



## Improvements in health-related quality of life among smokers who quit after hospitalization

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### ABSTRACT

Few rigorous longitudinal assessments have examined health-related quality of life (HRQoL) changes after smoking cessation, especially among recently-hospitalized smokers. We compared the change in HRQoL between those who did or did not quit smoking 6 months after hospital discharge. Participants were 1357 smokers recruited for a cessation trial between 2012 and 2014 while hospitalized at two hospitals in Massachusetts and one in Pennsylvania. Cessation was defined as biochemically confirmed 7-day point prevalence abstinence at 6 months or as self-reported continuous abstinence at 1, 3, or 6 months post discharge. HRQoL measures included a single-item global health measure (SF1); the Patient Health Questionnaire for Depression and Anxiety (PHQ-4) screening tool for psychological distress; and the EQ-5D-5L health utilities measure. Multivariable models controlled for age, sex, race, education, insurance, study site, study arm, discharge diagnoses, and baseline HRQoL. Improvements in HRQoL were evident in the first month after discharge among those achieving abstinence compared to continuing smokers. At 6 months post-discharge, those with biochemically confirmed cessation were 30% more likely to report at least good health by the SF1 (aRR 95% CI 1.14–1.45), 19% less likely to screen positive for psychological distress (aRR, 95% CI 0.68–0.93), and had EQ-5D-5L health utility scores 0.05 points (95% CI 0.02–0.08) higher than continuing smokers. Results were similar when assessed as a function of self-reported cessation. Hospital-initiated smoking cessation is associated with rapid statistically and clinically significant improvements in a range of HRQoL measures, providing an additional tool clinicians and health systems could use to encourage smoking cessation.

### 1. Introduction

Tobacco use is the leading preventable cause of death in the United States, responsible for 480,000 deaths per year and shortening life expectancy by an average of 11.5 years (U.S. Department of Health and Human Services, 2014; Jha et al., 2013). In addition, \$170 billion is spent annually treating smoking-related diseases (Xu et al., 2015). An extensive literature has established improvements in health following smoking cessation. For example, cardiovascular disease risks diminish quickly upon smoking cessation, reaching the levels of never smokers within approximately five years (U.S. Department of Health and Human Services, 2014; Lightwood and Glantz, 1997), and individuals who quit smoking have slower age-related declines in lung capacity than those

who continue smoking (Anthonisen et al., 2002; Scanlon et al., 2000). These clinical improvements have the potential to improve health-related quality of life (HRQoL), an umbrella term encompassing physical, mental and emotional, and social functioning (Ferrans, 2004). Improving HRQoL is beneficial on its face, but demonstrating short-term improvements in HRQoL following smoking cessation may also help clinicians and counselors motivate smokers to quit.

There have been very few rigorous assessments examining how smokers' HRQoL changes after smoking cessation. Many studies of HRQoL in relation to smoking cessation have been cross-sectional, examining differences in HRQoL across current, former, and never smokers (Olufade et al., 1999; Heikkinen et al., 2008; Hayes et al., 2010; Mulder et al., 2001). Others are quite small with sample sizes under 100

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(Rungruanghiranya et al., 2008; Balduyck et al., 2011; Sales et al., 2009; Erickson et al., 2004; Zillich et al., 2002). Some have specifically followed smokers who either quit or continued smoking during the observation period, or compared post-cessation quality of life for the two groups, but did not compare changes in quality of life from baseline (Sales et al., 2009; Guitérrez-Bedmar et al., 2009; Jensen et al., 2007). And some studies assessed changes in quality of life for smokers who quit, but did not include control groups of smokers who continued smoking (Sales et al., 2009; Erickson et al., 2004; Zillich et al., 2002; Papadopoulos et al., 2011).

None of these studies addressed cessation-related changes in HRQoL in the period following hospitalization, specifically. Hospitalized smokers may be different from others for at least two reasons. First, their hospitalizations, especially those for tobacco-related illnesses, may be both a culmination of serious illness and at the same time signal risks of future morbidity. Thus hospitalization could mark a point at which HRQoL improvements subsequent to smoking cessation will be less likely or of smaller magnitude. Alternatively, hospitalizations may be turning points where smoking cessation is a significant part of broader efforts by patients to improve their health. Establishing cessation-related improvements in HRQoL outcomes for hospitalized smokers could help spur more hospitals to adopt smoking cessation programs.

The Helping HAND 2 (HH2) study was a three-site randomized controlled trial testing a program to sustain hospital-initiated smoking cessation in the post-discharge period using automated telephonic outreach, connections to nationally available telephone quitline resources, and smoking cessation medications (Reid et al., 2015). Relative to usual care, the HH2 intervention produced a short-term increase in cessation at 3 months that waned by 6 months post discharge (Rigotti et al., 2016). The objective of the current study was to assess the impact of hospital-initiated smoking cessation on HRQoL for participants in the HH2 trial. We hypothesized that cessation would be associated with rapid improvements across domains of HRQoL.

## 2. Methods

### 2.1. The Helping HAND 2 trial

The study population is drawn from the participants in the Helping HAND 2 study, a randomized controlled smoking cessation trial among hospitalized smokers that took place from December 2012 to July 2014. Details of this study are published elsewhere (Reid et al., 2015; Rigotti et al., 2016). Briefly, smokers admitted to one of three hospitals – Massachusetts General Hospital in Boston, MA and the University of Pittsburgh Medical Center (UPMC) in Pittsburgh, PA (large urban teaching hospitals), as well as North Shore Medical Center (a community hospital in Salem, MA) – were recruited to participate in a hospital-initiated smoking cessation trial. Eligible participants were  $\geq 18$  years old, smoked  $\geq 1$  cigarette per day when smoking normally in the month prior to admission, had  $\geq 5$  min of smoking cessation counseling in the hospital, indicated they planned to quit upon discharge, and agreed to take smoking cessation medications home when leaving the hospital. At discharge, those randomized to the standard care (control) arm received a personalized medication recommendation and referral to the state tobacco quitline, while patients randomized to the sustained care (intervention) arm received free FDA-approved smoking cessation medications and five automated phone calls providing support and medication adherence messages, with the option to be transferred to a live counselor. The study was approved by the Institutional Review Boards of Partners HealthCare and the University of Pittsburgh.

Over the approximately 19-month recruitment period, 1357 eligible smokers were enrolled in the trial and randomized. Biochemically confirmed 7-day point prevalence abstinence at 6 months, established by saliva cotinine ( $\leq 10$  ng/mL) or CO ( $< 9$  ppm), was the primary HH2 outcome. Self-reported abstinence was assessed at 1, 3, and 6 months post-discharge. Patients randomized to the intervention arm

had higher rates of self-reported 7-day point prevalence abstinence at 1 and 3 months follow-up (43% vs. 32%, OR 1.35, 95% CI 1.18–1.56; 37% vs. 30%, OR 1.22, 95% CI 1.05–1.42; respectively), but the effect diminished by 6 months when there was no significant difference in 7-day point prevalence abstinence whether biochemically verified (17% vs. 16%, OR 1.07, 95% CI 0.84–1.37) or self-reported (31% vs. 27%, OR 1.16, 95% CI 0.98–1.37) (Rigotti et al., 2016).

### 2.2. Data elements

For the current study, the outcomes of interest were three measures of HRQoL. First was a single-item global health measure (“SF1”) asking, “In general would you say your health is...[excellent/very good/good/fair/poor].” The second was the 4-item Patient Health Questionnaire for Depression and Anxiety (PHQ-4, a brief depression/anxiety screening tool). Each was completed by subjects at baseline hospitalization, as well as 1, 3, and 6 months after discharge. The third was the 5-item EQ-5D-5L health utilities scale, an omnibus health measure which was completed by subjects at baseline and 6 months follow-up (Rabin et al., 2015).

The SF1 has been shown to be a robust measure of overall health and a predictor of clinical status, including mortality (Idler and Benyamini, 1997). It was analyzed both as a 5-level quasi-continuous measure (5 = “excellent”, 1 = “poor”) and dichotomized as excellent/very good/good (3–5) vs. fair/poor (1–2). The PHQ-4 is a measure of psychological distress which also demonstrates strong construct validity for HRQoL through correlations with all domains of the SF-20 instrument (Kroenke et al., 2009). The PHQ-4 consists of two two-item screeners, one for depression and the other for anxiety. Each item has four levels, 0–3, that may be summed. The two-item depression and anxiety screens (range 0–6), as well as the overall 4-item PHQ-4 score (range 0–12) are dichotomized as “normal” when their items sum to  $< 3$ , or indicative of psychological distress when scores are at least 3 (higher scores mean greater distress). We scored the EQ-5D-5L using published utility weights derived using time trade-off methods in a U.S. population (Euroqol Group, 2017). EQ-5D-5L scores range from 0 to 1 (0 is the worst possible health/death and 1 is perfect health) and were treated as a continuous outcome. We also assessed responses to the 5 individual 5-level EQ-5D items, measuring difficulties with mobility, self-care, and usual activities, pain/discomfort, and anxiety/depression, to investigate the relationship between cessation and changes in specific components of overall health. Response categories for each of these items ranged from 0 (inability/extreme difficulty) to 4 (“no problems”).

In the present study, the primary predictor of interest was smoking cessation. We used two alternate definitions of cessation. Biochemically-confirmed 7-day point prevalence abstinence at 6 months was defined as self-reported abstinence from all tobacco over the past 7 days (including e-cigarettes) confirmed by a cotinine value  $\leq 10$  ng/mL or a CO value of  $< 9$  ppm for those using nicotine replacement therapy. This was the primary definition of cessation used in the HH2 trial. The present study also used a time-varying measure of continuous abstinence calculated using self-reported 7-day point-prevalence abstinence from any tobacco (including e-cigarettes) assessed at 1, 3, and 6 months post-discharge. Participants were considered continuously abstinent if there was no indication of smoking from the measurement time point back to baseline. Study participants who did not report their smoking status were counted as smokers at the reporting time point, per standard procedure in smoking cessation trials. Covariates included in the analyses were age, sex, race/ethnicity, education, health insurance, and discharge diagnoses. Discharge diagnoses were used to identify patients with smoking-related diseases (U.S. Department of Health and Human Services, 2014) and to calculate the Elixhauser comorbidity index at baseline, a measure of clinical severity (van Walraven et al., 2009).

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