited to participate 3. Conscious: Clear=0 Disoriented=1 $\rightarrow$  subject is not invited to participate Unconscious  $= 2 \rightarrow$  subject is not invited to participate Use sedative medicine =3  $\rightarrow$  subject is not invited to participate 4. History of psychiatric disorder: No=0 Yes=1  $\rightarrow$  subject is not invited to participate Hemodynamic condition: Stable=0 Unstable=1  $\rightarrow$  subject is not invited to participate Post-procedural complication: None= 0 Yes =1 $\rightarrow$  subject is not invited to participate ------Data will be abstracted from the medical record 1 Date of hospital admission 1 1 Mo Day Year The length of hospital stay days Medical diagnoses: AP=1 MI=2 CHF=3 Arrhythmia=4 Other=5 Procedures PTCA=1 STENT=2 CABGS=3 VR=4 AVR=5 Other=6 Age in years: \_\_\_\_

施設名: 1=SIH, 2=KCRC, 3=CCC 研究対象者番号: インタビュー日時: / / /

- 喫煙・禁煙パターンの研究:スクリーニング質問

   今までに100本以上たばこを吸った経験がありますか?
   はい=0
   いいえ=1→研究参加の基準を満たさず、質問終了
- 最近毎日、また数日おきに煙草を(習慣的に)吸っていますか?
   毎日 =2
   毎日ではない =1
   吸っていない=0→研究参加の基準を満たさず、質問終了

3. 意識: 清明=0 目当難生涯なり-1→研究者

見当識生涯あり=1→研究参加の基準を満たさず、質問終了 清明ではない=2→研究参加の基準を満たさず、質問終了 鎮静薬を使用=3→研究参加の基準を満たさず、質問終了

 精神疾患の既往歴: なし=0 あり=1→研究参加の基準を満たさず、質問終了 循環血行動態: 安定=0 不安定=1→研究参加の基準を満たさず、質問終了 術後合併症の有無: なし=0 あり=1→研究参加の基準を満たさず、質問終了

#### 以下はカルテ記録より収集

------

入院年月日: / 1 1 年 月 日 入院在院日数: 日 診断名: 狭心症=1 心筋梗塞=2 心不全=3 不整脈=4 その他=5 内科·外科的治療法 PTCA=1 STENT=2 冠動脈バイパス術=3 弁置換=4 大動脈血管置換=5 その他=6

年齡:\_\_\_

2011年1月作成(岡田研究)

Name of institute: 1=SIH, 2=KCRC, 3=CCC, 4=KSH ID of subject: / Date and time of interview: 1 ( minutes) Start at  $\sim$  End at : :

# **Questionnaire (English)**

The items marked \* are questions that overlap between instruments and will be skipped during the interview.

#### **Demographic data**

- 1. What is your highest level of education that you have completed?
  - 1. No formal schooling
  - 2. Less than junior high school completed
  - 3. High school completed
  - 4. College or diploma school (2-3 years) completed
  - 5. University (4 years) completed
  - 6. Graduate master degree completed
  - 7. Doctoral degree competed
  - 8. Post graduate degree completed
  - 9. Don't know
- What is your marital status? 2.
  - 1. Single
  - 2. Married
  - 3. Separated
  - 4. Divorced
  - 5. Widowed
- 3. Which of the following best describes your household income last year?
  - 1. Less than 2,000,000 yen
  - 2. 2,000,000-3,999,999 yen
  - 3. 4,000,000-5,999,999 yen
  - 4. 6,000,000-7,999,999 yen
  - 5. Over 8000000 yen
- 4. How many adults does this income need to support?
  - 1) Adults 2) Children

- 5. Which of the following best described your main work status now?
  - 1. Full-time
  - 2. Part-time
  - 3. Unemployed
  - 4. Disabled
  - 5. Retired
  - 6. Student
  - 7. Home maker
- 6. Who is your employer
  - 1. Government employee
  - 2. Non-government employee
  - 3. Self-employed
  - 4. Agriculture, forestry, or fishery
  - 5. Homemaker
  - 6. Unemployed
- 7. Do you drink alcoholic beverages?
  - 1. No  $\rightarrow$  Go to Page 3, Question 10
  - 2. Yes

8. If yes on question #7, how much do you drink alcoholic beverage at one time?

- 1. Intake less than 20g of alcohol
- 2. Intake less than 40g of alcohol
- 3. Intake less than 60g of alcohol
- 4. Intake less than 80g of alcohol
- 5. Intake less than 100g of alcohol
- 6. Intake less than 120g of alcohol
- 7. Intake less than 140g of alcohol
- 8. Intake more than 140g of alcohol

9. How often do you drink alcohol during week?

- 1. Almost everyday
- 2. 4-5 times
- 3. 2-3 times
- 4. 1 times
- 5. Occasional \_\_\_\_\_times/month or year

Equivalent of 20g of alcohol content Beer 500ml Wine 200ml: 2 glasses Sake 180ml: 1gou Shochu 90ml: half gou Whisky 60ml

2/16

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# **Clinical Characteristics**

10. Have you experienced any of symptoms? The symptoms attributed with CVD or medical

	& s	urgical procedures							
	1.	Chest pain			No=0	Yes=1			
	2.	Incisional and procedural	pain etc		No=0	Yes=1			
	3.	Dyspnea etc			No=0	Yes=1			
	4.	Edema			No=0	Yes=1			
	5.	Fatigue			No=0	Yes=1			
	6.	Palpitation			No=0	Yes=1			
	7.	Others			No=0	Yes=1			
11.	Do	you have diagnoses of any	VCVD p	revious h	nistory?				
	1.	AP (Chest pain)	No=0	Yes=1					
	2.	MI (Heart Attack)	No=0	Yes=1					
	3.	CHF	No=0	Yes=1					
	4.	Arrhythmia	No=0	Yes=1					
	5.	Valve deformity	No=0	Yes=1					
	6.	Vessel dissection	No=0	Yes=1					
	7.	PAD	No=0	Yes=1					
	8.	Stroke	No=0	Yes=1					
12.	Do	you have any of CVD risk	c factors	before y	ou get s	ick?			
	1.	Family history of CVD	No=0				yr / Mother:		yr)
	2.	Hypertension		No=0	Yes=1				
	3.	Lipid abnormality		No=0	Yes=1				
	4.	Physical inactivity	X7 / X1	No=0	Yes=1	min E		times/ w	(deck
		(If No, exercise regularly	y: Yes/ N				equency:	times/ w	(CCK)
	5.	Diabetes (Type 2)	0 V.		Yes=1	(Height	cm/ We	eight	kg)
	6.	Overweight/ obese No	=0 Yes		11:	(neight		Jigin	K5)
C		II' to an a finaling	Dattorn	0					
		ng History and Smoking ow many cigarettes do you			/ da	av			
13	. не ц	ow soon after you wake up	do vou	smoke v	our first	cigarette	? min	utes	
		ow old were you when you							
		Then did you started to smo							
		umber of smoker who live							
1/		persons in house				oker(s)			
19		o you have a smoking ban			No=0		L		
		there a smoking ban at wo			No=0		l		
17	. 13	and a binoning out at the	O P						

# **Smoker's Beliefs about Health Benefits**

- 20. How likely do you think it is that you will avoid or decrease serious health problems from smoking if you quit?
  - 1. Very likely
  - 2. Likely
  - 3. Unlikely
  - 4. Very unlikely
  - 5. Uncertain
- 21. If a person has smoked for more than 20 years, there is little health benefit to quitting.
  - 1. Strongly agree
  - 2. Agree
  - 3. Disagree
  - 4. Strongly disagree
  - 5. I do not know
- 22. My smoking is harming my health
  - 1. Strongly agree
  - 2. Agree
  - 3. Disagree
  - 4. Strongly disagree
  - 5. I do not know
- 23. How likely do you think it is that you will avoid or decrease your chances of developing lung cancer if you quit smoking?
  - 1. Very likely
  - 2. Likely
  - 3. Unlikely
  - 4. Very unlikely
  - 5. Uncertain
- 24. How likely do you think it is that you will avoid or decrease your chances of developing heart disease if you quit smoking?"
  - 1. Very likely
  - 2. Likely
  - 3. Unlikely
  - 4. Very unlikely
  - 5. Uncertain

- 25. How likely do you think it is that you will avoid or decrease your chances of developing respiratory disease if you quit smoking?
  - 1. Very likely
  - 2. Likely
  - 3. Unlikely
  - 4. Very unlikely
  - 5. Uncertain

## **Past Quit Attempts**

26. Have you tried to stop smoking?

Yes =0

No=1 →Go to Page 7, Question 35

- 28. During the last 12 months, have you tried to stop smoking?
   Yes=0 No=1 →Go to Question 30

#### 30. What are the reason(s) for the previous quit attempt?

1.	Bad for health	Yes/ No	
2.	Have experienced bad health condition	Yes/ No	
3.	To protect health for family members	Yes/ No	
4.	Scared that I won't be able to stop smoking	Yes/ No	
5.	Advised by family or friends	Yes/ No	
6.	Advised by health care providers (MD=1, Nurse=2, Dentists	=3, Others =4)	Yes/ No
7.	Getting difficult to find a place to smoke in public place	Yes/ No	
8.	Become restricted to smoke in my office or place to work	Yes/ No	
9.	Troubles other people	Yes/ No	
10.	Cost of cigarette	Yes/ No	
11.	Other		

31. What methods or supports did you use in your previous quit attempt(s)? Please indicate all that you had applied.

		you nau apprica.		
1.	Му	own way	No=0	Yes=1
2.	Me	dication	No=0 →Go to Question 33-3	Yes=1
	1.	Nicotine patch	No=0	Yes=1
	2.	Nicotine gum	No=0	Yes=1
	3.	Others		
	4.	Single medication	No=0	Yes=1
	5.	Combination medication	No=0	Yes=1
	6.	High-dose nicotine patch	No=0	Yes=1
3.	Psy	chosocial intervention	No=0 $\rightarrow$ Go to Question 33	Yes=1
	1.	Self-help or self-administered	No=0	Yes=1
		ben neip of sen aanninsterea		
		1. Pamphlet	No=0	Yes=1
		A REAL PROPERTY AND A REAL		10000000
		1. Pamphlet	No=0	Yes=1
		<ol> <li>Pamphlet</li> <li>Audiotape or videotape</li> </ol>	No=0 No=0	Yes=1 Yes=1
		<ol> <li>Pamphlet</li> <li>Audiotape or videotape</li> <li>Mailed information</li> </ol>	No=0 No=0 No=0	Yes=1 Yes=1 Yes=1
	2.	<ol> <li>Pamphlet</li> <li>Audiotape or videotape</li> <li>Mailed information</li> </ol>	No=0 No=0 No=0 No=0	Yes=1 Yes=1 Yes=1
		<ol> <li>Pamphlet</li> <li>Audiotape or videotape</li> <li>Mailed information</li> <li>computer program</li> </ol>	No=0 No=0 No=0 No=0	Yes=1 Yes=1 Yes=1 Yes=1
	2.	<ol> <li>Pamphlet</li> <li>Audiotape or videotape</li> <li>Mailed information</li> <li>computer program</li> </ol> Individual counseling or containing or containinin	No=0 No=0 No=0 No=0 act No=0 No=0	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1
4.	2. 3. 4.	<ol> <li>Pamphlet</li> <li>Audiotape or videotape</li> <li>Mailed information</li> <li>computer program</li> <li>Individual counseling or conta Group counseling</li> </ol>	No=0 No=0 No=0 No=0 act No=0 No=0 No=0	Yes=1 Yes=1 Yes=1 Yes=1 Yes=1 Yes=1

32. What type of counseling and behavioral therapies have you used? Please indicate all that you had applied.

1.	Problem solving	No=0	Yes=1
2.	Coping skills	No=0	Yes=1
3.	Relapse prevention	No=0	Yes=1
4.	Stress management	No=0	Yes=1
5.	Negative affect/ depression intervention	No=0	Yes=1
6.	Weight, diet or nutrition intervention	No=0	Yes=1
7.	Social support intervention	No=0	Yes=1
8.	Others		
9.	Unknown	No=0	Yes=1

33. What format of smoking cessation intervention did you use? Please indicate all that you had applied.

1.	Smoking cessation program at outpatient clinic or hospital	No=0	Yes=1
2.	Smoking cessation program at public health center	No=0	Yes=1
3.	Internet program	No=0	Yes=1
4.	Others		
5.	Unknown	No=0	Yes=1

34. What type of clinician did you receive smoking cessation intervention treatment? Please indicate all that you had applied.

1.	No clinician	No=0	Yes=1 $\rightarrow$ Go to Question 35
2.	Non-physician health care clinician		No=0 Yes=1
	1. Psychologist		No=0 Yes=1
	2. Counselor		No=0 Yes=1
	3. Social worker		No=0 Yes=1
	4. Nurse		No=0 Yes=1
	5. Dentist		No=0 Yes=1
	6. Graduate students		No=0 Yes=1
	7. Pharmacists		No=0 Yes=1
	8. Tobacco treatment specialist		No=0 Yes=1
3.	Physician		No=0 Yes=1

# Preference to use of supports for future quit attempts

35. What methods do you prefer to use for future quit attempts? Please indicate all that you will apply.

1.	My own way	No=0	Yes=1	→Go to	Question 39
2.	Pharmacological medicine			No=0	Yes=1
3.	Non-pharmacological therapy			No=0	Yes=1
4.	Combination of pharmacological and nor	n-pharma	cologica	l methods	
				No=0	Yes=1

36. What pharmacological medications do you prefer to use for future quit attempts? Please indicate all that you will apply.

1. Not prefer to use any pharmacological medications

		No=0 $\rightarrow$ Go to Question 37	Yes=1
2.	Placebo medication	No=0	Yes=1
3.	Nicotine patch	No=0	Yes=1
4.	Nicotine gum	No=0	Yes=1
5.	Others	_	
6.	Single medication	No=0	Yes=1
7.	Combination medication	No=0	Yes=1
8.	High-dose nicotine patch	No=0	Yes=1

- 37. What non-pharmacological therapy do you prefer to use for future quit attempts? Please indicate all that you will apply.
  - 1. Not prefer to use any non-pharmacological therapy

	No=0 <u>→Go to</u>	Question 39	Yes=1
2.	Self-help or self-administered	No=0	Yes=1
3.	Pamphlet	No=0	Yes=1
4.	Audiotape or videotape	No=0	Yes=1
5.	Mailed information	No=0	Yes=1
6.	Computer program	No=0	Yes=1
7.	Individual counseling or contact	No=0	Yes=1
8.	Group counseling	No=0	Yes=1
9.	Proactive telephone counseling	No=0	Yes=1

38. What type of counseling and behavioral therapies do you prefer to use for future quit attempts? Please indicate all that you will apply.

1.	Problem solving	No=0	Yes=1
2.	Coping skills	No=0	Yes=1
3.	Relapse prevention	No=0	Yes=1
4.	Stress management	No=0	Yes=1
5.	Negative affect/ depression intervention	No=0	Yes=1
6.	Weight, diet or nutrition intervention	No=0	Yes=1
7.	Social support intervention	No=0	Yes=1
8.	Others		
9.	Unknown	No=0	Yes=1

39. What format of smoking cessation intervention do you prefer to use future quit attempts? Please indicate all that you will apply.

1.	Smoking cessation program at outpatient clinic or hospital	No=0	Yes=1
2.	Smoking cessation program at public health center	No=0	Yes=1
3.	Internet program	No=0	Yes=1
4.	Others		
5.	Unknown	No=0	Yes=1

•

40. What type of clinician do you prefer to receive smoking cessation intervention treatment? Please indicate all that you will apply.

use maleute un that you will apply.		
No clinician	No=0 →Go to Question 41	Yes=1
Non-physician health care clinician	No=0	Yes=1
1. Psychologist	No=0	Yes=1
2. Counselor	No=0	Yes=1
3. Social worker	No=0	Yes=1
4. Nurse	No=0	Yes=1
5. Dentist	No=0	Yes=1
6. Graduate students	No=0	Yes=1
7. Pharmacists	No=0	Yes=1
8. Tobacco treatment specialist	No=0	Yes=1
Physician	No=0	Yes=1
	No clinician Non-physician health care clinician 1. Psychologist 2. Counselor 3. Social worker 4. Nurse 5. Dentist 6. Graduate students 7. Pharmacists 8. Tobacco treatment specialist	No clinicianNo=0 $\rightarrow$ Go to Question 41Non-physician health care clinicianNo=01. PsychologistNo=02. CounselorNo=03. Social workerNo=04. NurseNo=05. DentistNo=06. Graduate studentsNo=07. PharmacistsNo=08. Tobacco treatment specialistNo=0

41. If there are available do you prefer to use any alternative medicine for future quit attempts? Please indicate all that you will apply.

1.	Not prefer to use	No=0 $\rightarrow$ Go to page 10, FTND	Yes=1
2.	Acupuncture	No=0	Yes=1
3.	Meditation	No=0	Yes=1
4.	Aroma therapy	No=0	Yes=1
5	Others		

5. Others\_\_\_\_\_

Fargerstrom Test for Nicotine Dependence

The items marked \* will be fill out based on the answer on previous smoking pattern questions

	Questions	Answers	Points
1.	How soon after you wake up do you smoke your first	Within 5 minutes	3
	cigarette? *	6-30 minutes	2
		31-60 minutes	1
		After 60 minutes	0
2.	Do you find it difficult to refrain from smoking in places	Yes	1
	where it is forbidden e.g. in church, at the library, in	No	0
	cinema, etc.?		
3.	Which cigarette would you hate to give up most?	The first one in	1
		the morning	
		All others	0
4.	How many cigarettes do you smoke/ day? *	10 or less	0
		11-20	1
		21-30	2
		31 or more	3
5.	Do you smoke more frequently during the first hours after	No=0	1
	waking than during the rest of the day?	Yes=1	0
6.	Do you smoke if you are so ill that you are in bed most of	No=0	1
	the day?	Yes=1	0

Permission obtained from Dr. Fagerstrom on Jan 5, 2011 by e-mail contact (Fagerstrom & Schneider, 1989; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991)

# Minnesota Nicotine Withdrawal Scale –Behavior Rating Scale

Please rate yourself for the period of the last 24 hours 0= none, 1= slight, 2= mild, 3= moderate, 4= severe

1.	Angry, irritable, frustrated	0	1	2	3	4
2.	Anxious, nervous	0	1	2	3	4
3.	Depressed mood, sad	0	1	2	3	4
4.	Desire or craving to smoke	0	1	2	3	4
5.	Difficulty concentrating	0	1	2	3	4
6.	Increased appetite, hungry,					
	weight gain	0	1	2	3	4
7.	Insomnia, sleep problem,					
	awakening at night	0	1	2	3	4
8.	Restlessness	0	1	2	3	4

There is no copyright (Hughes & Hatsukami, 1986)

# Patient Health Questionnaire-9 (PHQ-9)

Over the past 2 weeks, how often have you been bothered by any of the following problems?

		Not at	Several	More than	Nearly
		all	days	half the days	everyday
1.	Little interest or pleasure in doing things				
2.	Feeling down, depressed, or hopeless				
3.	Trouble failing or staying asleep, or sleeping too much		19		
4.	Feeling tired or having little energy				
5.	Poor appetite or overeating				
6.	Feeling bad about yourself- or that you are a failure or have let yourself or your family down				
7.	Trouble concentrating on things, such as reading the newspaper or watching television				82
8.	Moving or speaking so slowly that other people could have noticed? Or the opposite- being so fidgety or restless that you have been moving around a lot more than usual				
9.	Thoughts that you would be better off dead or of hurting yourself in some way				

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(Lichtman et al., 2008; Spitzer et al., 1999)

#### WINS: Confidence Questionnaire

How confident are you that you can resist the urge to smoke in the 14 situations below?

Not a	ıt all		Slightly		Fairly				Very	
Conf	ident		Confident		Confident			Co	nfident	
0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

1. When you feel bored or depressed.

2. When you see others smoking

3. When you want to relax or rest

4. When you just want to sit back and enjoy a cigarette

\_\_\_\_\_5. When you are watching TV

6. When you are driving, or riding in a car

\_\_\_\_\_7. When you have finished a meal or snack

8. When you feel frustrated, worried, upset, tense, nervous, angry, anxious or annoyed

9. When you want a snack but don't want to gain weight

10. When you need more energy or can't concentrate

\_\_\_\_\_11. When someone offers you a cigarette

\_\_\_\_\_12. When you are drinking coffee or tea

13. When you are in a situation where alcohol is served

\_\_\_\_\_14. When you feel smoking is part of yourself image.

confiden.win 11/6/96

Permission obtained from Dr. Froelicher, Erika.

#### **Self-Construal Scale**

This is a questionnaire that measures a variety of feelings and behaviors in various situations. Listed below are a number of statements. Read each one as if it referred to you. Beside each statement write the number that best matches your agreement or disagreement. Please respond to every statement.

- 1=Strongly Disagree
- 2=Disagree
- 3=Somewhat Disagree
- 4=Don't Agree or Disagree
- 5=Agree Somewhat

6=Agree

7=Strongly Agree

- 1. \_\_\_\_I enjoy being unique and different from others in many respects.
- 2. \_\_\_\_I can talk openly with a person who I meet for the first time, even when this person is much older than I am.
- 3. \_\_\_\_Even when I strongly disagree with group members, I avoid an argument.
- 4. \_\_\_\_I have respect for the authority figures with whom I interact.
- 5. \_\_\_\_I do my own thing, regardless of what others think.
- 6. \_\_\_\_I respect people who are modest about themselves.
- 7. \_\_\_\_I feel it is important for me to act as an independent person.
- 8. \_\_\_\_I will sacrifice myself interest for the benefit of the group I am in.
- 9. \_\_\_\_I'd rather say "No" directly, than risk being misunderstood.
- 10. \_\_\_\_Having a lively imagination is important to me.
- I should take into consideration my parents' advice when making education/career plans.
- 12. \_\_\_\_I feel my fate is intertwined with the fate of those around me.
- 13. \_\_\_\_I prefer to be direct and forthright when dealing with people I've just met.
- 14. \_\_\_\_I feel good when I cooperate with others.
- 15. \_\_\_\_I am comfortable with being singled out for praise or rewards.
- 16. \_\_\_\_If my brother or sister fails, I feel responsible.
- 17. \_\_\_\_I often have the feeling that my relationships with others are more important than my own accomplishments.
- 18. \_\_\_\_Speaking up during a class (or a meeting) is not a problem for me.
- 19. \_\_\_\_I would offer my seat in a bus to my professor (or my boss).
- 20. \_\_\_\_I act the same way no matter who I am with.
- 21. \_\_\_\_My happiness depends on the happiness of those around me.
- 22. \_\_\_\_I value being in good health above everything.

#### **Self-Construal Scale**

This is a questionnaire that measures a variety of feelings and behaviors in various situations. Listed below are a number of statements. Read each one as if it referred to you. Beside each statement write the number that best matches your agreement or disagreement. Please respond to every statement.

- 1=Strongly Disagree
- 2=Disagree
- 3=Somewhat Disagree
- 4=Don't Agree or Disagree
- 5=Agree Somewhat

6=Agree

7=Strongly Agree

- I enjoy being unique and different from others in many respects.
- 2. \_\_\_\_I can talk openly with a person who I meet for the first time, even when this person is much older than I am.
- 3. \_\_\_\_Even when I strongly disagree with group members, I avoid an argument.
- 4. \_\_\_\_I have respect for the authority figures with whom I interact.
- 5. \_\_\_\_I do my own thing, regardless of what others think.
- 6. \_\_\_\_I respect people who are modest about themselves.
- 7. \_\_\_\_I feel it is important for me to act as an independent person.
- 8. \_\_\_\_I will sacrifice myself interest for the benefit of the group I am in.
- 9. \_\_\_\_I'd rather say "No" directly, than risk being misunderstood.
- 10. \_\_\_\_Having a lively imagination is important to me.
- I should take into consideration my parents' advice when making education/career plans.
- 12. \_\_\_\_I feel my fate is intertwined with the fate of those around me.
- 13. \_\_\_\_ I prefer to be direct and forthright when dealing with people I've just met.
- 14. \_\_\_\_I feel good when I cooperate with others.
- 15. \_\_\_\_I am comfortable with being singled out for praise or rewards.
- 16. \_\_\_\_If my brother or sister fails, I feel responsible.
- 17. \_\_\_\_I often have the feeling that my relationships with others are more important than my own accomplishments.
- 18. \_\_\_\_Speaking up during a class (or a meeting) is not a problem for me.
- 19. \_\_\_\_I would offer my seat in a bus to my professor (or my boss).
- 20. \_\_\_\_I act the same way no matter who I am with.
- 21. \_\_\_\_My happiness depends on the happiness of those around me.
- 22. \_\_\_\_I value being in good health above everything.

23. \_\_\_\_I will stay in a group if they need me, even when I am not happy with the group.

24. \_\_\_\_I try to do what is best for me, regardless of how that might affect others.

25. \_\_\_\_Being able to take care of myself is a primary concern for me.

26. \_\_\_\_It is important to me to respect decisions made by the group.

27. \_\_\_\_My personal identity, independent of others, is very important to me.

28. \_\_\_\_It is important for me to maintain harmony within my group.

29. \_\_\_\_I act the same way at home that I do at school (or work).

30. \_\_\_\_I usually go along with what others want to do, even when I would rather do something different.

Permission obtained from Dr. Theodore M, Singelis o Dec 22, 2010. (Singelis, 1994 and 1995)

# **ENRICHD Social Support Instrument**

1.	Is there so	meone availabl	e to you who	m you can cour	nt on to listen to you when you need
	to talk?				
	None of	Alittle	Some of	Most of	All of
	the time	of the time	the time	the time	the time
	1	2	3	4	5
2.	Is there se	omeone availab	le to give you	a good advice a	bout a problem?
	None of	Alittle	Some of	Most of	All of
	the time	of the time	the time	the time	the time
	1	2	3	4	5
3.	Is there se	omeone availab	le to you who	o shows you lov	ve and affection?
	None of	Alittle	Some of	Most of	All of
	the time	of the time	the time	the time	the time
	1	2	3	4	5
4.	Is there se	omeone availab	le to help you	a with daily cho	pres?
	None of	Alittle	Some of	Most of	All of
	the time	of the time	the time	the time	the time
	1	2	3	4	5
5.	Can you	count on anyone	e to provide y	ou with emotic	onal support (talking over problems
	or helping	g you make a di	fficult decision	on)?	
	None of	Alittle	Some of	Most of	All of
	the time	of the time	the time	the time	the time
	1	2	3	4	5
6.	Do you h	ave as much con	ntacts as you	would like to v	vith someone you feel close to,
	someone	in whom you ca	an trust and c	onfide?	
	None of	Alittle	Some of	Most of	All of
	the time	of the time	the time	the time	the time
	1	2	3	4	5
7.	Are you o	currently marrie	d or living w	ith a partner?	
	Yes	No			
(Ei	nhancing re	ecovery in coror	ary heart dis	ease patients (E	ENRICHD): Study design and

methods. the ENRICHD investigators.2000 & Mitchell et al., 2003)

Thank you very much for you willingness to participate!

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施設名: 1=SIH, 2=KCRC, 3=CCC, 4=KSH 対象のコード#: インタビュー実施日: / / / 開始時間 : ~ 終了時間 : (

分)

# インタビュー用質問紙 (日本語)

質問\* は、質問内容が重複する為、インタビュー時には省略する

#### 人口統計学的データ

- 1. あなたの教育歴に関して、以下の中で最も適切な記載はどれですか?
  - 1. 公的な教育を終了していない
  - 2. 中等教育課程修了
  - 3. 高等教育課程卒業
  - 4. 短期大学もしくは専門学校を修了(2-3 年課程)
  - 5. 4年制大学修了
  - 6. 大学院修士課程修了
  - 7. 大学院博士課程修了
  - 8. ポストドクトレイトフェロー修了
  - 9. 不明
- 2. あなたの婚姻の状況に関して、以下の記載で最も適切なものはどれですか?
  - 1. 独身
  - 2. 結婚
  - 3. 別居
  - 4. 離婚
  - 5. 死別
- 3. あなたの世帯の昨年1年間の収入はどれくらいですか?
  - 1. 2,000,000 円以下
  - 2. 2,000,000-3,999,999 円
  - 3. 4,000,000-5,999,999 円
  - 4. 6,000,000-7,999,999 円
  - 5. 8,000,000 円以上
- 4. 上記の収入で何人の家族を養っていますか?
  - 1) 大人\_\_\_\_人 2) 子供\_\_\_\_人

- 5. 現在のあなたの就労状況で以下の中で最も適切な記載はどれですか?
  - 1. 常勤職員

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- 2. パート・アルバイト、臨時職員
- 3. 非雇用·無職
- 4. 身体障害
- 5. 定年退職
- 6. 学生
- 7. 主婦
- 6. 雇用先、雇用状況
  - 1. 国家公務員
  - 2. 会社員、団体職員
  - 3. 自営業
  - 4. 農業, 林業, 漁業
  - 5. 主婦
  - 6. 無職
- 7. あなたはアルコールを飲みますか?
  - 1. いいえ <u>→ 3ページ問い10 へ</u>
  - 2. はい

8. 問い7で「はい」と答えた方に質問します。どこくらいの量を1回に飲みますか?

- 1. 20g 以下を摂取
- 2. 40g以下を摂取
- 3. 60g以下を摂取
- 4. 80g以下を摂取
- 5. 100g以下を摂取
- 6. 120g 以下を摂取
- 7. 140g 以下を摂取
- 8. 140g 以上摂取

9. 週にどれくらいお酒を飲む機会がありますか?

- 1. 殆ど毎日
- 2. 4-5 回
- 3. 2-3 回
- 4. 1回
- 5. 飲む機会がある時 \_\_\_\_\_回/月・年

2/16

アルコール 20g 換算目安表 ビール 500ml ワイン 200ml: 2 グラス 日本酒 180ml: 1 合 焼酎 90ml: 半合 ウイスキー 60ml

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施設名: 1=SIH, 2=KCRC, 3=CCC, 4=KSH 対象コード#: 臨床的特徵 10. 循環器疾患の罹患及び、内科・外科的治療に伴う症状の体験 以下の症状を体験しましたか? 1. 胸痛 いいえ=0 はい=1 いいえ=0 はい=1 2. 創部痛もしくは治療手技による痛み 3. 息切れ・呼吸苦など いいえ=0 はい=1 いいえ=0 はい=1 4. むくみ・浮腫 5. 疲労感·倦怠感 いいえ=0 はい=1 6. ドキドキ感・動悸 いいえ=0 はい=1 いいえ=0 はい=1 \_ 7. その他 11. 今回の入院前に以下の循環器疾患の診断を受けたことがありますか? 1. 狭心症 (胸痛) いいえ=0 はい=1 2. 心筋梗塞 (心臟発作) いいえ=0 はい=1 いいえ=0 はい=1 3. 心不全 4. 不整脈 いいえ=0 はい=1 5. 心臟弁疾患 いいえ=0 はい=1 6. 大動脈解離 いいえ=0 はい=1 いいえ=0 はい=1 7. 末梢血管(動脈)疾患 8. 脳卒中 いいえ=0 はい=1 12. 今回の病気(診断)の前に循環器疾患の危険因子がありましたか? 1. 循環器疾患の家族歴 いいえ=0 はい=1 (父: \_ \_\_\_\_\_歳 / 母:\_\_\_\_\_ 歳) 2. 高血圧 いいえ=0 はい=1 3. 血中脂質異常 いいえ=0 はい=1 4. 運動不足 いいえ=0 はい=1 (定期的な運動;はい・いいえ:「はい」の場合 分/回 /週) 5. 糖尿病 (2型) いいえ=0 はい=1 6. 体重過多/肥満 いいえ=0 はい=1 BMI: (身長 cm/ 体重 kg) 喫煙歴及び喫煙パターン 13.1日に何本のタバコを吸いますか? \_\_/日 14. 朝、 目覚めてから何分位で最初のタバコを吸いますか? 分 15. 何歳の時に初めてタバコを吸いましたか? \_\_\_\_歳 16. 何歳の時にタバコを習慣的に吸い始めましたか? 歳 17. 同居している人の中で何人喫煙者がいますか? 同居家族 \_\_\_\_人、喫煙者人数 \_\_\_ 人 18. あなたの家は禁煙ですか?または喫煙制限がありますか? いいえ=0 はい=1 19. 職場は禁煙ですか? いいえ=0 はい=1

# 喫煙者の健康利益に関する考え

- 20. あなたは禁煙することで喫煙による健康問題を回避したり、その重症度を軽減するとどれくらい
  - 思いますか?
  - 1. とてもそう思う
  - 2. そう思う
  - 3. そうは思わない
  - 4. 全くそうとは思わない
  - 5. 不確かである
- 21. もし20年以上タバコを吸い続けていたら、禁煙よる健康利益は少ない
  - 1. 強く同意
  - 2. 同意
  - 3. 不同意
  - 4. 強く不同意
  - 5. わからない
- 22. 喫煙は自分の健康を害している
  - 1. 強く同意
  - 2. 同意
  - 3. 不同意
  - 4. 強く不同意
  - 5. わからない
- 23. もしあなたが禁煙したら、肺がんを予防したり、その発生リスクを減らすとどれくらい思いますか?
  - 1. とてもそう思う
  - 2. そう思う
  - 3. そうは思わない
  - 4. 全くそうとは思わない
  - 5. 不確かである
- 24. もしあなたが禁煙したら、循環器疾患を予防したり、その発生リスクを減らすとどれくらい思いますか?
  - 1. とてもそう思う
  - 2. そう思う
  - 3. そうは思わない
  - 4. 全くそうとは思わない
  - 5. 不確かである

- 25. もしあなたが禁煙したら、呼吸器疾患を予防したり、その発生リスクを減らすとどれくらい思い ますか?
  - 1. とてもそう思う
  - 2. そう思う
  - 3. そうは思わない
  - 4. 全くそうとは思わない
  - 5. 不確かである

# 過去の禁煙への試み

26. 今までに禁煙を試みた事がありますか? はい =0 いいえ=1 <u>→ 7ページ問い35へ</u>

- 27. 質問 26 で「はい」と答えた方:真剣に禁煙を試みた事が何回位ありますか?
- 28. 過去12カ月間に禁煙を試みたことがありますか?
   はい=0 いいえ=1 → 問い30 へ

29. 質問 28 で「はい」と答えた方:過去 12 カ月間に何回禁煙を試みましたか? \_\_\_\_\_回

30. どのような理由で禁煙を試みましたか?該当するもの全てにお答えください。

1.	健康に悪いから	はい	いいえ
2.	体調が悪くなった経験があったから	はい/	いいえ
3.	家族の健康を守るため	はい	いいえ
4.	タバコをやめられなくなるのが心配な為	はい	いいえ
5.	家族や友人からの助言	はい	いいえ
6.	医療従事者からの助言 (医師=1, 看護師=2, 歯科医=3, その他=4)	はい	いいえ
7.	公共の場所で喫煙場所を見つけるのが難しくなったため	はい	いいえ
8.	就労場所・職場が禁煙になったため	はい	いいえ
9.	他の人へ迷惑になるから	はい	いいえ
10.	タバコの値段	はい	いいえ
11.	その他		

- 31. どのような方法・サポートを過去の禁煙挑戦時に利用しましたか? 該当するもの全てにお答えく ださい。
  - 1. 自分のやり方 (My own way) いいえ=0 はい=1 2. 薬物療法
    - いいえ=0 <u>→ (問い 31-3 へ)</u> はい=1 いいえ=0 はい=1
    - 1. ニコチンパッチ いいえ=0 はい=1
    - 2. ニコチンガム 3. その他\_\_\_\_
      - 1種類の薬物療法 いいえ=0 はい=1
      - 5. 組み合わせの薬物療法 いいえ=0 はい=1
    - 6. 高い含有量のニコチンパッチ いいえ=0 はい=1
  - 3. 非薬物療法/社会心理学的介入 (行動療法) いいえ=0 <u>→ (問い 33 へ)</u> はい=1 1. セルフヘルプまたは自己主導 いいえ=0 はい=1 いいえ=0 はい=1 (ア)パンフレット (イ)音声のテープやビデオテープ いいえ=0 はい=1 (ウ)情報提供の配信・郵送 いいえ=0 はい=1 (エ) コンピュタープログラム いいえ=0 はい=1 2. 個人的なカウンセリングやコンタクト いいえ=0 はい=1
    - 3. グループカウンセリング いいえ=0 はい=1
    - 4. 事前対策となる電話カウンセリング いいえ=0 はい=1
  - 4. 社会心理学的介入(行動療法)と薬物療法の組み合わせ いいえ=0 はい=1
- 32. どのような種類のカウンセリングや行動療法を利用しましたか?該当するもの全てにお答えく ださい。
  - 1. 問題解決 いいえ=0 はい=1 2. コーピング技術(ストレスに対して対処・適応しようとする適応機構) いいえ=0 はい=1 3. 再喫煙予防 いいえ=0 はい=1 4. ストレス管理 いいえ=0 はい=1 5. 否定的な感情や鬱への介入 いいえ=0 はい=1 6. 体重、食事、栄養に関する介入 いいえ=0 はい=1 7. 社会支援獲得への介入 いいえ=0 はい=1 8. その他 9. 不明 いいえ=0 はい=1

33. どのような形態の禁煙指導・支援を利用しましたか?該当するもの全てにお答えください。

1.	病院の外来や、診療所で行う禁煙支援プログラム	いいえ=0	はい=1	
2.	保健所で行う禁煙支援プログラム	いいえ=0	はい=1	
3.	インターネットで行う禁煙支援プログラム	いいえ=0	はい=1	
4.	その他			

5. 不明 いいえ=0 はい=1

#### 34. どの医療従事者から禁煙治療・支援を受けましたか?該当するもの全てにお答えください。

1.	医療征	従事者以外	いいえ=0	はい=1 <u>(→問い</u>	35~)
2.	医師	以外の医療従事者		いいえ=0	はい=1
	1.	心理学者		いいえ=0	はい=1
	2.	カウンセラー(相談員)		いいえ=0	はい=1
	3.	社会福祉士(ソーシャルワーカー)		いいえ=0	はい=1
	4.	看護師		いいえ=0	はい=1
	5.	歯科医		いいえ=0	はい=1
	6.	大学院生		いいえ=0	はい=1
	7.	薬剤師		いいえ=0	はい=1
	8.	禁煙支援者		いいえ=0	はい=1
3.	医師			いいえ=0	はい=1

今後禁煙挑戦時に利用したいサポート

35. 今後の禁煙挑戦時にどのような方法を使用したいですか? 該当するもの全てにお答えください。

1.	自分のやり方(My own way)	いいえ=0	はい=1	→ (問い 39 へ)
2.	薬物療法	いいえ=0	はい=1	
3.	非薬物療法(行動療法)	いいえ=0	はい=1	
4.	薬物療法と非薬物療法(行動療法)の組み合わせ	いいえ=0	はい=1	

36. 今後の禁煙挑戦時にどのような薬物療法を利用したいと思いますか? 該当するもの全てにお答

	>	25	2	1 .	
x	5	E	9	V.	

1.	利用したいとは思わない	いいえ=0	はい=1	→ (問い 37 へ)
2.	気休めの薬、プラシーボ	いいえ=0	はい=1	
3.	ニコチンパッチ	いいえ=0	はい=1	
4.	ニコチンガム	いいえ=0	はい=1	
5.	その他			
6.	1種類の薬物療法	いいえ=0	はい=1	
7.	組み合わせの薬物療法	いいえ=0	はい=1	
8.	高い含有量のニコチンパッチ	いいえ=0	はい=1	

- 37. 今後の禁煙挑戦時に、どのような種類の非薬物療法的な禁煙支援を好みますか? または利用した いと思いますか? 該当するもの全てにお答えください。
  - 利用したいとは思わない
     いいえ=0 はい=1 → (問い 39 へ)
  - セルフヘルプまたは自己主導型
     パンフレット
     音声のテープやビデオテープ
     情報提供の配信・郵送
     コンピュタープログラム
     いいえ=0 はい=1
     いいえ=0 はい=1
     いいえ=0 はい=1
  - 7. 個人的なカウンセリングやコンタクト いいえ=0 はい=1
  - 8. グループカウンセリング いいえ=0 はい=1
  - 9. 事前対策となる電話カウンセリング いいえ=0 はい=1

# 38. 今後の禁煙挑戦時に、どのようなカウンセリングや行動療法を好みますか? または利用したいと 思いますか? 該当するもの全てにお答えください。

- 1. 問題解決 いいえ=0 はい=1
- 2. コーピング技術(ストレスに対して対処・適応しようとする適応機構)

		いいえ=0	はい=1
3.	再喫煙予防	いいえ=0	はい=1
4.	ストレス管理	いいえ=0	はい=1
5.	否定的な感情や鬱への介入	いいえ=0	はい=1
6.	体重、食事、栄養に関する介入	いいえ=0	はい=1
7.	社会支援獲得への介入	いいえ=0	はい=1
8.	その他		
9.	不明	いいえ=0	はい=1

- 39. 今後の禁煙挑戦時に、どのような形態の禁煙指導・支援を好みますか?または利用したいと思い
  - ますか?該当するもの全てにお答えください。

     1. 病院の外来や、診療所で行う禁煙支援プログラム
     いいえ=0 はい=1

     2. 保健所で行う禁煙支援プログラム
     いいえ=0 はい=1

     3. インターネットで行う禁煙支援プログラム
     いいえ=0 はい=1

     4. その他\_\_\_\_\_\_
     いいえ=0 はい=1

     5. 不明
     いいえ=0 はい=1

- 40. どの医療従事者から禁煙指導・支援を受けたいと思いますか?該当するもの全てにお答えくださ
  - い。

2. 3. 4. 5.

 1. 医療従事者以外
 いいえ=0 はい=1 → (問い 41 へ)

 2. 医師以外の医療従事者
 いいえ=0 はい=1

2.	医即以外の医療促事有		いいえ=0	1=1 121
	1.	心理学者	いいえ=0	はい=1
	2.	カウンセラー(相談員)	いいえ=0	はい=1
	3.	社会福祉士(ソーシャルワーカー)	いいえ=0	はい=1
	4.	看護師	いいえ=0	はい=1
	5.	歯科医	いいえ=0	はい=1
	6.	大学院生	いいえ=0	はい=1
	7.	薬剤師	いいえ=0	はい=1
	8.	禁煙支援者	いいえ=0	はい=1
3.	医師		いいえ=0	はい=1

# 41. もし利用可能であれば、以下の代替療法を今後の禁煙挑戦時に使用したいと思いますか? 該当す

るもの全てにお答えください。 1. 利用したいとは思わない

利用したいとは思わない	いいえ=0	はい=1	<u>→ (10 ページ、</u>	FTND ~)
針			いいえ=0	はい=1
瞑想			いいえ=0	はい=1
アロマセラピー			いいえ=0	はい=1
その他				

# 日本語 Fagerstrom ニコチン依存度調査票

\*は重複するため、前の問いの答えを参考に記入

	質問	回答	得点
1.	* 朝,目覚めてから何分位で最初のタバコを吸いますか	5 分以内	3
		6-30分	2
		31 - 60 分	1
		61 分以降	0
2.	禁煙の場所でタバコを我慢するが難しいですか?	はい	1
		いいえ	0
3.	あなたは1日の中でどの時間帯のタバコをやめるのに最も	朝起きた時の目覚	1
	未練が残ますか?	めに1本	
		その他	0
4.	* 1日に何本吸いますか?	10本以下	0
		11 - 20 本	1
		21 - 30 本	2
		31 本以上	3
5.	目覚めて 2~3 時間と、その後の時間帯とどちらが頻繁にタ	目覚めて 2~3 時間	1
	バコを吸いますか?	その後の時間帯	0
6.	病気でほとんど寝ている時でも、タバコを吸いますか?	はい	1
		いいえ	0

日本語版

禁煙ガイドライン(2005): 循環器病の診断と治療に関するガイドライン 2003-2004 年度合同研究半報告, Circulation Journal, vol 69, suppl IV, 2005, p.1020 より引用

英語版

2011 年 1 月 5 日 e-mail による連絡により、 Dr. Karl Fagerstrom より FTND を本研究で使用することの承諾取 得

(Fagerstrom & Schneider, 1989; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991)

ミネソタ式ニコチン禁断症状調査票(Minnesota Nicotine Withdrawal Scale) 日本語版

下記のそれぞれの質問について、この1日(24時間)のあなたの状態に一番よくあてはまる番号に 〇をつけてください。

	ぜんぜん	わずかに	少し	かなり	非常に
	あてはまらない	あてはまる	あてはまる	あてはまる	あてはまる
とてもタバコが吸いたい	0	1	2	3	4
気分が落ち込む	0	1	2	3	4
イライラ・欲求不満・	0	1	2	3	4
怒りを感じる					
不安を感じる	0	1	2	3	4
集中できない	0	1	2	3	4
落ち着かない	0	1	2	3	4
食欲が増す	0	1	2	3	4
寝付きが悪い	0	1	2	3	4
寝ても途中で目が覚める	0	1	2	3	4

財団法人パブリックヘルスリサーチセンターより MNWS 日本語版を本研究で使用することの承諾取

得(2011年1月6日) (Ohishi, Green, Nakamura, & Ohashi, 2005)

英語オリジナル版の copyright なし (Hughes & Hatsukami, 1986)

監修 上島 国利、村松 公美子、				
この2週間、次のような問題にどれくらいひんぱん	全くない	数日	半分以上	ほとんど
に悩まされていますか?				毎日
物事に対して興味がない、または楽しめ	0	1	2	3
ない				
気分が落ち込む、憂うつになる、または絶望的な	0	1	2	3
気持ちになる				
寝付きが悪い、途中で目が覚める、または逆に寝す	0	1	2	3
ぎたりする			-	
疲れた感じがする、または気力がない	0	1	2	3
食欲が無い、または食べ過ぎる	0	1	2	3
自分自身はだめな人間だ、人生の敗北者だと気に病	0	1	2	3
むーまたは、自分自身あるいは家族に申し訳ないと				
感じる			-	
新聞を読む、またはテレビを見ることなどに集中す	0	1	2	3
ることが難しい				
他人が気づくくらいに動きや話し方が遅くなる、あ	0	1	2	3
るいはこれと反対にそわそわしたり、落ち着かず、				
普段よりも動き回ることがある				
死んだほうがましだ、あるいは自分を何らかの方法	0	1	2	3
で傷つけようと思ったことがある				
	この2週間、次のような問題にどれくらいひんぱん に悩まされていますか? 物事に対して興味がない、または楽しめ ない 気分が落ち込む、憂うつになる、または絶望的な 気持ちになる 寝付きが悪い、途中で目が覚める、または逆に寝す ぎたりする 疲れた感じがする、または気力がない 食欲が無い、または食べ過ぎる 自分自身はだめな人間だ、人生の敗北者だと気に病 むーまたは、自分自身あるいは家族に申し訳ないと 感じる 新聞を読む、またはテレビを見ることなどに集中す ることが難しい 他人が気づくくらいに動きや話し方が遅くなる、あ るいはこれと反対にそわそわしたり、落ち着かず、 普段よりも動き回ることがある	この2週間、次のような問題にどれくらいひんぱん       全くない         に悩まされていますか?       0         物事に対して興味がない、または楽しめ       0         ない       0         気分が落ち込む、憂うつになる、または絶望的な       0         気分が落ち込む、憂うつになる、または絶望的な       0         気付きが悪い、途中で目が覚める、または逆に寝す       0         ぎたりする       0         度れた感じがする、または気力がない       0         食欲が無い、または食べ過ぎる       0         自分自身はだめな人間だ、人生の敗北者だと気に病       0         むーまたは、自分自身あるいは家族に申し訳ないと 感じる       0         新聞を読む、またはテレビを見ることなどに集中す       0         ることが難しい       0         他人が気づくくらいに動きや話し方が遅くなる、あ       0         るいはこれと反対にそわそわしたり、落ち着かず、       1         普段よりも動き回ることがある       0         死んだほうがましだ、あるいは自分を何らかの方法       0	この2週間、次のような問題にどれくらいひんぱん に悩まされていますか?       全くない       数日         1       に悩まされていますか?       0       1         物事に対して興味がない、または楽しめ ない       0       1         気分が落ち込む、憂うつになる、または絶望的な 気持ちになる       0       1         気分が落ち込む、憂うつになる、または絶望的な 気持ちになる       0       1         寝付きが悪い、途中で目が覚める、または逆に寝す ぎたりする       0       1         寝付きが悪い、途中で目が覚める、または逆に寝す ざたりする       0       1         寝がた感じがする、または気力がない ない、または食べ過ぎる       0       1         自分自身はだめな人間だ、人生の敗北者だと気に病 むーまたは、自分自身あるいは家族に申し訳ないと 感じる       0       1         新聞を読む、またはテレビを見ることなどに集中す ることが難しい       0       1         他人が気づくくらいに動きや話し方が遅くなる、あ るいはこれと反対にそわそわしたり、落ち着かず、 普段よりも動き回ることがある       0       1         死んだほうがましだ、あるいは自分を何らかの方法       0       1	この2週間、次のような問題にどれくらいひんぱんに         全くない         数日         半分以上           に悩まされていますか?         0         1         2           物事に対して興味がない、または楽しめない         0         1         2           ない         0         1         2           気分が落ち込む、憂うつになる、または絶望的な         0         1         2           気持ちになる         0         1         2           寝付きが悪い、途中で目が覚める、または逆に寝す         0         1         2           寝付きが悪い、途中で目が覚める、または逆に寝す         0         1         2           度なが無い、または食べ過ぎる         0         1         2           食欲が無い、または食べ過ぎる         0         1         2           自分自身はだめな人間だ、人生の敗北者だと気に病         0         1         2           自分自身あるいは家族に申し訳ないとなど感じる         0         1         2           新聞を読む、またはテレビを見ることなどに集中することなどに集中する         0         1         2           新聞を読む、またはテレビを見ることなどに集中する         0         1         2           低人が気づくくらいに動きや話し方が遅くなる、あるのいはこれと反対にそわそわしたり、落ち着かず、普段よりも動き回ることがある         0         1         2           死んだほうがましだ、あるいは自分を何らかの方法         0         1         2

Copyright hold by the Pfizer Inc: Pfizer Japan Inc1999 よりこころとからだ質問票を自主研究で 使用すること許諾(2011年1月4日)

出展: K.Muramatsu, H.Miyaoka, K.Kamijima, Y.Muramatsu, et al. Psychological Reports, 2007, 101, 952-960. 村松公美子, 上島国利.プライマリ・ケア診療とうつ病スクリーニング

評価ツール: Patient Health Questionnare-9 日本語版「こころとからだの質問票」. 診断と治療、97,1465-1473,

禁煙への自信に関する質問

以下の 14 の状況の中で、あなたはどれくらい煙草を吸いたいという衝動に耐える自信があ りますか?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
全く目	自信がない	N 4	少し自信がある			まずまず		とても自信がある		
	自信がある									

- \_\_\_\_\_1. 退屈、または気分が沈んだと感じた時
- \_\_\_\_\_2. 他の人が煙草を吸っているのを見たとき
- \_\_\_\_\_3. くつろいだり、休憩・休息をしたい時
- \_\_\_\_\_4. ちょっといっぷくしてたばこを楽しみたいなと思った時
- \_\_\_\_\_5. テレビを見ている時
- \_\_\_\_\_6. 車の運転中、もしくは車に乗っているとき
- \_\_\_\_\_7. 食後や間食(おやつ)の後
- 8. 次のような事を感じた時、苛立ち、心配、動揺又はいらいら、緊張、神経質に なる・そわそわする、怒り、不安や気がかり、腹立ち(むかつく)
- \_\_\_\_\_9. 間食をしたいが、体重増を避けたいとき
- \_\_\_\_\_10. 気力・活力が必要な時、または集中できない時
- \_\_\_\_\_11. 誰かに煙草を勧められた時
- \_\_\_\_\_12. コーヒーやお茶を飲んでいる時
- \_\_\_\_\_13. お酒の席
- 14. 煙草を吸うことが自分のイメージの一部と感じる時

Dr. Froelicher, Erikaより禁煙への自信に関する質問を日本語への翻訳し、本研究で使用することの承諾取得(2010年12月20日)

#### Self-Construal Scale

これは色々な状況において様々な気持ちや行動を調査するものです。以下の文章を読み、それぞれ をあなた自身に当てはめて考えて下さい。各文章で、あなたに一番合う番号を(1~7の記述の中か ら選んで)答えて下さい。全ての質問に答えて下さい。ご協力ありがとうございます。

1=全く当てはまらない 2=当てはまらない 3=あまり当てはまらない 4=どちらでもない 5=少し当てまはる 6=当てはまる 7=とても当てはまる

- 1. \_\_\_\_ 私は色々な点で他人との違いや、ユニークであることを好む
- 2. \_\_\_\_ 私は初対面の年上の人に対してもオープンに話ができる
- 3. \_\_\_\_ 私は、グループの仲間の意見と強く異する時でも、論争は避けるようする
- 4. \_\_\_\_ 私は自分が関わる権威のある人に対し、尊敬の念を抱いている
- 5. \_\_\_\_ 私は他人が何を思おうと自分の好きなようにする(思いどおりにする)
- 6. \_\_\_\_ 私は自分に対して謙虚な人を尊敬する
- 7. \_\_\_\_ 私は一人の独立した人間として振る舞う事は大切であると思う
- 8. \_\_\_\_ 私は自分の属するグループの利益の為なら、自分の興味・関心を犠牲にする
- 9. \_\_\_\_ 私は誤解を招くより、むしろはっきりと「No」という
- 10. \_\_\_\_ 私にとって活発な想像力をもつことは大切である
- 11. \_\_\_\_ 私は自分の進学や就職などの計画を立てるとき、両親の助言を考慮に入れるべきだと思う
- 12. 私は自分の運命は周囲の人々の運命と深く絡み合って(関わって)いると思う
- 13. \_\_\_\_ 私は、初対面の人に対して、単刀直入であることを好む
- 14. \_\_\_\_ 私にとって、他人と協力して何かをする事は気持ちがいいことだ
- 15. \_\_\_\_ 私は自分だけが賞賛や報酬を得ても、抵抗がない、または心地よく思う
- 16. \_\_\_\_ 自分の兄弟・姉妹が失敗をしたら、自分も責任を感じる
- 17. \_\_\_\_ 私は個人的な目標達成よりも人との繋がりの方が大切だとしばしば感じる
- 18. \_\_\_\_ 私は、授業中(または会議で)発言することに何の抵抗もない
- 19. \_\_\_\_ 私はバスの車中で自分の教授(または上司)に席を譲る
- 20. \_\_\_\_ 私は誰と一緒にいても同じように振る舞う
- 21. \_\_\_\_ 私の幸せは私の周りの人達の幸せ次第である
- 22. \_\_\_\_ 私にとって健康であるということは何よりも大切な事である
- たとえ自分が楽しくない時でも、もしグループの仲間達が自分を必要とするならば、私は グループに留まるだろう
- 24. \_\_\_\_ 私は、自分の行動が他人にどのように影響するかではなく、自分にとって最善となる事を する
- 25. \_\_\_\_ 私にとって、自分自身を大切にする事が何よりも重要である
- 26. \_\_\_\_ 私にとって、グループで決められた事を尊重する事は、大切である
- 27. \_\_\_\_ 私にとって、自分の個性や他の人々から独立する事は、とても重要である
- 28. \_\_\_\_ 私にとって、グループ内の調和を保つことは、とても大切である

施設名: 1=SIH, 2=KCRC, 3=CCC, 4=KSH
 対象コード#:
 29. \_\_\_\_ 私は家でも学校(職場)でも同じように振る舞う
 30. \_\_\_\_ 私は大抵、自分が何か違うことをやりたいと思う時でも、他の人達がしたい事に合わせてしまう

Dr. Theodore M, Singelis より Self-construal 質問紙の日本語版を本研究で使用することの承諾取得 (2010年12月22日) (Singelis, 1994 and 1995)

施設名: 1=SIH, 2=KCRC, 3=CCC, 4=KSH 対象コード#:										
ENRICHD 社会的支援に関する質問										
1.	あなたが話 すか?	舌しをしたいと	とき、ただお	あなたの話を	聞いてくれて、	、かつ信頼できる誰かいま				
	1	2	3	4	5					
	全くいない	殆どいない	時々いる	大体いる	いつもいる					
2.	困ったこと	がある時、あ	っなたに良い	い助言をくれ	る誰かはいまで	すか?				
	1	2	3	4	5					
	全くいない	殆どいない	時々いる	大体いる	いつもいる					
3.	あなたに思	いやりを示し	てくれる諸	進かはいます	カッ?					
	1	2	3	4	5					
	全くいない	殆どいない	時々いる	大体いる	5 いつもいる					
4.	あなたの日	々の家事や雑	鮮用を手伝っ	ってくれる誰	かはいますか	?				
	1	2	3	4	5					
	全くいない	殆どいない	時々いる	大体いる	いつもいる					
5.	あなたの精	神的な支えと	して、(問題	題に直面して	ている時の相談	や、難しい決断を迫られて				
	いる時の即	めけ)頼りに7	なる誰かはい	いますか?						
	1	2	3	4	5					
	全くいない	殆どいない	時々いる	大体いる	いつもいる					
6.	あなたが必	要なだけまた	は欲してい	るだけ連絡	を取ることがで	できる、ごく親しい誰かはい				
	ますか?									
	1	2	3	4	5					
	全くいない	殆どいない	時々いる	大体いる	いつもいる					
7.	7. あなたは現在、結婚していますか?または恋人と一緒に住んでいますか?									

はい いいえ

(Enhancing recovery in coronary heart disease patients (ENRICHD): Study design and methods. the ENRICHD investigators.2000 & Mitchell et al., 2003).

Wolters Kluwer Health imprint より ENRICHD 社会的支援に関する質問を日本語への翻訳し、本研究 で使用することの承諾取得(2011 年 1 月 31 日)

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